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FOREWORD

It is a great privilege to be asked to provide this foreword to the UWA Law Review's special edition on Health Law and Policy. The law relating to health and medicine has long been a particular interest of mine, dealing as it does with the intersection of two human enterprises that have deep historical roots: the law and medicine. The depth and variety of the articles in this edition of the UWA Law Review, however, remind us that there will always be new challenges that both the law and medicine must face to meet the contemporary needs of society. Many of the issues discussed in the edition raise complex issues that would have been unheard of only decades ago: the impact of the COVID-19 pandemic, the use of artificial intelligence and high-risk technologies, national disability schemes, and assisted dying. All of these issues require careful deliberation and examination, of the kind evident in these articles, to ensure that new policies and innovations respect long established and important values of the law, including human dignity, personal autonomy and public accountability. I commend the edition to all.

The Honourable Justice Peter Quinlan
Chief Justice of Western Australia

November 2025

INTRODUCTION

This special issue of the UWA Law Review celebrates health law and policy scholarship, with a focus on the Western Australian context and an eye on national and international developments.

As guest editors of this edition, we would like to extend our gratitude to the general editor of the UWA Law Review, Dr Jessica Kerr, and her student editorial team who have been exceptional in their sourcing of referees and their review of manuscripts to ensure that they are meeting the very highest standard of scholarship. They have done a wonderful job.

We are also very thankful to the Honourable Justice Peter Quinlan for composing the foreword to this issue. Chief Justice Quinlan practised in health law prior to his appointment to the judiciary and we value his input to this collection of scholarly essays.

This publication also marks the launch of the UWA Law School Centre for Health Law and Policy. The Centre has been a long-held ambition for several academics in the Law School and it is wonderful that it came to fruition in early 2025. We are grateful to Professor Anna Nowak, Deputy Vice-Chancellor (Research), who has from the very start provided support for this endeavour, and to our Dean, Professor Sharon Mascher, for championing our efforts.

Before canvassing the contents of this special issue, we would like to set out the motivation for the Centre, its underlying ethos, and our ambitions for it moving forward.

We are fortunate at UWA Law School to have colleagues who believe in the contributions that research, teaching, and professional education in relation to health law and policy can make towards a fairer society and healthier communities locally and globally. Our collective belief in the values of inclusiveness, equality, and evidence-based and inter-disciplinary research is the foundational platform for our Centre. We are particularly conscious of the health needs and inequality experienced by our First Nations Peoples, and hope that, in time, and in ways that are driven by our Aboriginal colleagues, we can contribute to meaningful progression in this context. More generally, the Centre strives to make an impact across three principal pillars. First, the production and dissemination of high-quality research in health law and policy through scholarly publications, leadership of, and participation in, interdisciplinary research

projects, as well as the organisation of impactful conferences in the field. Secondly, direct engagement with relevant policy and law reform processes, through concise but highly evidence-based submissions (or other forms of appropriate contributions). Thirdly, contribution to ongoing professional development for legal and policy professionals engaged in the day-to-day practice of health law and policy, which we aim to achieve by taking an active role in CPD offerings as well as more structured formats as the Centre becomes more established.

The expertise in the Centre ranges across embryology, end-of-life decision-making, the regulation of therapeutic goods, the healthcare challenges for children and older people, issues arising in the treatment of mental illness, health related issues arising in the context of the criminal justice system, and contemporary public health challenges such as obesity, body image, and tobacco control.

We are proud to edit this special issue which represents a diverse range of articles, commentaries and reviews, mirroring (if only in part) the broad array of interests with which the Centre engages. For that, we are very grateful to the authors who have put such time and effort into their contributions. While most of the contributors are members of the Centre and on faculty at UWA Law School, we have also been pleased to welcome contributions from outside current staff, including former students.

The contributions to this special issue naturally cluster into a series of thematic groups. A first theme is that of mental health. Jamie Walvisch's article examines the High Court of Australia's decision in *KMD v CEO (Department of Health NT)* [2025] HCA 4, a case that raised critical questions about the obligations of forensic patients under indefinite custodial supervision orders. It argues that the High Court's judgment represents a necessary recalibration of forensic mental health law, steering it away from indefinite preventive detention and towards a more ethically grounded framework. In her contribution, Hayley Passmore looks at the issue of neurodiversity in relation to justice settings, and identifies urgent reforms required across Australia to ensure the rights of people with disability are upheld in our criminal justice system. She utilises learnings from prisons and youth detention centres in the United Kingdom, the United States of America, Canada, and Aotearoa New Zealand to make recommendations for the current Australian criminal justice context.

The COVID pandemic has presented a fertile opportunity for scholarship examining the various legal issues connected with this global public health emergency, and two of the articles in this issue explore two different perspectives associated with the Australian government's response to the pandemic. Amy Thomasson looks at the line between consent and coercion in connection with vaccine mandates and argues for internal logic and consistency in how the right to bodily integrity in its various legal forms is understood and treated by the law, particularly in the context of mandatory vaccination, and thinking prospectively about future public health emergencies. Sophia Stannard and Meredith Blake interrogate Western Australia's use of executive powers to create a range of restrictions associated with criminal penalties, questioning whether there was justification for these given the jurisprudence associated with risk-based offences, and their analysis of several court decisions involving the sentencing of those charged with these offences.

The benefits and challenges which Artificial Intelligence ('AI') brings to healthcare systems are explored in two articles. Kuen Yei Chin, Meredith Blake, and Marco Rizzi outline the ways in which Western Australian law could address patient harms connected with the use of AI in clinical settings (particularly diagnostics) and identify the specific challenges facing current civil liability schemes. They discuss possible alternative frameworks for addressing this type of harm in the local context, considering current international developments. Haris Yusoff examines the Australian government's policy agenda in relation to AI, including its intention to introduce legislation reflecting the European risk-based framework, arguing that this may not be the most suitable approach to mitigate the risks associated with healthcare. Rather, he suggests that the proposed legislation should have regard to existing regulation of gene technology and draw meaningful lessons from that experience.

The ability to access healthcare services has long been a topic in health law scholarship, particularly where that access is associated with complex ethical discourse. Mark Rankin engages in a comparative analysis of abortion legislation in each Australian jurisdiction, analysing whether these frameworks sufficiently recognise a woman's access to abortion services. His analysis concludes that the practical recognition of a woman's right to abortion occurs when the law regulates abortion care in the same manner as other standard healthcare. Meredith Blake tackles the issue of assisted dying, comparing provisions in the Terminally Ill Adults (End of Life) Bill 2024 (UK) with provisions in the Western Australian *Voluntary Assisted Dying Act 2019.* She focuses on the issue of access to each scheme, and questions whether the United Kingdom Bill, if passed, will

prove unduly obstructive for those seeking assisted dying services. Aidan Ricciardo's commentary considers two recent reviews of gender-affirming healthcare to minors in Australia and argues that national guidelines provide an evidence-based foundation for clinical practice, legal and regulatory certainty, supporting access to gender-affirming care for minors.

Two of the articles in this issue focus on specific doctrinal issues arising in connection with the healthcare system. Richard Maddever examines the doctrine of necessity, analysing medical treatment legislation in each Australian jurisdiction in seeking to establish first, whether the doctrine exists in Australian civil law, and second, if it does, the implications of this doctrine for healthcare professionals. Julie Falck critically examines the 2024 National Disability Insurance Scheme reforms. She argues that these represent a systematic hardening of discretionary soft law into binding rules to blunt the application of principles established by judicial and merits review. She concludes that this produces negative impacts for participants and circumvents accountability mechanisms provided for in administrative law.

The special issue concludes with two book reviews. Marco Rizzi reviews Penny Gleeson's recent book, *The Regulation of Medical Products: Dope, Drugs and Devices* (Routledge, 2025), which constitutes an important first attempt at analysing the Australian regulation of therapeutic goods as a standalone object of scholarly research.

Finally, Stephan Millett reviews our colleague Michelle de Souza's book, *The Regulation of Embryo Testing in Australia: A Principles-Based Approach* (Springer Nature, 2025), arguing for the conceptual fitness of the proposed regulatory approach for the purpose of tackling an inherently wicked legal and ethical topic.

We believe that this special issue offers a substantive range of engaging and important scholarship on a variety of issues pertaining to Australian healthcare. We trust it will provide the UWA Law Review's readership enjoyable reading and food for thought.

Meredith Blake and Marco Rizzi

November 2025

UNWELL, UNCONVICTED AND UNCOOPERATIVE: SHOULD FORENSIC PATIENTS BE REQUIRED TO ENGAGE WITH MENTAL HEALTH EXPERTS TO SECURE THEIR RELEASE FROM CUSTODY?

JAMIE WALVISCH*

This article examines whether forensic patients — individuals found not guilty of criminal acts by reason of mental impairment — can be required to engage with mental health experts to secure their release from custodial supervision. Centred on the High Court of Australia's decision in KMD v CEO (Department of Health NT), the paper explores the tension between protecting public safety and the patient's rights to liberty and autonomy. It critiques making non-cooperation with psychiatric assessments a de facto barrier to release, arguing this approach unfairly reverses the onus of proof and undermines the presumption of liberty. The article contends that while a patient's refusal to be assessed is a relevant factor in determining risk, it should not be determinative. It advocates for a rights-based framework where restrictions on liberty must be proven necessary and proportionate, based on a holistic evaluation of all available evidence, rather than making freedom contingent on procedural compliance.

* Senior Lecturer, UWA Law School, University of Western Australia. I would like to thank Marco Rizzi and Meredith Blake for bringing this special issue together, and for providing me with the opportunity to contribute to it. I am also grateful to the anonymous reviewers for their insightful comments, which enhanced the quality and clarity of this article.

INTRODUCTION

Across the common law world, legal frameworks allow individuals to be found not guilty of criminal offences where, due to a mental impairment, they lacked certain key capacities at the time of the relevant conduct (such as the capacity to understand the nature or wrongfulness of their actions).[1] Although such individuals are not convicted, they are not fully acquitted either. Instead, they receive what is often termed a 'qualified acquittal', which places them under ongoing court supervision. While this supervision may occur in the community, courts will frequently order that such individuals be detained in a custodial setting, such as a mental health facility or correctional centre, for the public's protection.[2]

In some jurisdictions, these 'custodial supervision orders' ('CSOs') may have no fixed end date: the individual (commonly referred to as a 'forensic patient') will remain detained in a custodial setting until a court or tribunal determines that it is safe for them to be released (usually on a 'non-custodial supervision order' ('NCSO')).[3] In other jurisdictions, legislation will set a maximum end date for detaining forensic patients in custody, but will require a court or tribunal to

[1] This defence was traditionally known as the 'insanity' defence. For a useful overview of the scope and history of this offence, see Nigel Walker, *Crime and Insanity in England* (Edinburgh University Press, 1968). For a survey of different jurisdictional versions of the defence, see Law Commission, *Insanity and Automatism: Supplementary Material to the Scoping Paper* (Report, 18 July 2012) app C.

[2] See, eg, *Criminal Law (Mental Impairment) Act 2023* (WA) s 46; *Crimes (Mental Impairment and Unfitness to be Tried) Act 1997* (Vic) s 26; *Criminal Code Act 1983* (NT) s 43ZA; *Criminal Procedure (Insanity) Act 1964* (UK) s 5(2); *Criminal Code*, RSC 1985, c C-46 (Can) s 672.54.

[3] See, eg, *Mental Health and Cognitive Impairment Forensic Provisions Act 2020* (NSW) s 33; *Criminal Code Act 1983* (NT) s 43ZA–ZH; *Criminal Justice (Mental Impairment) Act 1999* (Tas) s 24; *Crimes (Mental Impairment and Unfitness to be Tried) Act 1997* (Vic) s 27.

release them earlier if their detention is no longer necessary for the community's protection.[4] These laws reflect the general principle that as forensic patients have not been convicted of a criminal offence, they should be held in conditions that are 'the least restrictive of [their] freedom and personal autonomy as is consistent with the safety of the community'.[5]

While legislative schemes differ, they will generally establish a process for periodically reviewing the need for a forensic patient's continued custodial detention. In determining whether to replace a CSO with an NCSO, the decision-maker is likely to consider factors such as the nature of the individual's mental impairment, whether their mental health has improved while they have been in custody, their medical prognosis, and the supports they would receive if released into the community.[6] To assist them in making this determination, the decision-maker will usually seek and consider reports from expert mental health practitioners, such as forensic psychiatrists and psychologists, who have examined and assessed the forensic patient. In some jurisdictions they will be required to do so.[7] This raises a critical question: what happens if the forensic patient refuses to engage with the relevant experts? Should they be required to remain under custodial supervision until they do? Or should a court or tribunal be permitted to release them into the community regardless of their failure to cooperate?

This was the issue at the heart of the recent High Court of Australia ('High Court') decision in *KMD v CEO (Department of Health NT)* ('*KMD*').[8] The case concerned a forensic patient ('KMD') who sought to be released from a longstanding CSO, but who declined to participate in an interview with a state-appointed forensic psychologist. While the High Court's reasoning turned on the interpretation of the Northern Territory's *Criminal Code Act 1983* ('the Code'), the case raises broader questions about how courts should balance the imperative of community

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[4] See, eg, *Criminal Law (Mental Impairment) Act 2023* (WA) ss 50, 74; *Criminal Law Consolidation Act 1935* (SA) ss 269P–T.

[5] *R v Tzeegankoff* [1998] SASC 6639, quoted in Sentencing Advisory Council (SA), *Mental Impairment and the Law: A Report on the Operation of Part 8A of the Criminal Law Consolidation Act 1935 (SA)* (Report, November 2014) [3.73].

[6] See, eg, *Criminal Code Act 1983* (NT) s 43ZN(1); *Mental Health and Cognitive Impairment Forensic Provisions Act 2020* (NSW) s 84; *Criminal Law (Mental Impairment) Act 2003* (WA) s 72; *Mental Health Act 2016* (Qld) s 442; *Criminal Law Consolidation Act 1935* (SA) s 269T(1).

[7] See, eg, *Criminal Code Act 1983* (NT) s 43ZN(2); *Criminal Law Consolidation Act 1935* (SA) s 269T(2); *Crimes Act 1914* (Cth) s 20BK(2); *Mental Health and Cognitive Impairment Forensic Provisions Act 2020* (NSW) s 84; *Crimes (Mental Impairment and Unfitness to be Tried) Act 1997* (Vic) s 40(2).

[8] [2025] HCA 4.

protection with the rights of individuals who have acted harmfully but are not criminally responsible for their conduct.

This article addresses these questions in two stages. Part One traces KMD's journey through the criminal justice system, from the events that gave rise to her offending through to the High Court's resolution of her case. This account provides the context needed to fully understand and respond to the normative questions addressed in Part Two: whether it is legitimate to make liberty contingent on cooperation with mental health experts, whether shifting the evidentiary burden onto forensic patients can be justified, and how principles of proportionality, necessity and human rights should shape supervision regimes. While the analysis in this article is situated within the broader common law tradition, its primary focus is on Australian law.

PART ONE: KMD'S JOURNEY THROUGH THE CRIMINAL JUSTICE SYSTEM

A *The Events of 7 May 2013*

KMD is an Indigenous woman who was born and raised in the Northern Territory ('NT').[9] In the early 2000s, KMD married RL, and in 2006 they had a son. Following the breakdown of their relationship in 2007, they became entangled in protracted Family Court proceedings concerning custody and parenting arrangements. During those proceedings, KMD made repeated and serious allegations that RL and others had sexually abused her son. These allegations were investigated by various authorities and found to be unsubstantiated.

Despite these findings, KMD remained convinced that her son was in imminent danger. She attempted to raise her concerns with police, the Family Court, and health professionals, but her claims were consistently dismissed. Over time, she developed the belief that the authorities were unwilling or unable to protect her son, and that she alone was responsible for ensuring his safety. This delusional conviction drove the events of 7 May 2013.

On that day, KMD travelled to RL's home in Virginia, a rural suburb on the outskirts of Darwin, armed with a .44 Magnum Smith & Wesson revolver. She entered the house unlawfully and hid under a bed, waiting for someone to arrive. RL was not home, but his mother, Mrs L, entered the premises later that day. KMD

[9] The facts reported in this section have been obtained from the following judgments: *R v KMD* [2015] NTSC 31; *R v KMD* (No 5) [2022] NTSC 69; *R v KMD (No 6)* [2023] NTSC 51; *Chief Executive Officer Department of Health v KMD* [2024] NTCCA 8; *KMD v CEO (Department of Health NT)* [2025] HCA 4.

confronted her at gunpoint, accused her of involvement in the alleged abuse, and detained her inside the house. KMD then forced Mrs L, at gunpoint, to drive her to her son's school. She wanted to take her son to the police for his protection.

While on the road, they happened to encounter RL driving in the opposite direction. Mrs L flashed the headlights to attract his attention, prompting RL to stop his car. When RL attempted to approach KMD to talk to her, she shot at him, narrowly missing his head. RL sprinted away and KMD tried to follow. To protect RL, Mrs L drove her car between him and KMD. KMD walked around to the passenger side of the car and shot Mrs L in the arm. Mrs L slumped over the steering wheel and pretended to be dead.

KMD then jumped into RL's car (which he had left by the side of the road) and pursued him. RL waved down a passing vehicle driven by Mr I to request assistance. As he was explaining the situation to Mr I, KMD fired at Mr I's car, shattering its rear window. RL then got into the car and Mr I drove off quickly. KMD pursued them, ramming Mr I's vehicle on several occasions. She then pulled next to the passenger side of the vehicle and shot at RL. The bullet hit him in the thumb.

Mr I and RL kept driving, and KMD continued to pursue them for a time, but eventually gave up after she ran out of bullets. She then drove to her son's school, where she collected him contrary to a Family Court order. She drove him to her home, where she asked her partner, JC, to take them to the police station. On the way there they were stopped at a police roadblock and KMD was arrested. She was charged with several offences, including detaining Mrs L against her will, unlawfully attempting to kill RL, and possessing a firearm with an altered serial number.

B *KMD's Special Hearing*

Ordinarily, charges of this nature would be heard in the Supreme Court of the Northern Territory ('Supreme Court'). However, concerns were raised about KMD's fitness to stand trial.[10] Three psychiatrists provided reports to the Supreme Court, in which they each concluded that KMD was experiencing a delusional disorder: she believed (contrary to any evidence) that 'there were threats to her life from a wide range of people' and that 'her son was being

[10] In the NT, a person is deemed unfit to stand trial if they are unable to understand the nature of the charge, plead to the charge, understand the nature of the trial, follow the course of the proceedings, understand the substantial effect of any evidence presented, or provide instructions to their legal counsel: *Criminal Code Act 1983* (NT) s 43J.

sexually assaulted and was in danger of further sexual assault by her former husband and other people'.[11]

Based on this evidence, on 1 May 2014 Riley CJ declared that KMD was unfit to stand trial, and that she was not likely to become fit in the next 12 months. Consequently, the Supreme Court was required to conduct a 'special hearing'.[12] At that hearing, the jury found KMD not guilty of eight offences because of mental impairment.[13]

Where an individual is found not guilty because of mental impairment, the judge must determine whether to release them unconditionally or impose a supervision order.[14] If a supervision order is to be imposed, the judge needs to determine whether to make it custodial or non-custodial. In KMD's case, Riley CJ was of the view that supervision was required, but needed more evidence to determine whether to impose a CSO or an NCSO. His Honour therefore required the provision of additional expert reports. Based on those reports, his Honour imposed a CSO as he was of the opinion that

> if KMD is not in custody, she is likely to be a danger to those people whom she incorrectly believes were a danger to her son and may still be a danger to her son. The level of risk of similar conduct is difficult to assess but the consequences of such conduct are extreme. She has demonstrated the lengths to which she will go because of her deluded beliefs. I am not satisfied that the danger has abated.[15]

In the NT, while CSOs are imposed for an indefinite period,[16] the court must set a 'nominal term' for the order. While the patient does not need to be released at the end of the nominal term, a major review of the order must be conducted three to six months before its expiry, to determine whether the patient should be unconditionally released.[17] The length of the nominal term is to be determined by

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[11] *R v KMD* [2015] NTSC 31, [2].

[12] *Criminal Code Act 1983* (NT) s 43R(3). A 'special hearing' is similar to a trial; however as the accused person cannot defend themselves, they cannot be convicted of an offence. Instead, the possible verdicts are: not guilty; not guilty because of mental impairment (a qualified acquittal); or committed the offence charged (a qualified finding of guilt). The NT special hearing procedures are set out in ss 43V–Y. Similar procedures exist in other Australian jurisdictions.

[13] In the NT, a person is found not guilty because of mental impairment if, at the time they committed the relevant acts, it is found that they had a mental impairment, and as a consequence of that impairment they did not know the nature and quality of the conduct, did not know it was wrong, or were not able to control their actions: ibid s 43C.

[14] Ibid s 43X.

[15] *R v KMD* [2015] NTSC 31, [60].

[16] They may, however, be varied or revoked on application to the court: *Criminal Code Act 1983* (NT) s 43ZD.

[17] Ibid s 43ZG(5).

reference to the term of imprisonment that would have been imposed had the individual been convicted of the relevant offences. In KMD's case Riley CJ set a nominal term of 16 years.

Ordinarily, a CSO would be served in a mental health facility. However, as KMD did not acknowledge that she had a mental illness, and did not agree to receive treatment, she was instead detained at Darwin Correctional Centre.

C *Reviews of KMD's Custodial Supervision Order*

Under the Code, every 12 months after making a supervision order, the 'appropriate person' (currently the Chief Executive Officer (Department of Health NT) ('the CEO')) must submit a report to the Supreme Court on the treatment and management of the forensic patient's mental impairment.[18] After considering this report, the Court may choose to conduct a review to determine whether the supervision order should be varied or revoked.[19] If the Court conducts a review, it must vary a CSO to an NCSO unless satisfied that the safety of the forensic patient or the public will be seriously at risk if they are released on an NCSO.[20]

Section 43ZN(1) of the Code sets out the factors that the court must have regard to in making this determination. These include the nature of the forensic patient's mental impairment, the relationship between that impairment and their offending conduct, whether as a result of that impairment they are likely to endanger themselves or others if released, whether there are adequate resources available for their treatment and support in the community, and whether they are likely to comply with the conditions of the NCSO. Importantly, s 43ZN(2)(a) prevents the Court from releasing a forensic patient from custody unless it has obtained and considered two expert reports.[21]

KMD's CSO was reviewed by Hiley J in 2017 and 2021. In both cases his Honour confirmed the order, finding that KMD's condition had not improved and that she continued to pose a serious risk to public safety.[22] Her CSO was reviewed again in 2022 by Brownhill J, who agreed that KMD posed some level of risk, but held that whether the safety of KMD or the public would be *seriously* at risk if she was released on an NCSO would depend 'significantly upon the terms of any such order and the mechanisms in place to support KMD to live in the community in

[18] Ibid s 43ZK.
[19] Ibid s 43ZH(1).
[20] Ibid s 43ZH(2)(a).
[21] These reports may be prepared by a psychiatrist or 'other expert': ibid s 43ZN(2)(a)(i).
[22] *R v KMD (No 3)* [2017] NTSC 95, [127]–[128]; *R v KMD (No 4)* [2021] NTSC 27, [14]–[15].

compliance with such terms',[23] a matter upon which her Honour had insufficient information. Consequently, in accordance with s 43ZN(2)(a), Brownhill J ordered the production of two expert reports: one to be written by a psychologist, and the other to be written by 'an occupational therapist or social worker or other expert experienced in managing and supporting people with mental health conditions in the community'.[24]

KMD engaged a clinical social worker, Janet Guy, to prepare the latter report. This report was based on approximately 50 hours of sessions with KMD, as well as discussions with KMD's family. Ms Guy reported seeing no signs of active mental illness, noting that KMD's thinking was logical, her judgment intact, and that she had not expressed any threats of harm.[25] While she acknowledged that, as a social worker, she was not qualified to provide a formal forensic risk assessment, Ms Guy drew on her clinical experience with individuals with mental illnesses to assert that KMD's risk could be managed safely in the community.[26] She recommended that KMD be immediately released on an NCSO.

The CEO engaged a forensic psychologist, Professor James Ogloff, to prepare the other report. However, KMD refused to be interviewed by Professor Ogloff, as she did not consider that

> 'co-rumination', that is talking about the same traumatic experience over and over again, will be of any utility for her, and is likely to be detrimental to her mental health. She considered her counselling with Ms Guy, which has a forward looking, rather than a backward looking, approach, to be most helpful to her. She said she would like to have the choice to speak to who she wants, when she wants, on her terms, and there is nothing to be gained from her speaking to forensic mental health personnel about her original offending or what precipitated it because 10 years has passed and she has moved on from that situation. She said that speaking about what she was feeling or thinking 10 years ago will not assist when she does not have those same feelings, experiences or beliefs now.[27]

Consequently, Professor Ogloff's report was largely based on prior assessments that had been conducted by other mental health professionals and other collateral information. Based on this material, Professor Ogloff concluded that KMD 'continues to present a high level of risk for future violence, with little

[23] *R v KMD (No 5)* [2022] NTSC 69, [144].
[24] Ibid [154].
[25] *R v KMD (No 6)* [2023] NTSC 51, [18].
[26] Ibid [20].
[27] Ibid [109].

evidence to suggest that her existing risk factors, which have been contained whilst she has been incarcerated, are being remediated'.[28] He was of the view that she could not be safely managed in the community.[29]

Justice Brownhill considered the information contained in these reports, along with several other reports that were presented to the Court. Her Honour acknowledged that KMD continued to experience a delusional disorder and lacked insight into her condition, but also recognised the absence of violent behaviour during her lengthy period in custody[30] and the substantial protective factors offered by her family and cultural supports.[31] She found that the risk of future violence, while real, could be mitigated to an acceptable level through a well-structured supervision order and supported transition plan. Consequently, her Honour concluded that there was insufficient evidence of serious risk to justify KMD's continued detention. She ordered KMD's CSO be varied to an NCSO,[32] and KMD was released from custody on 12 July 2023.

D *The NT Court of Criminal Appeal Decision*

The CEO appealed Brownhill J's decision to the Northern Territory Court of Criminal Appeal ('NTCCA') on several grounds, including that Brownhill J had placed too much weight on Ms Guy's evidence given her lack of expertise in the area of risk assessment, and that the terms of the NCSO were insufficient to address the forensic risk issues.[33] Most significantly, it contended that Brownhill J had erred in finding that the safety of the public would not be seriously at risk if KMD were released on an NCSO. It argued that this finding was not reasonably open, given the statutory requirement to obtain and consider two expert reports in making this determination,[34] and KMD's failure to engage with one of the report writers.

In a split decision, the NTCCA upheld the appeal.[35] The majority found that the requirement that the court obtain and consider two expert reports is central to the legislative scheme set out in the Code, and that 'this process was effectively

[28] Ibid [92].
[29] Ibid [105].
[30] Ibid [132].
[31] Ibid [166].
[32] Ibid [167].
[33] *Chief Executive Officer Department of Health v KMD* [2024] NTCCA 8, [76].
[34] Ibid; *Criminal Code Act 1983* (NT) s 43ZN(2).
[35] *Chief Executive Officer Department of Health v KMD* [2024] NTCCA 8 (Reeves and Burns JJ; Blokland J dissenting).

rendered nugatory by KMD's refusal to be examined by Professor Ogloff'. It stated that:

> The purpose of obtaining reports was to enable the Court to be informed of KMD's current mental state and to enable the Court to make an assessment of the risk (if any) that KMD currently posed either to herself or the public. KMD's refusal to be examined by Professor Ogloff made it effectively impossible for the primary judge to make a proper assessment of KMD's current mental state and any risk she may present to the public if she were released from custody.[36]

In the majority's view, the review conducted by Brownhill J 'required a balancing of personal and public interests', but 'KMD's refusal to engage with mental health practitioners skewed the focus of the review away from this balance to a focus on KMD's interests, because the effect of her refusal to engage was to ensure that evidence relevant to the public interest was not contemporary and of questionable weight'.[37] Consequently, it concluded that the review had fundamentally miscarried. The NTCCA therefore ordered the CSO be reinstated, and KMD was returned to custody (after having spent over 12 months in the community).

E *The High Court Decision*

KMD appealed this decision to the High Court on four grounds: that the NTCCA had applied the wrong standard of appellate review; that it had denied her procedural fairness; that it had erred in confirming the CSO without receiving evidence of KMD's progress during the period she was released under the NCSO; and that it had erred in finding that Brownhill J's review had miscarried because of her refusal to engage with medical experts.[38]

The High Court unanimously upheld the final ground of appeal, finding that Brownhill J was permitted to vary KMD's CSO to an NCSO despite her refusal to engage with Professor Ogloff. The plurality (Gordon, Steward, Gleeson and Beech-Jones JJ) held that

> KMD was under no statutory obligation to cooperate with the medical experts whose reports were provided pursuant to ss 43ZK and 43ZN(2)(a). While it may be informative for a review of a CSO, and even in the best interests of persons such as KMD to cooperate with experts whose reports inform a review, nothing in those provisions or

[36] Ibid [187] (Reeves and Burns JJ).
[37] Ibid [193].
[38] *KMD v CEO (Department of Health NT)* [2025] HCA 4, [2].

> any other provision of Pt IIA makes such cooperation a prerequisite to the preparation of their reports, much less the conduct of the review under s 43ZH.[39]

The plurality emphasised that the task of the reviewing judge is to assess whether the safety of the person or the public would be 'seriously at risk' on the evidence available. Such an assessment can occur even if the forensic patient does not cooperate, with the patient's non-cooperation being a relevant factor for the judge to consider.[40]

In the plurality's view, as Brownhill J had complied with the statutory requirements, her decision should not have been overturned on this basis. Her Honour had carefully considered all of the available evidence, including expert reports, reports from victims of the original offending, and reports from KMD's next of kin and Aboriginal community.[41] Her Honour had also appropriately taken into account KMD's refusal to engage with the NT or to receive any treatment for her mental health condition.[42]

Justice Jagot, writing separately, also rejected the suggestion that KMD's refusal to engage with forensic experts could be treated as a de facto bar to release. Her Honour noted that under the Code's statutory scheme, upon completing a review a judge *must* vary a CSO to an NCSO unless it is satisfied, on the evidence available, that the safety of the supervised person or the public will be seriously at risk if this occurs. This requirement exists irrespective of the reasons why the judge is not satisfied that such a risk exists. So even if the cause is the forensic patient's failure to engage with the relevant experts, that does not matter; if the court is not satisfied that the safety of the patient or the community would be seriously at risk if they were placed on an NCSO, the judge must release the patient from custody.[43]

The plurality further held that the NTCCA failed to apply the correct statutory framework when exercising its appellate powers under s 43ZB(3). Having purported to identify error in Brownhill J's reasoning, the NTCCA was required to determine the matter in accordance with the statutory requirements in ss 43ZH(2), 43ZM and 43ZN — which included considering what had occurred during the year that KMD had lived in the community under an NCSO. It failed to

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[39] Ibid [25] (Gordon, Steward, Gleeson and Beech-Jones JJ).
[40] Ibid.
[41] Ibid [13].
[42] Ibid.
[43] Ibid [46].

do so, instead reinstating the CSO without engaging with any evidence about that period.[44]

Justice Jagot strongly reinforced this point. Her Honour held that the NTCCA's decision was incompatible with the structure and purpose of the relevant part of the Code (Part IIA), which expressly requires courts to ensure that liberty is only curtailed to the minimum extent necessary for public safety.[45] Her Honour noted that s 43ZH(2)(a) requires a court to vary a CSO to an NCSO unless it is satisfied, on the evidence available, that the supervised person or the public would be seriously at risk if released, and that this inquiry must be grounded in '"the most recent and accurate information" reasonably available to the Court'.[46] In this regard, Jagot J observed that by the time of the NTCCA hearing, KMD had lived in the community for a year under supervision, and had complied with her NCSO conditions. That period of supervised release was highly relevant to assessing current risk. In those circumstances, the NTCCA should have either obtained and considered updated information or remitted the matter to Brownhill J for reconsideration. Instead, it improperly substituted its own judgment and imposed a CSO based on outdated evidence.[47]

In light of these errors, the High Court set aside the NTCCA's orders, restored the NCSO made by Brownhill J (returning KMD to the community), and remitted the matter to a differently constituted bench of the NTCCA for reconsideration in accordance with the Court's reasons. At the time of writing, that matter has not yet been heard.

PART TWO: HOW SHOULD COURTS DEAL WITH FORENSIC PATIENTS WHO REFUSE TO ENGAGE WITH EXPERTS?

While on its face the High Court's decision in *KMD* is an exercise in statutory interpretation, it raises important questions about how we should address the enduring tension between the community's interest in public safety and the rights of forensic patients to liberty, autonomy and dignity. These questions are particularly pressing in cases like KMD's, where the patient has committed serious acts of violence, but has not been held criminally responsible for those acts.

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[44] Ibid [28]–[31].
[45] See *Criminal Code Act 1983* (NT) s 43ZM.
[46] *KMD v CEO (Department of Health NT)* [2025] HCA 4, [42], quoting *Minister for Aboriginal Affairs v Peko-Wallsend Ltd* (1986) 162 CLR 24, 44.
[47] Ibid [43].

This is not a new issue: it is one that common law courts and legislatures have been grappling with since the development of the insanity defence in 1843.[48] What KMD's case exposes, however, is the difficult ethical terrain that must be navigated when a forensic patient refuses to engage with the psychiatric system. At stake is whether courts should condition release from custody on cooperation with mental health experts, or whether doing so would improperly trample on the forensic patient's rights.

A *The Protective Purpose of Custodial Supervision Orders*

In answering these questions, it is useful to start by considering the purpose of a CSO. It is a legal mechanism that authorises the detention of a forensic patient on the basis that they pose a serious risk to the safety of others.[49] Unlike a sentence imposed following conviction, a CSO is not grounded in punishment, retribution or deterrence. Its primary function is protection: to safeguard the community from future harm that may be caused by the forensic patient. While CSOs may also create opportunities for therapeutic intervention, this role is ultimately instrumental, in that any benefits to the individual are justified by the broader goal of community protection.[50]

The need for protection arises not simply because the individual has a mental impairment, but because there is a nexus between that impairment and prior criminal conduct. The person's past actions, though not criminally punishable, nonetheless evidence a risk that may materialise again, unless appropriately managed. In such circumstances, the CSO provides a structure for risk containment where less restrictive forms of supervision are considered inadequate.

This risk-based justification is the dominant organising principle for determining whether a CSO should be imposed; a person should not be made subject to such an order if they are unlikely to threaten the public's safety if they are not detained. The protective function also shapes the nature of the conditions imposed under a CSO. Forensic patients subject to such orders may be confined in secure hospitals or correctional environments, monitored by mental health professionals, and

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[48] *R v M'Naghten* (1843) 10 Cl & Fin 200; 8 ER 718 (HL).

[49] In some jurisdictions, CSOs may also be imposed to prevent harm to the forensic patient themselves: see, eg, *Crimes (Mental Impairment and Unfitness to be Tried) Act 1997* (Vic) ss 32(2), 35(3)(a); *Criminal Code Act 1983* (NT) s 43ZH(2). However, their primary function remains the protection of the public.

[50] See, eg, *Re PL* [1998] VSC 209, [15].

required to comply with intensive restrictions. While these conditions are often experienced as punitive, their legal purpose is not to punish but to mitigate risk.

B *A Just Redistribution of Responsibility?*

Given that the core function of a CSO is to protect the community from serious harm, it may be thought justifiable to continue such an order where a forensic patient refuses to cooperate with a court-ordered forensic mental health assessment. This is especially so where, like KMD, the person has previously engaged in violent conduct that has caused serious harm to the individuals involved (Mrs L, RL, Mr I) as well as endangering the public. In such circumstances, as the individual has already demonstrated a high degree of risk, it may be considered appropriate to shift the evidentiary burden to them — to expect them to demonstrate, with supporting evidence, that they no longer pose an unacceptable risk to the public.

Given the harm the individual has caused, shifting the evidential burden in this way may be seen to constitute a just redistribution of risk. In this regard, the 1981 Committee on Mentally Disordered Offenders (the 'Floud Committee') argued that

> each of us is presumed free of harmful intentions and therefore cannot justifiably be deprived of liberty on the basis that someone thinks we are dangerous; but, as soon as it is proved that we have done a dangerous act, that presumption disappears and it is fair to redistribute the risk of further harm by incarcerating the dangerous person rather than exposing others to the danger.[51]

Such an approach is consistent with the 'precautionary principle', which holds that when the risks of error are high — particularly where public safety is at stake — decision-makers are justified in erring on the side of caution.[52] In the current context, adherence to the precautionary principle suggests that given KMD has demonstrated seriously harmful conduct, and may do so again, the onus should

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[51] Jean Floud and Warren Young, *Dangerousness and Criminal Justice* (London, Heinemann, 1981), cited in Andrew Ashworth, 'Criminal Law, Human Rights and Preventative Justice' in Bernadette McSherry, Alan Norrie and Simon Bronitt (eds), *Regulating Deviance: The Redirection of Criminalisation and the Futures of Criminal Law* (Hart Publishing, 2009) 87–108, 103. The Floud Committee was a working party established by the Howard League for Penal Reform to examine the best approach to take to 'dangerous offenders'. Its report was considered to be 'a document of major importance both academically and in policy terms': AE Bottoms and Roger Brownsword, 'The Dangerousness Debate After the Floud Report' (1982) 22(3) *British Journal of Criminology* 229, 229.

[52] See generally Cass Sunstein, *Laws of Fear: Beyond the Precautionary Principle* (Cambridge University Press, 2005).

lie on her to establish that it is safe for her to return to the community. This arguably includes requiring her to take all reasonable steps to satisfy the court that she no longer poses a risk — including by engaging with court-ordered mental health practitioners. If she fails to do so, then caution dictates that she should remain in detention.

Framed differently, this obligation could be understood as a civic responsibility placed on the forensic patient due to their previously harmful conduct. In this regard, Ramsay has argued in the context of civil preventive orders that a person who has acted harmfully may have a duty to reassure the community that they are no longer a threat.[53] This may be the case even if they were not criminally responsible for their conduct. Given the harm they have caused, it may reasonably be expected that they will engage in procedures that enable others to properly assess risk, such as participating in court-ordered mental health assessments.

It is important to note that advocates of this approach are not suggesting that forensic patients be *forced* to engage with mental health practitioners, or that they should be punished for failing to do so. They remain free to decline to participate in assessments. However, it is suggested that making that choice should carry the consequence of continued detention, as they will not have met the burden of providing sufficient information to demonstrate that they no longer pose a risk to public safety.[54]

Two interrelated claims are implicit in this approach: first, that it is appropriate to place the evidentiary burden on the forensic patient to demonstrate that they no longer pose a serious risk to the community; and second, that this burden can only be discharged through meaningful engagement with mental health experts.[55] These claims are addressed in turn below.

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[53] Peter Ramsay, 'The Theory of Vulnerable Autonomy and the Legitimacy of the Civil Preventative Order' in Bernadette McSherry, Alan Norrie and Simon Bronitt (eds), *Regulating Deviance: The Redirection of Criminalisation and the Futures of Criminal Law* (Hart Publishing, 2009) 109, 116–7.

[54] This point was made by the NTCCA when returning KMD to custody: *Chief Executive Officer Department of Health v KMD* [2024] NTCCA 8, [191].

[55] There is a third claim implicit in this approach: that mental health assessments can accurately predict future risk. This claim is contested. Recent research suggests that even widely used tools have only modest predictive validity: see Maya GT Ogonah et al, 'Violence Risk Assessment Instruments in Forensic Psychiatric Populations: A Systematic Review and Meta-Analysis' (2023) 10(1) *The Lancet Psychiatry* 780, 789. These problems may be compounded where the tools used have not been validated in relation to the relevant population, or where specific training in relation to that population has not been provided (as was the case in *KMD*: see *R v KMD (No 5)* [2022] NTSC 69, [47]). It is beyond the scope of this article to engage with the substantial literature that addresses the limits of risk assessment in forensic psychiatry.

C *Should the Evidentiary Burden be Placed on the Forensic Patient?*

The proposition that a forensic patient should bear the burden of proving their safety rests uneasily with core principles of criminal justice, civil liberties and human rights. While it may seem sensible to require individuals who have previously caused harm to demonstrate that they no longer pose a threat, doing so overlooks the unique legal and moral position of those who have been found not guilty by reason of mental impairment.

In this regard, it is essential to bear in mind that forensic patients, such as KMD, have not been held criminally responsible for their actions. The law has acknowledged that, at the time of the criminal conduct, they lacked the capacity to understand, assess or control their behaviour due to a mental impairment. Placing an evidentiary burden on them to justify their release treats them in a manner analogous to convicted persons, despite the absence of criminal culpability. This approach erodes the normative significance of the mental impairment defence.

Further, requiring a forensic patient to prove that they no longer pose an unacceptable risk to the public in order to secure their release from custody reverses the traditional onus of proof that underpins the criminal law. It transforms what has historically been a presumption in favour of liberty into a presumption of unacceptable risk. This reversal is particularly troubling given the evidentiary difficulty of proving a negative: it is inherently challenging to demonstrate that one will not cause future harm.[56] It is also arguably unnecessary, given that the individual will generally remain under court supervision even after release on an NCSO. Such individuals may be returned to custody at any time if they are deemed non-compliant with the terms of their supervision order, or if their mental health condition deteriorates. This provides the state with scope to address any unacceptable risks that may arise.

Placing the burden of proof on the forensic patient also conflicts with the foundational legal principle that liberty is (and should be) the default condition of the citizen. Since the time of the Magna Carta, it has generally been accepted that in a free society a person should only be deprived of their liberty if the state can justify that deprivation through lawful, necessary and proportionate means.[57]

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[56] Ian Freckelton, 'The Preventive Detention of Insanity Acquittees: A Case Study from Victoria, Australia' in Bernadette McSherry and Patrick Keyzer (eds), *Dangerous People: Policy, Prediction, and Practice* (Routledge, 2011) 83, 90.

[57] Bernadette McSherry and Patrick Keyzer, *Sex Offenders and Preventive Detention: Politics, Policy and Practice* (Federation Press, 2009) 42–3.

In other words, the right to liberty should only be overridden where the cost to society of not taking action would be substantial and sufficient to justify the loss of the right.[58] In the current context, this means that it should not be enough to suggest that a forensic patient's liberty might lead to harm and so they should remain in custody: to continue their detention the state should be required to demonstrate that harm is probable, and that confinement is the least drastic means of prevention.[59]

This principle is reflected in international human rights law. For example, art 9 of the *International Covenant on Civil and Political Rights* ('ICCPR') provides that no one shall be subjected to arbitrary arrest or detention, and requires that any deprivation of liberty be lawful, reasonable and necessary in the circumstances.[60] While protecting the community from serious harm may constitute a legitimate justification for detaining a forensic patient, this is only so where the state can demonstrate that such detention is necessary and proportionate to the risks they pose. Placing the evidentiary burden on the forensic patient to prove they are safe to release undermines this right, as it enables detention not because the individual poses a demonstrable risk, but simply because they are unable to disprove one.

Article 14(1)(b) of the *Convention on the Rights of Persons with Disabilities* ('CRPD') goes further still. It states that 'the existence of a disability shall in no case justify a deprivation of liberty'.[61] While the scope and interpretation of this provision remain contested, the UN Committee on the Rights of Persons with Disabilities has taken a firm stance; it has consistently held that involuntary detention based on psychosocial disability is incompatible with the CRPD, including where it is framed in protective or therapeutic terms.[62] The Committee's Guidelines on art 14 explicitly reject mental health laws that permit detention based on disability-related risk, asserting that such laws discriminate on the basis of disability and violate the right to liberty. Even if one does not adopt this maximalist interpretation, it is clear that any deprivation of liberty under art 14 must be both necessary and proportionate to the actual risk posed by the

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[58] Ashworth (n 51) 107.
[59] Christopher Slobogin, 'Legal Limitations on the Scope of Preventive Detention' in Bernadette McSherry and Patrick Keyzer (eds), *Dangerous People: Policy, Prediction, and Practice* (Routledge, 2011) 37, 41.
[60] *International Covenant on Civil and Political Rights*, opened for signature 16 December 1966, 999 UNTS 171 (entered into force 23 March 1976) art 9.
[61] *Convention on the Rights of Persons with Disabilities*, opened for signature 30 March 2007, 2515 UNTS 3 (entered into force 3 May 2008).
[62] Committee on the Rights of Persons with Disabilities, *Guidelines on Article 14 of the Convention on the Rights of Persons with Disabilities,* 14th Session (September 2015) 2–3.

individual. Where the burden of proof is placed on a forensic patient to establish that they no longer pose a threat, rather than on the state to justify continued detention, it becomes increasingly difficult to maintain that the deprivation of liberty complies with the principles of necessity, proportionality and non-discrimination that underpin art 14.

It is also important to acknowledge that, at a practical level, risk prediction itself remains an inexact science. Despite advances in risk assessment tools, forensic experts still struggle to make consistently accurate assessments of future risk.[63] False positives — where a person is assessed as posing an acceptable risk but in fact does not — are common.[64] When combined with a reversed burden of proof, this practical reality greatly increases the likelihood of erroneous deprivations of liberty.

D *Should Forensic Patients be Required to Engage with Experts to Secure their Release?*

Regardless of where the burden of proof lies, the central issue in any application to vary a CSO to an NCSO is whether the forensic patient can be safely managed in the community. This is a factual question; if the patient is released, will they pose an unacceptable risk to public safety? To avoid the problems of 'sanism' that often accompany 'common sense' judgments of the risks posed by people with mental illnesses,[65] a proper evidentiary foundation is essential to answer that question. Judges must consider, by reference to the patient's past and current circumstances, not only whether harm may occur, but also the probability that it will occur and the magnitude of the potential harm.

Reaching an appropriate evidence-based conclusion will require judges to consider a broad range of factors. They must evaluate not only clinical assessments of the forensic patient's mental state and history of illness, but also patterns of past behaviour, compliance with previous treatment plans, the availability and reliability of community supports, and any relevant insights offered by family members or carers. The forensic patient's insight into their condition, attitude towards risk factors, and willingness to engage with therapeutic supports will also be relevant. Environmental circumstances, such as the stability of the proposed living arrangements and access to ongoing care, may

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[63] See, eg, Ogonah et al (n 55).
[64] See generally Seena Fazel et al, 'Use of Risk Assessment Instruments to Predict Violence and Antisocial Behaviour in 73 Samples Involving 24,827 People: Systematic Review and Meta-Analysis' (2012) 345 *BMJ* e4692.
[65] See generally Michael Perlin, 'Sanism and the Law' (2013) 15(10) *Virtual Mentor* 878.

also bear significantly on risk. Ultimately, the court's task is to synthesise these diverse strands of information into a coherent risk profile, acknowledging both the inherent uncertainty of future predictions and the serious consequences of getting it wrong.

A recent report from a court-appointed expert who has interviewed and assessed the patient will, in most cases, be extremely helpful. Such a report can provide up-to-date information about the patient's current mental state, their level of insight and engagement, and any changes in presentation since their last formal review. However, while this kind of evidence is clearly valuable, it is not essential. The court is still able to make an informed decision based on the other evidence in the case.

In this regard, it is important to note that even in the absence of a recent expert assessment, the court will seldom be without several other sources of evidence (as was demonstrated in KMD's case). Forensic patients are typically subject to extensive monitoring while in custody. Clinical records, behavioural observations, reports from treating teams, compliance with medication, and institutional incident reports can all provide valuable insights. Previous expert evaluations and collateral input from family members or support workers may also assist. This kind of information forms part of the evidentiary matrix on which risk can be assessed and managed, and may well be sufficient to properly assess risk. The court's role is to make the best possible determination on the basis of the material available — it should not be precluded from acting simply because the patient has not participated in a new assessment.

Of course, the fact that a forensic patient has not engaged with an expert will inevitably be a highly relevant consideration. It may suggest a lack of insight, unwillingness to comply with treatment, or an elevated risk of future harm. However, it should not be treated as determinative. The nature of the forensic patient's condition and the reasons for non-engagement must also be carefully considered. In KMD's case, she declined to participate in a forensic assessment because she, perhaps reasonably, believed that discussing the events surrounding her offending would not assist her recovery and could, in fact, be harmful. It is also relevant that KMD's delusional belief appears to have been monosymptomatic, centred exclusively on the alleged risk to her son. By the time of her review hearings, her son was no longer a child, and the immediate circumstances that had sustained the delusion had largely dissipated. Against that backdrop, her refusal to revisit those events with a forensic psychologist may have carried less significance for assessing her current risk than in cases where the delusional content continues to be reinforced by present circumstances.

In other cases, an individual may refuse to cooperate due to adverse past experiences with mental health services, the debilitating side effects of certain medications, or a principled objection to the forensic mental health system itself; or they may be unable to engage due to a cognitive impairment or a psychiatric condition such as catatonia. It would be unjust to impose indefinite detention on a person simply because they are unable, or understandably unwilling, to participate in a court-ordered assessment.

Importantly, the court must avoid treating non-engagement with experts as a proxy for posing an unacceptable risk. Refusal to cooperate is one factor among many and should be weighed accordingly. The court's task is to determine, on *all* of the available evidence, whether the person would pose an unacceptable risk if released from custody — not to punish them for failing to participate in a mental health assessment. This decision should rest on a holistic assessment of risk, not a procedural default.

Requiring engagement with mental health experts as a de facto condition of release also raises serious concerns about the infringement of the patient's autonomy and dignity. Although they may not be formally compelled to participate, the consequences of declining to do so may be so grave as to render the choice illusory. For example, in the NT, where CSOs are indefinite in nature, the 'choice' to not engage would result in lifelong detention. In this context, autonomy is undermined not through direct coercion, but through the structuring of consequences so severe that refusal becomes untenable. This reflects what Szmukler has described as the spectrum of 'treatment pressures', where liberty is undermined not only by formal compulsion but also by subtler forms of coercion, inducement and threat.[66]

At a practical level, it is important to note that situations like KMD's are extremely rare. Most forensic patients are likely to engage with court-appointed experts, given it is likely to be in their best interests to do so.[67] This is due to the fact that judges tend to place considerable weight on matters such as insight, treatment adherence, and willingness to engage with supports: matters that may be best evaluated from a recent assessment.[68] Judges also tend to be cautious in releasing forensic patients from custody, often maintaining supervision orders even when

[66] George Szmukler, *Men in White Coats: Treatment under Coercion* (Oxford University Press, 2018) 153–70.

[67] In this regard, it is worth noting that KMD did engage with experts at her special hearing, as well as during the first two reviews of her CSO.

[68] See generally Ian Freckelton, 'Distractors and Distressors in Involuntary Status Decision-Making' (2005) 12(1) *Psychiatry, Psychology and Law* 88.

expert opinion favours discharge.[69] This judicial tendency toward caution underscores the importance of having clear and fair processes for assessing risk, and ensuring that non-engagement is not misunderstood or unfairly penalised.

CONCLUSION

KMD's case raises important questions about how the justice system should respond to forensic patients who decline to engage with mental health assessments. This article has argued that while cooperation with mental health experts can provide valuable insight into a person's current risk profile, it should not be treated as a prerequisite for liberty. The justification for ongoing detention must rest not on procedural compliance but on clear, evidence-based findings of necessity and proportionality.

This is not to deny the validity of people's desire to adopt a precautionary approach: to detain individuals who have committed harmful acts unless and until it can be affirmatively proven that they are safe to release. However, while such an approach may offer a sense of security, its application in this context sits uneasily with established criminal justice norms. Traditionally, the criminal law requires the state to prove the need for detention, not the individual to prove their entitlement to release. Reversing this logic, even implicitly, risks undermining core protections, particularly for individuals who have not been found criminally responsible. Moreover, it risks transforming the qualified acquittal of 'not guilty by reason of mental impairment' into a kind of indeterminate sentence, contingent on the individual's capacity and willingness to engage with systems they may justifiably mistrust or fear. This creates a fundamental disparity between the protections afforded in ordinary criminal proceedings and those available to forensic patients.

The effects of this disparity are particularly striking when forensic patients are compared with convicted offenders who have committed similar acts but are found criminally responsible. A person who is convicted will ordinarily receive a finite sentence, after which they are entitled to their liberty regardless of ongoing risk. By contrast, forensic patients subject to CSOs may spend significantly longer in custody than convicted offenders sentenced for equivalent conduct. This is because release depends not on the expiry of a fixed term but on periodic assessments of future risk. Such assessments are inherently uncertain and tend to be approached cautiously, with courts inclined to continue detention where doubts remain about community safety. Detaining people on the basis of risk

[69] Freckelton (n 566) 92.

rather than culpability creates a clear potential for disproportionate and discriminatory outcomes.

Part of the problem here lies in how the issue of release from custody is often framed: as a balancing act between protection of the individual and the community. When framed in this way, community protection is highly likely to prevail.[70] That framing was adopted by the NTCCA judgment in *KMD*, which spoke of 'a balancing of personal and public interests' and concluded that KMD's refusal to engage with practitioners had 'skewed the focus' too far in her favour.[71] By reducing the matter to competing interests rather than recognising it as a question of rights, individual liberty was left vulnerable to being eclipsed by community concerns. The better approach, adopted by the High Court, is to begin from a rights-based position, requiring restrictions on liberty to be kept to the minimum consistent with community safety and grounded in the most accurate information reasonably available.[72] This approach better aligns with international human rights instruments such as the ICCPR and the CRPD, which make it clear that liberty may *only* be curtailed where it is lawful, necessary and proportionate. On this view, the liberty of people like KMD should not be treated as a privilege or a reward for cooperation, but as a right that endures regardless of their criminal history, mental health status or willingness to engage with forensic assessments.

The broader significance of *KMD* remains uncertain. While it may ultimately be confined to the peculiarities of Northern Territory legislation, the High Court's insistence that liberty cannot be made contingent on cooperation with experts has the potential to resonate more broadly. The case could inform advocacy for forensic patients in other jurisdictions, and even for civil patients subject to involuntary treatment orders, where non-compliance is often treated as sufficient justification for detention or compulsory treatment. Whether courts will extend *KMD* in this way remains to be seen, but the decision underscores a critical principle: refusal to engage with medical experts should not, in itself, determine a person's right to liberty.

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[70] Bernadette McSherry and Patrick Keyzer, '"Dangerous" People: The Road Ahead for Policy, Prediction, and Practice' in Bernadette McSherry and Patrick Keyzer (eds), *Dangerous People: Policy, Prediction, and Practice* (Routledge, 2011) 251, 253.

[71] *Chief Executive Officer Department of Health v KMD* [2024] NTCCA 8, [193] (Reeves and Burns JJ).

[72] *KMD v CEO (Department of Health NT)* [2025] HCA 4, [25] (Gordon, Steward, Gleeson and Beech-Jones JJ), [46] (Jagot J).

NEURODIVERSITY (IN)JUSTICE: LEARNINGS FOR AUSTRALIA FROM INTERNATIONAL APPROACHES TO SUPPORTING NEURODIVERGENT PEOPLE IN JUSTICE FACILITIES

HAYLEY PASSMORE *

To function in a world developed for neurotypical people, those who are neurodivergent sometimes require additional support, modified expectations, or environmental adaptations. While international evidence indicates a high prevalence of neurodivergent people within criminal justice systems, often their needs are not recognised or supported adequately by these systems. Instead, we see the challenges for neurodivergent people exacerbated, given the stressors of criminal justice environments and the lack of awareness or capacity to accommodate individual needs. As the recent Royal Commission into Violence, Abuse, Neglect and Exploitation of People with Disability has described, there is urgent reform required across Australia to ensure the rights of people with disability are upheld in our criminal justice system. This article utilises learnings from prisons and youth detention centres in the United Kingdom, the United States of America, Canada, and Aotearoa New Zealand to make recommendations for the current Australian criminal justice context.

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I INTRODUCTION

People who are neurodivergent face an elevated risk of encountering the justice system compared to those who are neurotypical.[1] With complex legal language, fast-paced decision making processes, abstract concepts, and implicit power dynamics, the criminal justice system can be challenging to navigate.[2] For those who are neurodivergent, these challenges may be exacerbated, particularly if the appropriate supports and modifications are not put in place.[3] Once within the justice system, neurodivergent people may encounter barriers related to accessing support, self-advocacy, following instructions, understanding social expectations, and comprehending behavioural repercussions, potentially leading to recurrent involvement with the system.[4] Implementing tailored support and accommodations is essential to enhance the accessibility and fairness of the criminal justice system for neurodivergent individuals. This article considers current evidence and international approaches to supporting neurodivergent individuals in justice facilities to produce high-level recommendations for the Australian justice system.

A *Terminology*

Diverse terminology has been used across disability support services, academic literature, legislation, and clinical practice. It is important to note that people with lived experience of disability, including neurodivergence, are the primary experts regarding appropriate terminology. As such, they will have individual preferences

[1] See generally Rohan Borschmann et al, 'The Health of Adolescents in Detention: A Global Scoping Review' (2020) 5(2) *Lancet Public Health* e114; Mike Hellenbach, Thanos Karatzias and Michael Brown, 'Intellectual Disabilities Among Prisoners: Prevalence and Mental and Physical Health Comorbidities' (2017) 30(2) *Journal of Applied Research in Intellectual Disabilities* 230.

[2] See generally Natasha Reid et al, 'Fetal Alcohol Spectrum Disorder: The Importance of Assessment, Diagnosis and Support in the Australian Justice Context' (2020) 27(2) *Psychiatry, Psychology and Law* 265.

[3] Eileen Baldry et al, 'Reducing Vulnerability to Harm in Adults with Cognitive Disabilities in the Australian Criminal Justice System' (2013) 10(3) *Journal of Policy and Practice in Intellectual Disabilities* 222, 227.

[4] Reid et al (n 2) 266.

for the terms used to describe themselves, their abilities, and their disabilities. Various terminology is often used for different settings and purposes, such as diagnostic terminology used in medical settings which may not reflect current community preferences or the social model of disability.[5] Understanding nuanced terminology is essential for creating a more inclusive and accommodating society.

The term neurodiversity describes the natural variation in how human brains develop and function, underlining the fact that no two brains (and therefore no two individuals) are exactly alike. Commonly preferred by lived experience communities, 'neurodivergent' is used to specifically refer to individuals whose brain functions deviate from what is conventionally expected, or 'neurotypical'.[6] The terms 'neurodisability' and 'neurodevelopmental disorders' have been used within academic literature, and encompass a group of conditions that can be congenital or acquired which result in functional limitations due to impairment of the brain or nervous system.[7] This includes conditions such as Intellectual Disability, Autism Spectrum Disorder, Fetal Alcohol Spectrum Disorder ('FASD'), Language Disorder, Dyslexia, and Attention Deficit Hyperactivity Disorder ('ADHD'), among others.[8]

B *Background*

Global evidence indicates a much higher prevalence of neurodisability among justice-involved populations when compared to community-based peers.[9] Evidence involving adult prison populations has reported prevalence rates of people with cognitive disabilities between 2% and 69%.[10] In the youth justice system, where much of the research to date has focused, more diagnosis specific prevalence rates are available. Language disorder and other communication impairments, for example, have been reported in 60–65% of justice-involved

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[5] See generally People with Disability Australia, *PWDA Language Guide: A Guide to Language About Disability* (Report, August 2021).
[6] Ibid 13.
[7] See generally Christopher Morris et al, 'Informing the NHS Outcomes Framework: Evaluating Meaningful Health Outcomes for Children with Neurodisability Using Multiple Methods Including Systematic Review, Qualitative Research, Delphi Survey and Consensus Meeting' (2014) 2(15) *Health Services and Delivery Research* 149.
[8] Nathan Hughes et al, *Nobody Made the Connection: The Prevalence of Neurodisability in Young People Who Offend* (Report, Office of the Children's Commissioner for England, October 2012) 9–11.
[9] Borschmann et al (n 1) e118; Hellenbach, Karatzias and Brown (n 1) 230–1.
[10] Calum Henderson and Melissa Bull, 'Sentencing and the Over-Representation of People with Cognitive Disability in the Australian Criminal Justice System' (2024) 36(1) *Current Issues in Criminal Justice* 81, 83.

youth, approximately 13 times higher than youth in the community.[11] At a rate of approximately 16 times higher than community peers, youth in the justice system have an ADHD prevalence rate of up to 50%.[12] Reported prevalence of FASD ranges from 11–36% of youth within the justice system, approximately 19 times higher than in the general community.[13] Learning disabilities, traumatic brain injuries, and intellectual disabilities also exhibit significantly elevated rates in justice-involved youth, ranging from three to 16 times higher compared to community rates.[14] Given most justice populations will not have had access to comprehensive assessments of their health and development, these rates are likely underestimated.[15]

While these disproportionate rates of disability among people involved in the justice system do not indicate an innate relationship between disability and criminal behaviour, they do reflect the systemic barriers and disadvantages disabled people often experience. Such disadvantages include poverty, family violence or separation, adverse childhood experiences, substance misuse, homelessness, and unemployment.[16] For Indigenous peoples with disability, these disadvantages are often compounded by ongoing colonisation, transgenerational trauma, discrimination, systemic racism and oppression, and a lack of culturally safe support.[17] Frameworks such as the Social Determinants of Health, Cultural Emotional, Social and Wellbeing Models, and more recently the

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[11] Borschmann et al (n 1) e118.

[12] Ibid; Seena Fazel, Helen Doll and Niklas Långström, 'Mental Disorders Among Adolescents in Juvenile Detention and Correctional Facilities: A Systematic Review and Metaregression Analysis of 25 Surveys' (2008) 47(9) *Journal of the American Academy of Child & Adolescent Psychiatry* 1010, 1015–16; Susan Young et al, 'A Meta-Analysis of the Prevalence of Attention Deficit Hyperactivity Disorder in Incarcerated Populations' (2015) 45(2) *Psychological Medicine* 247, 252.

[13] Borschmann et al (n 1) e119; Carol Bower et al, 'Fetal Alcohol Spectrum Disorder and Youth Justice: A Prevalence Study Among Young People Sentenced to Detention in Western Australia' (2018) 8(2) *BMJ Open* e019605, 1, 6–7; Svetlana Popova et al, 'Fetal Alcohol Spectrum Disorder Prevalence Estimates in Correctional Systems: A Systematic Literature Review' (2011) 102(5) *Canadian Journal of Public Health* 336, 339.

[14] Borschmann et al (n 1) e118.

[15] See generally Keith McVilly et al, 'Identifying and Responding to Young People with Cognitive Disability and Neurodiversity in Australian and Aotearoa New Zealand Youth Justice Systems' (2023) 30(6) *Psychiatry, Psychology and Law* 789.

[16] Ruth McCausland and Eileen Baldry, 'Who Does Australia Lock Up?: The Social Determinants of Justice' (2023) 12(3) *International Journal for Crime, Justice and Social Democracy* 37, 42–8.

[17] See generally Sophie Russell, James Beaufils and Chris Cunneen, 'Rehabilitation and Beyond in Settler Colonial Australia: Current and Future Directions in Policy and Practice' in Maurice Vanstone and Philip Priestley (eds), *The Palgrave Handbook of Global Rehabilitation in Criminal Justice* (Springer International Publishing, 2022) 33; Chris Cunneen, 'Racism, Discrimination and the Over-Representation of Indigenous People in the Criminal Justice System: Some Conceptual and Explanatory Issues' (2006) 17(3) *Current Issues in Criminal Justice* 329.

Social Determinants of Justice, describe the interaction of such disadvantages and justice involvement, highlighting that justice involvement is almost always an indicator of wider unmet needs.[18]

Each stage of justice involvement requires particular cognitive and social skills to navigate it successfully. Typical contact with the criminal justice system initially begins with police contact followed by investigative interviews which require skills involving memory, verbal communication, and narrative discourse.[19] For some neurodivergent people, this poses challenges if they have difficulties recalling events or telling a narrative in chronological order.[20] The potential for misinterpretations and miscommunications is significant, and may result in a neurodivergent person appearing as if they are being evasive or lying.[21] Participating in court proceedings often requires receptive and expressive language skills, self-advocacy, and the ability to process both verbal and written information quickly. Challenges with each of these are common among neurodivergent individuals, potentially impacting their ability to participate fully in their own defence.[22] Further, at sentencing an individual is often expected to comprehend cause-and-effect relationships and demonstrate social cognition and empathy. A lack of consequential thinking and the inability to express remorse may have substantial influence on the sentencing outcomes for neurodivergent individuals.[23] Conditions given to individuals, such as community-based orders or directives within custodial environments, also present challenges, relying on memory retention, comprehension of instructions, understanding abstract concepts such as time, and adherence to social rules and expectations.[24] Such expectations may be difficult to meet for neurodivergent individuals, inadvertently leading to non-compliance and further justice-involvement.

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[18] McCausland and Baldry (n 16) 45; Graham Gee et al, 'Aboriginal and Torres Strait Islander Social and Emotional Wellbeing' in Pat Dudgeon, Helen Milroy and Roz Walker, *Working Together: Aboriginal and Torres Strait Islander Mental Health and Wellbeing Principles and Practice* (Report, 2014) 57; James Wilson, 'Justice and the Social Determinants of Health: An Overview' (2009) 2(3) *Public Health Ethics* 210, 210.

[19] See generally Linda Hand et al, 'Oral Language and Communication Factors to Consider when Supporting People with FASD Involved with the Legal System' in *Fetal Alcohol Spectrum Disorders in Adults: Ethical and Legal Perspectives: An Overview on FASD for Professionals* (Springer, 2015) 139; Reid et al (n 2).

[20] See generally Pamela Rosenthal Rollins, 'Narrative Skills in Young Adults With High-Functioning Autism Spectrum Disorders' (2014) 36(1) *Communication Disorders Quarterly* 21.

[21] Reid et al (n 2) 267.

[22] Pamela Snow, Martine Powell and Dixie Sanger, 'Oral Language Competence, Young Speakers, and the Law' (2012) 43(4) *Language Speech and Hearing Services in Schools* 496, 503.

[23] Baldry et al (n 3) 223; Diane Fast and Julianne Conry, 'Fetal Alcohol Spectrum Disorders and the Criminal Justice System' (2009) 15(3) *Developmental Disabilities Research Reviews* 250, 251.

[24] Reid et al (n 2) 268.

II AUSTRALIAN CONTEXT

While there is considerable progress internationally in terms of recognising and responding to neurodiversity within criminal justice settings, until recently there were limited efforts across Australia to provide appropriate accommodations and support. Volume Eight of the 2023 Royal Commission into Violence, Abuse, Neglect and Exploitation of People with Disability described the extensive and repeated failings of Australian justice systems, particularly youth justice systems, to uphold the rights of people with disability.[25] Australia has international obligations to take appropriate systemic and administrative approaches to protect the rights of people with disability, the rights of children, the rights of Indigenous peoples, and the rights of those deprived of liberty: obligations which the United Nations has repeatedly identified as not met by Australian criminal justice systems.[26] Health care and therapeutic interventions within prisons and youth detention centres vary greatly across Australia, given our health care services are state-based as opposed to federal.[27] Primary health care within prisons may be provided by corrective services, the health department, Aboriginal community-controlled health organisations, non-government organisations, private services, or a combination of these services.[28] There is limited consistency in screening and assessment processes for neurodiversity, with many neurodivergent people in Australian justice systems remaining undiagnosed or misdiagnosed.[29] Disability supports and accessible programs are

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[25] See generally *Royal Commission into Violence, Abuse, Neglect, and Exploitation of People with Disability* (Final Report, 2 November 2023) vol 8(1) ('*Royal Commission*').

[26] See generally *Convention on the Rights of the Child*, opened for signature 20 November 1989, 1577 UNTS 3 (entered into force 2 September 1990) art 1; *Convention of the Rights of Persons with Disabilities*, opened for signature 13 December 2006, 2515 UNTS 3 (entered into force 3 May 2008); *United Nations Declaration on the Rights of Indigenous Peoples*, GA Res 61/295, UN Doc A/RES/61/295 (2 October 2007, adopted 13 September 2007); *Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment*, opened for signature 10 December 1984, 1465 UNTS 85 (entered into force 26 June 1987); Australian National Preventive Mechanism, *Monitoring Places of Detention Under the Optional Protocol to the Convention Against Torture: Annual Report of the Australian National Preventive Mechanism* (Report, 2023) <https://www.oics.wa.gov.au/wp-content/uploads/2024/07/Australian-NPM-Annual-Report-2022-23-304534.pdf>; Janani Muhunthan, Anne-Marie Eades and Stephen Jan, 'UN-Led Universal Periodic Review Highly Critical of Australia's Record on Human Rights and Health for Indigenous Australians' (2016) 1(1) *BMJ Global Health* e000018; Anita Mackay, *Towards Human Rights Compliance in Australian Prisons* (ANU Press, 2020); United Nations, *Youth Justice Systems Across Australia in Crisis: UN Experts* (Media Release, 2025) <https://www.ohchr.org/en/media-advisories/2025/05/youth-justice-systems-across-australia-crisis-un-experts>.

[27] Craig Cumming et al, 'In Sickness and in Prison: The Case for Removing the Medicare Exclusion for Australian Prisoners' (2018) 26(1) *Journal of Law and Medicine* 140, 140.

[28] Ibid 150.

[29] McVilly et al (n 15) 793.

lacking, and significant gaps between evidence and practice exist.[30] Further, there is limited evidence for culturally valid screening and assessment processes for Aboriginal and Torres Strait Islander people, and the risk of misdiagnosis is high.[31] Given the systemic racism well documented in past and present Australian criminal justice processes, there is a critical need for Indigenous people who may be neurodivergent to receive culturally safe health care, including tailored disability support.[32]

The limited existing neurodisability prevalence data further highlights significant need for adequate disability support in justice settings across Australia.[33] The Australian Institute of Health and Welfare reports that 39% of people entering Australian prisons have a disability or chronic condition that affects their daily function, compared to 18% of general community members with disability.[34] Research in New South Wales prisons reported between 40% to 90% of adults in prisons may have an acquired brain injury.[35] In Western Australia, child health researchers (including this author) conducted a FASD prevalence study among youth in detention, in which extensive neurodevelopmental impairments were identified.[36] The study involved a multidisciplinary team, including a paediatrician, neuropsychologist, speech and language therapist, and occupational therapist, who comprehensively assessed young people over a two-year period.[37] The assessments covered nine different areas of neurodevelopmental function, such as memory, communication, social skills, executive functioning, cognition, motor skills, and academic abilities. In this study, we identified that 36% of the 99 young people assessed had FASD based on the

[30] Ibid.
[31] Ibid; Lorelle Holland, Natasha Reid and Andrew Smirnov, 'Neurodevelopmental Disorders in Youth Justice: A Systematic Review of Screening, Assessment and Interventions' (2021) 19(1) *Journal of Experimental Criminology* 31, 35.
[32] Russell, Beaufils and Cunneen (n 17) 44; Simon Pettit et al, 'Holistic Primary Health Care for Aboriginal and Torres Strait Islander Prisoners: Exploring the Role of Aboriginal Community Controlled Health Organisations' (2019) 43(6) *Australian and New Zealand Journal of Public Health* 538, 542.
[33] McVilly et al (n 15) 804; Borschmann et al (n 1) e118.
[34] Australian Institute of Health and Welfare, *The Health of People in Australia's Prisons 2022* (Report, Catalogue no PHE 334, 2023) 39.
[35] New South Wales State Government Justice Health and Forensic Mental Health Network, *Network*
Patient Health Survey – Aboriginal People's Health Report 2015 (Report, November 2017) 20.
[36] Bower et al (n 13) 6.
[37] Hayley Passmore et al, 'Study Protocol for Screening and Diagnosis of Fetal Alcohol Spectrum Disorders (FASD) Among Young People Sentenced to Detention in Western Australia' (2016) 6(6) *BMJ open* e012184, 8.

2016 Australian Guide to Diagnosis of FASD.[38] This was the highest known prevalence of FASD in a justice setting worldwide. More pertinently, our study found that 89% of the young people had a severe impairment in at least one of the nine areas of neurodevelopment assessed, with 65% severely impaired in three or more areas simultaneously.[39] This indicates that the development of these young people deviates significantly from what is expected for their chronological age. Almost all these young people did not have these needs identified prior to the study, potentially impacting their involvement with various systems and services, including education, law enforcement, child protection, community services, and the justice system.[40]

III INTERNATIONAL APPROACHES

Internationally, responses to supporting neurodivergent people in justice facilities are varied. Resourcing, service availability, diagnostic approaches, and cross-agency collaborations within a jurisdiction affect the quality of responses and support provided.[41] While there is no one "best practice" approach, there are many elements of evidence-based and evidence-informed practice occurring internationally which provide scaffolding for what an effective neurodiversity-informed justice system should entail.[42]

One key element is the meaningful integration of health services within justice facilities. Global evidence indicates that when a person's health and wellbeing needs are met, their ability to actively participate in and complete rehabilitation and reintegration programs during and after justice-involvement improves.[43] Meeting these needs involves comprehensive and routine assessment practices, multidisciplinary teams, sufficient resources, effective information sharing processes, and appropriate caseloads and staff-to-resident ratios.[44] In the United Kingdom ('UK'), for example, the National Health Service commissions all health

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[38] Bower et al (n 13) 6. See generally Carol Bower and Elizabeth Elliott, *Report to the Australian Government Department of Health: "Australian Guide to the Diagnosis of Fetal Alcohol Spectrum Disorder (FASD)"* (Report, 2016).
[39] Bower et al (n 13) 5.
[40] Ibid.
[41] Holland, Reid and Smirnov (n 31) 60–3.
[42] Reid et al (n 2) 269.
[43] Seena Fazel and Jacques Baillargeon, 'The Health of Prisoners' (2011) 377(9769) *Lancet* 956, 962; Borschmann et al (n 1) e121.
[44] See generally Stuart Kinner et al, 'Low-Intensity Case Management Increases Contact with Primary Care in Recently Released Prisoners: A Single-Blinded, Multisite, Randomised Controlled Trial' (2016) 70(7) *Journal of Epidemiology & Community Health* 683; Katherine McLeod et al, 'Global Prison Health Care Governance and Health Equity: A Critical Lack of Evidence' (2020) 110(3) *American Journal of Public Health* 303.

care services within prisons, typically involving a primary health care team for physical needs working alongside mental health and wellbeing care teams.[45] In many prisons, youth offending institutions, and secure care facilities, these care teams involve allied health professionals such as psychologists, speech and language pathologists, and occupational therapists. Case coordination and management teams are also involved, and are key to supporting individuals to navigate their health and wellbeing support.[46] Facilities with appropriate staffing have the greatest opportunity to progress not only clinical assessment and intervention, but also involve health professionals in delivering therapeutic programs, educating operational staff in appropriate practices, and providing psychoeducation to neurodivergent people about their functionality.[47] However, given that there are no national minimum health care commissioning requirements, there is limited consistency in the resourcing of health teams across UK prisons.[48] Such diversities also exist in most other countries, including Australia, where responses vary within each state and territory.[49] Both the UK and Aotearoa New Zealand have made considerable efforts to incorporate the expertise of speech and language pathologists into justice settings, with intermediaries and communication assistants involved in police interviews and court proceedings in these jurisdictions.[50] The role of these professionals is to provide impartial communication support for either a defendant, witness, or victim, to ensure those with a language disorder or other communication challenges are able to fully participate in and access justice processes.[51] While intermediary services are growing in Australia, there have been discrepancies across jurisdictions, and limited availability of these services for defendants.[52]

Internationally, there are challenges with using consistent, evidence-based approaches to the identification of neurodivergent people, and the sharing of

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[45] See generally Roger Watson, Anne Stimpson and Tony Hostick, 'Prison Health Care: A Review of the Literature' (2004) 41(2) *International Journal of Nursing Studies* 119; United Kingdom Ministry of Justice, *A Response to Criminal Justice Joint Inspection: Neurodiversity in the Criminal Justice System, A Review of Evidence* (Neurodiversity Action Plan, 2022).

[46] Kinner et al (n 44) 685.

[47] Megan Georgiou and Jemini Jethwa, 'Planning Effective Mental Healthcare in Prisons: Findings from a National Consultation on the Care Programme Approach in Prisons' (2021) 77 *Journal of Forensic and Legal Medicine* 102105, 102107.

[48] Watson, Stimpson and Hostick (n 45) 121.

[49] See generally Cumming et al (n 27); McLeod et al (n 44).

[50] See generally Aine Kearns et al, 'Perspectives on the Role of the Intermediary in the Justice System: A Systematic Review and Qualitative Synthesis' (2025) 29(3) *International Journal of Evidence & Proof* 163.

[51] Ibid.

[52] See generally Jacqueline Giuffrida and Anita Mackay, 'Extending Witness Intermediary Schemes to Vulnerable Adult Defendants' (2021) 33(4) *Current Issues in Criminal Justice* 498.

information across agencies and services.[53] Prisons and youth detention centres, even within one jurisdiction, often use varied and sometimes unvalidated tools, leading to unreliable identification of needs. While some jurisdictions are working to develop more comprehensive screening processes, such as Aotearoa New Zealand progressing administration of culturally safe and holistic screening tools, there are significant evidence gaps globally.[54] It is crucial that assessment tools align with both the specific population and the purpose for which they are used, and that results are interpreted accordingly.

Staff training in neurodiversity, cultural safety, and trauma-informed approaches is critical to foster safe and inclusive justice environments for neurodivergent populations.[55] This training should be routine, evidence-informed, and regularly updated. Evidence indicates that communication styles emphasising active listening, concrete and explicit instructions, and respectful engagement can lead to improvements in wellbeing for both staff and residents.[56] When individuals are actively involved in decisions about their daily routines, behavioural management plans, throughcare or reintegration plans, and disability support plans, their autonomy and engagement can improve substantially.[57] The UK has made progress by introducing Neurodiversity Support Managers in all prisons to coordinate support strategies, provide psychoeducation and advocacy services, improve neurodiversity awareness among operational staff, deliver staff training, and develop tailored visual communication tools.[58] A more targeted initiative in Canada, the Manitoba FASD program, involves a team of experts trained in FASD

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[53] Borschmann et al (n 1) e121; Hellenbach, Karatzias and Brown (n 1) 237.

[54] Borschmann et al (n 1) e122; Hellenbach, Karatzias and Brown (n 1) 237; McVilly et al (n 15) 799. See generally Mark Henaghan and Jean Choi, 'Promising Steps in Aotearoa New Zealand Criminal Law to Recognise Neurodiversity' in Hannah Wishart and Ray Arthur (eds), *International Perspectives of Neuroscience in the Youth Justice Courtroom* (Routledge, 2025) 55.

[55] Hayley Passmore et al, 'Reframe the Behaviour: Evaluation of a Training Intervention to Increase Capacity in Managing Detained Youth with Fetal Alcohol Spectrum Disorder and Neurodevelopmental Impairments' (2021) 28(3) *Psychiatry, Psychology and Law* 382, 383; Hayley Passmore et al, 'Fetal Alcohol Spectrum Disorder (FASD): Knowledge, Attitudes, Experiences and Practices of the Western Australian Youth Custodial Workforce' (2018) 59 *International Journal of Law and Psychiatry* 44, 50.

[56] Deborah Denton and Linda Grenade, 'Connecting with Clients: Building Therapeutic Alliances with People Who are Incarcerated' (2022) 10(1) *Psychotherapy and Counselling Journal of Australia* 1; Davinia Rizzo, Belinda Davey and Melanie Irons, 'Interpersonal Interaction Between Prisoners and Officers in Prisons: A Qualitative Meta-Synthesis Exploring Prison Officer Wellbeing' (2021) 10(1) *Journal of Qualitative Criminal Justice & Criminology* 1.

[57] McVilly et al (n 15) 790.

[58] See generally United Kingdom Ministry of Justice (n 45); United Kingdom Ministry of Justice, 'Greater Support for Neurodivergent Offenders in Bid to Cut Crime' (Press Release, 16 May 2024) <https://www.gov.uk/government/news/greater-support-for-neurodivergent-offenders-in-bid-to-cut-crime>.

who provide psychoeducation to youth and adults in custody, upskill other service providers in FASD knowledge and practice, provide referrals for further assessment, diagnosis, and intervention, and work with the specialist FASD court to provide individualised neurodevelopmental profiles and tailored support recommendations.[59] Psychoeducation for both diagnosed and undiagnosed neurodivergent people is critical to empower individuals to understand their cognitive strengths, difficulties, and opportunities for support and self-advocacy.[60]

Appropriately supporting people in justice facilities also requires intentional environmental design and infrastructure conducive to therapeutic responses. For neurodivergent people, small, purpose-built facilities with higher staff-to-resident ratios often provide more opportunity for meaningful engagement and support compared to larger, more traditional prison facilities.[61] Currently, many facilities are unsuitable for and not conducive to therapeutic or trauma-informed approaches, with rehabilitation and educational programs often facilitated in overstimulating and chaotic environments.[62] While some jurisdictions, such as the UK and the United States of America, have begun incorporating sensory considerations into new prison designs (such as providing specialised sensory rooms where a resident can self-regulate or decompress in an environment where they have choices regarding lighting, sounds, and furniture textures) there remains a significant gap in modifying existing facilities to reduce environmental barriers.[63]

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[59] See generally Sally Longstaffe et al, 'The Manitoba Youth Justice Program: Empowering and supporting Youth with FASD in Conflict with the Law' (2018) 96(2) *Biochemistry and Cell Biology* 260.

[60] See generally Lauren Amy Powell et al, 'Psychoeducation Intervention Effectiveness to Improve Social Skills in Young People with ADHD: A Meta-Analysis' (2022) 26(3) *Journal of Attention Disorders* 340; Louise Buchan and Tom McMillan, 'Prisoner Knowledge About Head Injury is Improved by Brief Psychoeducation' (2022) 36(3) *Brain Injury* 401.

[61] Elizabeth Grant, 'Ravenhall Correctional Centre: The Master Planning and Architectural Design of a Multifaceted, People-Oriented Prison for Men with Complex Physical and Mental Health Needs in Victoria, Australia' (2020) 9(1) *Advancing Corrections* 146, 153.

[62] See generally Caitlin Gormley, 'The Hidden Harms of Prison Life for People with Learning Disabilities' (2022) 62(2) *British Journal of Criminology* 261.

[63] See generally Gisele Craswell, Crystal Dieleman and Parisa Ghanouni, 'An Integrative Review of Sensory Approaches in Adult Inpatient Mental Health: Implications for Occupational Therapy in Prison-Based Mental Health Services' (2021) 37(2) *Occupational Therapy in Mental Health* 130.

IV RECOMMENDATIONS

Immediate change is needed across Australian criminal justice facilities to ensure people who are neurodivergent have their needs identified and responded to.[64] This is essential to facilitate equitable access to justice, support, health care, and rehabilitation opportunities for people in all justice settings. Simultaneously, we need comprehensive mechanisms to support neurodivergent people in the community and prevent justice involvement at the outset.

To this end, this article offers a series of short, medium, and long-term recommendations to better support neurodivergent people in justice facilities. The following discussion does not order the recommendations by priority or importance, as all matters raised require a sense of urgency. Instead the recommendations are ordered by feasibility, which is likely to be persuasive to the agencies and decision makers involved. However, these high-level recommendations are also relevant to all who work within the justice sector, regardless of decision-making power. This includes frontline staff, service providers, government agencies, politicians, researchers, advocates and funders. These recommendations are made in addition to, and hopefully in alignment with, recommendations from people with lived experience who are the experts in these matters, as well as their families and communities. Given that common Western approaches to criminal justice and penalty can be fundamentally flawed and rooted in discrimination, it is challenging to develop recommendations for a system that needs complete reform.[65] However, in the absence of that reform, there must still be meaningful and immediate action taken.

A *Short-Term Recommendations*

Firstly, meaningful investment into Indigenous-led and bicultural approaches to disability support are required. Australia's colonial legacy continues to permeate justice institutions, and substantial reform is needed to ensure culturally safe services are implemented in both health and justice responses.[66] This must be achieved through respectful consultation and partnership with Aboriginal and Torres Strait Islander communities and Aboriginal community-controlled health organisations, empowering culturally informed practices which reflect the values, knowledge, self-determination, and needs of the populations involved.[67] For example, adequate resourcing could support Aboriginal community-controlled

[64] See generally *Royal Commission* (n 25).
[65] McCausland and Baldry (n 16) 40.
[66] Cunneen (n 17) 334.
[67] Russell, Beaufils and Cunneen (n 17) 45.

health organisations or Aboriginal Medical Services to provide services within prisons and other community justice settings. These services might include conducting health and wellbeing assessments, providing disability support workers, and facilitating therapeutic services based on Indigenous knowledge and healing practices. Bicultural practices have become common within the mental health system in Aotearoa New Zealand, with service providers now commonly recognising Indigenous and Western approaches as parallel and equal.[68] If simplified, biculturalism in this context can be described as both a goal and a process, with elements including consultation with Māori elders, the hiring of cultural practitioners, challenging systemic racism, cultural competency training, and the adoption of Māori mental health knowledge and practice.[69]

Immediate priorities also include ensuring that operational staff such as police and prison officers receive routine, evidence-based training about neurodiversity, trauma-informed practices, cultural safety, and mental health. Workforce knowledge is critical to fostering inclusive interactions and avoiding exacerbation of vulnerabilities, and is needed to create a system-wide emphasis on basic and humane engagement practices, such as active listening and respectful communication.[70] While this type of training exists and is delivered to these workforces already, it is often not available frequently and routinely to all staff; typically occurs only at induction or orientation; often excludes some types of disability (such as FASD); and focuses on increasing knowledge but not the practical application or skill development required by frontline justice staff.[71] In Western Australia, a novel neurodisability training program was developed and evaluated in consultation with the youth justice system, following reports from this workforce that they had received limited disability training and did not feel prepared to support young people with FASD.[72] The training involved workshops in which short videos filmed inside the Western Australian youth detention centre were viewed and peer-to-peer skill sharing was encouraged. This program was deemed experiential, practical, and meaningful by participants.[73]

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[68] See generally Lorien Jordan et al, '"Hopefully You've Landed the Waka on the Shore": Negotiated Spaces in New Zealand's Bicultural Mental Health System' (2024) 61(3) *Transcultural Psychiatry* 473.
[69] See generally ibid.
[70] Passmore et al, 'Reframe the Behaviour: Evaluation of a Training Intervention to Increase Capacity in Managing Detained Youth with Fetal Alcohol Spectrum Disorder and Neurodevelopmental Impairments' (n 55) 401.
[71] Ibid 384.
[72] Ibid.
[73] Ibid.

In addition, the development and deployment of visual communication tools such as instructional storyboards and easy-read guides would provide further opportunity for comprehension and engagement for individuals with communication challenges.[74] Australia does have some visual tools in use, such as Legal Aid WA's Blurred Borders cards. These are a set of cards depicting elements of the legal system using art and storytelling, with the aim of making legal processes more accessible for culturally and linguistically diverse people.[75] There are also other tailored tools used in some Australian youth detention centres, such as visual daily schedules, but there is scope to expand upon this to ensure visual tools are available more frequently, tailored to the needs of the individual and environment, developed with adequate allied health or education expertise, and extended into adult prisons too.

Another key early intervention is the promotion of psychoeducation. Equipping neurodivergent individuals with an understanding of their own strengths and challenges can build self-advocacy skills and improve rehabilitative outcomes.[76] Furthermore, justice environments must begin adopting more collaborative and person-centred decision-making processes.[77] In practice, this would mean involving residents in decisions about their daily routines, behavioural management practices (such as tailored rewards and consequences), and throughcare or reintegration planning. This not only promotes autonomy but may also reduce tension and conflict between operational staff and people in prison, particularly if sensory triggers or needs are identified and addressed in the process.[78]

B *Medium-Term Recommendations*

The allocation of more allied health professionals, including speech pathologists and occupational therapists, within all justice settings is essential to ensure neurodivergent individuals are properly identified, supported, and

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[74] See generally Kelly Howard, Clare McCann and Margaret Dudley, '"It's Really Good… Why Hasn't it Happened Earlier?" Professionals' Perspectives on the Benefits of Communication Assistance in the New Zealand Youth Justice System' (2020) 53(2) *Australian & New Zealand Journal of Criminology* 265; Kelly Howard, Clare McCann and Margaret Dudley, '"It was like More Easier": Rangatahi (Young People) and their Whānau (Family) Talk About Communication Assistance in the New Zealand Youth Justice System' (2021) 21(2) *Youth Justice* 210.

[75] See generally Legal Aid WA, *Blurred Borders* (Web Page) <https://blurredborders.legalaid.wa.gov.au>.

[76] See generally Powell et al (n 60); Buchan and McMillan (n 60).

[77] McVilly et al (n 15) 790.

[78] Ibid 800.

accommodated.[79] Similarly, increased efforts to provide comprehensive case coordination within justice facilities to help individuals navigate the complex interface between justice, health, and social systems are required.[80] In practice, this would involve a consistent case management role with appropriate resourcing and caseloads; effective inter-agency collaboration with clearly defined responsibilities for each agency; information sharing mechanisms to avoid duplication of efforts; a combining of agency resources where appropriate; and meaningful assessment and monitoring of an individual's outcomes.[81] Additionally, improving staff-to-resident ratios, particularly in therapeutic and health care roles, is likely to enhance responsiveness, reduce system strain, and improve safety for staff and residents.[82] Evidence from smaller, purpose-built facilities demonstrates that higher staffing levels enable more individualised and effective care.[83]

Australia must invest in comprehensive data capture systems and information-sharing protocols for agencies working with neurodivergent people in the justice system. The current fragmentation of systems across corrective services, health, and community supports undermines coordinated care and creates additional barriers for the individual navigating such systems.[84] Integrated data infrastructure would enhance service delivery, track outcomes, and inform systemic improvements.[85] While confidentiality is key for individuals in the justice system, particularly regarding sensitive medical and legal information, there are mechanisms by which an individual's engagement or communication needs can be shared with consent to create a meaningful circle of care.

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[79] See generally Penelope Abbott et al, 'Supporting Continuity of Care Between Prison and the Community for Women in Prison: A Medical Record Review' (2016) 41(3) *Australian Health Review* 268; Monique Hooper, Claudia Virdun and Jane L Phillips, 'Capacity-Building Strategies that Support Correctional and Justice Health Professionals to Provide Best-Evidenced Based Healthcare for People in Prison: A Systematic Review' (2025) 24(1) *International Journal for Equity in Health* 115; Gabrielle Wolf and Mirko Bagaric, 'Addressing a Human Rights Crisis: Health Care for Prisoners in Australia' (2024) 31(2) *Journal of Law & Medicine* 42.

[80] Kinner et al (n 44) 685.

[81] Tazeen Majeed et al, 'A Better Future Beyond the Walls: Narrative Review of Best Practice Components of Services and Programs for People Exiting Custody' (2025) 52(10) *Criminal Justice and Behavior* 1489, 1500.

[82] Barbara Zaitzow and Anthony Willis, 'Behind the Wall of Indifference: Prisoner Voices about the Realities of Prison Health Care' (2021) 10(1) *Laws* 11, 17.

[83] See generally Grant (n 61).

[84] Cumming et al (n 27) 156.

[85] Hooper, Virdun and Phillips (n 79) 131–3.

C *Long-Term Recommendations*

Long-term reform cannot occur without first addressing the broader systemic and social determinants that contribute to neurodivergent individuals becoming involved in the justice system in the first place.[86] Comprehensive and progressive systemic reforms aligned with Indigenous-led initiatives and evidence-based approaches, shown to reduce crime and recidivism, are urgently required.[87] This includes meeting obligations under international treaties such as the Optional Protocol to the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, as well as national recommendations, such as those from the Royal Commission into Violence, Abuse, Neglect, and Exploitation of People with Disability.[88] Punitively designed facilities based on outdated prison design knowledge should not be used to house neurodivergent people (or any people, for that matter). In cases where facilities are needed to protect communities and individuals from harm to themselves or others, they should be used as a last resort, with a move towards small, purpose-built facilities close to the communities where people are from. These environments enable more tailored and humane support, foster connections to family and local services, and enhance opportunities for successful reintegration.[89] Such facilities are better suited to accommodating the needs of neurodivergent residents and relieving pressure on larger institutions.

Central to this reform is the early identification of neurodisability, ideally during childhood through routine health and educational assessments.[90] Proactive, culturally safe screening processes must be developed and implemented broadly to ensure early support. Linked to this is the implementation of early therapeutic interventions, designed to address developmental, social, and emotional needs before justice involvement occurs. This preventative focus is key to reducing justice system contact for neurodivergent individuals.

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[86] McCausland and Baldry (n 16) 40.
[87] See generally Mateja Vuk et al, 'The Pragmatic Public? The Impact of Practical Concerns on Support for Punitive and Rehabilitative Prison Policies' (2020) 45(2) *American Journal of Criminal Justice* 273; Russell, Beaufils and Cunneen (n 17) 45.
[88] See generally *Royal Commission* (n 25); *Optional Protocol to the Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment*, GA Res 57/199, UN GAOR, 57th sess, Agenda Item 109(a), UN Doc A/RES/57/199 (9 January 2003).
[89] See generally Muhammad Asad, 'The Effectiveness of Different Criminal Justice Systems: Examining Punitive and Rehabilitative Approaches' (2023) 1(2) *Policy Research Journal* 5.
[90] Holland, Reid and Smirnov (n 31) 62.

V CONCLUSIONS

Evidence from across Australia and internationally repeatedly identifies the importance of acknowledging and addressing the needs of neurodivergent people within justice facilities, and outlines processes for developing more inclusive and effective practices.[91] The learnings drawn from international jurisdictions demonstrate that meaningful change is achievable when systems are designed to consider neurodiversity, such as through early identification, tailored support utilising allied health skills, psychoeducation regardless of diagnosis, staff training, and the creation of environments that reduce harm and promote rehabilitation. These examples provide insight into evidence-informed practices that could be adapted for the Australian context.

Ensuring equity in criminal justice responses is not only about accommodating difference, but about dismantling systemic barriers that perpetuate marginalisation.[92] Australia's criminal justice responses must move beyond rhetorical commitments to disability inclusion and implement structural reforms that reflect the realities experienced by neurodivergent individuals.[93] Urgent, coordinated action is required to ensure the rights of neurodivergent people are upheld in the Australian criminal justice system, and to ensure that they are not further disadvantaged or harmed by systems ill-equipped to meet their needs. Deliberate, systemic reform informed by lived experience, Indigenous knowledge, and both domestic and international evidence must underpin the future of Australia's justice system to ensure it is equitable, inclusive, and responsive to neurodivergent people.

[91] Ibid 36.
[92] McCausland and Baldry (n 16) 40.
[93] See generally *Royal Commission* (n 25).

TREADING THE LINE BETWEEN CONSENT AND COERCION: THE LEGAL TREATMENT OF THE RIGHT TO BODILY INTEGRITY IN THE CONTEXT OF COVID-19 VACCINE MANDATES IN AUSTRALIA

AMY THOMASSON*

Superior courts were required to consider what it means to consent to vaccination in the face of mandatory vaccination requirements introduced by Australian states and territories during the COVID-19 pandemic. The concern commonly raised by applicants in these cases was that such policies may be so coercive — given the attendant pressure of making a "choice" that may result in the loss of one's job, and therefore livelihood — as to undermine consent, or at least limit a person's right to bodily integrity. In determining such cases, superior courts provided different reasoning as to what it means to consent to vaccination across jurisdictions and legal frameworks in Australia — but is this difference in reasoning justified? Should we not have a common understanding of, or at least a consistent frame of reference for, what it means to consent to vaccination in the face of coercive policies like mandates? This article argues for internal logic and consistency in how the right to bodily integrity in its various legal forms is understood and treated by the law, particularly in the context of mandates and any future public health emergency. This is best achieved in Australia through (1) the introduction of legislation protecting human rights (either at a federal or state and territory level), that provides: (a) a right to refuse medical treatment, rather than a requirement that a person not to be subject to medical treatment without full, free and informed consent; and (b) a direct cause of action for an alleged breach of human rights; and (2) amendments to public health legislation in each state and territory to provide a mandate-specific decision-making framework.

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I INTRODUCTION

Decision-makers are required to govern differently during public health emergencies.[1] Public health emergencies demand speed and agility of decision-makers,[2] a characteristic usually associated with the executive branch of government. There are increasing calls among human rights commentators and academics for accountability and scrutiny of the executive's exercise of power during the COVID-19 pandemic.[3] The law is one mechanism through which this can be achieved. Superior courts were required to consider what it means to consent to vaccination in the face of 'mandatory'[4] vaccination requirements

[1] Eric L Windholz, 'Governing in a Pandemic: From Parliamentary Sovereignty to Autocratic Technocracy' (2020) 8(1–2) *The Theory and Practice of Legislation* 93, 93.

[2] Sarah Moulds and Anja Pich, 'Reviewing Executive Decision-Making in Emergencies: Time to Consider a More Systematic Approach to Post Legislative Scrutiny in Australia' (2022) 41(2) *University of Tasmania Law Review* 43, 43.

[3] Ibid; Rosalind Croucher, 'Executive Discretion in a Time of COVID-19: Promoting, Protecting and Fulfilling Human Rights in the Contemporary Public Health Context' (Speech, 11th Austin Asche Oration in Law and Governance, Australian Academy of Law and Charles Darwin University, 17 November 2022); Lorraine Finlay and Rosalind Croucher, 'Limiting Rights and Freedoms in the Name of Public Health: Ensuring Accountability During the COVID-19 Pandemic Response' in Belinda Bennett and Ian Freckelton (eds), *Australian Public Health Law: Contemporary Issues and Challenges* (Federation Press, 2023) 120.

[4] Gabrielle Wolf, Jason Taliadoros and Penny Gleeson, 'A Panacea for Australia's COVID-19 Crisis? Weighing Some Legal Implications of Mandatory Vaccination' (2021) 28 *Journal of Law and Medicine* 993; Kay Wilson and Christopher Rudge, 'COVID-19 Vaccine Mandates: A Coercive but Justified Public Health Necessity' (2023) 46(2) *UNSW Law Journal* 381; Madeline Rohini Fisher, 'Chasing Immunity: How Viable Is a Mandatory COVID-19 Vaccination Scheme for Australia?' (2021) 28 *Journal of Law and Medicine* 718.

introduced by Australian states and territories during the COVID-19 pandemic.[5] For the purpose of this paper, mandatory vaccination refers to any policy or directive that imposes meaningful consequences for non-vaccination,[6] or makes vaccination a condition of being able to participate in a particular activity or receive a particular benefit.[7] The concern commonly raised by applicants in the cases challenging mandates was that such policies may be so coercive — given the attendant pressure of making a 'choice' that may result in the loss of one's livelihood — as to undermine consent, or at least limit a person's right to bodily integrity. In determining such cases, superior courts provided different reasoning as to what it means to consent to vaccination across jurisdictions and legal frameworks in Australia — but is this difference in reasoning justified? Should we not have a common understanding of, or at least a consistent frame of reference for, what it means to consent to vaccination in the face of coercive policies like mandates? While courts are not necessarily best placed to address these largely ethical concerns, the law still needs an 'appropriate framework and workable guidelines in order to function with internal logic and consistency'.[8]

As explored in Part II, one of the reasons courts were unable to properly interrogate the decision to introduce mandates is because Australia's public health legislation is broadly worded — generally the relevant decision-maker can do whatever they deem 'necessary' or 'reasonably necessary' in response to a threat to public health.[9] Such broad discretionary power does not require consideration of the specific aspects of public interest relevant to mandatory vaccination during a pandemic. Section 11AA(2) of the *COVID-19 Public Health Response Act 2020* (NZ) (now repealed) required the Minister to consider a particularised definition of the public interest before a vaccine mandate could be introduced.[10] This article takes pause to consider the introduction of a similar framework in Australia with the benefit of hindsight. To lay the groundwork for

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[5] This article uses the phrases 'vaccine direction' and 'vaccine mandate' interchangeably.

[6] Katie Attwell and Mark C Navin, 'Childhood Vaccination Mandates: Scope, Sanctions, Severity, Selectivity, and Salience' (2019) 97(4) *The Milbank Quarterly* 978, 980; Katie Attwell et al, 'COVID-19 Vaccine Mandates: An Australian Attitudinal Study' (2022) 40 *Vaccine* 7360, 7361–2.

[7] WHO COVID-19 Ethics and Governance Working Group, 'COVID-19 and Mandatory Vaccination: Ethical Considerations' (Policy Brief, 30 May 2022) <https://iris.who.int/bitstream/handle/10665/354585/WHO-2019-nCoV-Policy-brief-Mandatory-vaccination-2022.1-eng.pdf?sequence=1>.

[8] Sheila A M McLean, *Autonomy, Consent and the Law* (Taylor & Francis Group, 2009) 69.

[9] See, eg, *Public Health Act 2010* (NSW) s 7(2); *Public Health and Wellbeing Act 2008* (Vic) s 165AI; *Public Health Act 2016* (WA) s 202A(3)(a); *Public Health and Other Legislation (COVID-19 Management) Amendment Act 2022* (Qld) s 142E(3)(a).

[10] Namely, '(a) ensuring continuity of services that are essential for public safety, national defence, or crisis response: (b) supporting the continued provision of lifeline utilities or other essential services: (c) maintaining trust in public services: (d) maintaining access to overseas markets.'

this, comprehensive consideration must be given to the rights that were limited during the COVID-19 pandemic in the name of public health.[11] Should we fail to scrutinise government decision-making and the performance of legal tools during emergencies, we risk permanently undermining trust in government,[12] public health,[13] the rule of law, and even democracy itself.[14] As argued by Nicholas J McBride, 'the health of a legal system can only be judged when it comes under strain';[15] there is no better recent example of such strain than the COVID-19 pandemic.

Of the cases challenging vaccine mandates that have resulted from the COVID-19 pandemic to date in Australia, three dealt with the issue of what it means to consent to vaccination in the face of variously coercive policies in detail.[16] In *Kassam v Hazzard; Henry v Hazzard* ('*Kassam*')[17] and *Falconer v Commissioner of Police* ('*Falconer*'),[18] the question was — relevantly — whether the vaccine mandate impermissibly limited the applicant's common law right to bodily integrity (and was therefore a battery) in violation of the principle of legality, whereas in *Johnston & Ors v Carroll (Commissioner of the Queensland Police Service) & Anor; Witthahn & Ors v Wakefield (Chief Executive of Hospital and Health Services and Director General of Queensland Health); Sutton & Ors v Carroll (Commissioner of the Queensland Police Service)* ('*Johnston*'),[19] the question was whether the applicants' statutory right under human rights legislation not to be subject to medical treatment without 'full, free and informed' consent was impermissibly infringed.[20]

Only the applicants in *Johnston* were successful, and on a different basis to their consent argument, although Martin SJA found that the applicants' human rights

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[11] Finlay and Croucher (n 3) 137.
[12] Commonwealth of Australia Department of the Prime Minister and Cabinet, *COVID-19 Response Inquiry Report* (Report, 2024) 126.
[13] Wendy E Parmet, 'Informed Consent and Public Health: Are They Compatible When It Comes to Vaccines?' (2005) 8(1) *Journal of Health Care Law and Policy* 71, 100.
[14] Croucher (n 3); Finlay and Croucher (n 3) 137.
[15] Nicholas J McBride, 'Ill Fares the Land: Has COVID-19 Killed the Principle of Legality?' (2022) *SSRN Electronic Journal* 1, 24.
[16] *Dunn v Director of Public Health* [2021] TASFC 16 ('*Dunn*') and *Larter v Hazzard* [2022] NSWCA 238 ('*Larter*') also dealt with the issue. However, *Dunn* was a short judgment on an interlocutory application for an injunction, referring to *Kassam* and finding there was no serious question to be tried. *Larter* was also decided after *Kassam* (in the same state), so although the factual matrix was different, the legislation empowering the Minister to mandate vaccination was the same.
[17] (2021) 106 NSWLR 520 ('*Kassam*').
[18] [2024] WASCA 47 ('*Falconer*').
[19] [2024] QSC 2 ('*Johnston*').
[20] *Human Rights Act 2019* (Qld) s 17(c) ('*HRA* (Qld)').

were limited, just not impermissibly.[21] Similarly, on appeal in *Falconer*, Buss P and Vaughan JA found that the right to bodily integrity of one of the applicants was infringed by the vaccine direction, but that such infringement was within power. This reasoning differs from *Kassam*, one of the first superior court cases to emerge from the pandemic, where the New South Wales ('NSW') Court of Appeal found that the right to bodily integrity was not infringed by the mandate. This article analyses the legislative settings giving rise to this difference in reasoning and considers how Australia's legal frameworks responded to the inherent tension between individual rights and the collective interest in public health. This case law also provides a unique opportunity to consider how the law understands what it means to consent to vaccination, both in the context of the right to bodily integrity and the closest expression of that right in human rights legislation, in the face of coercion.

As will become clear in this article, current legal accountability tools do not adequately address the problems that can arise when decisions that exist to serve collective interests do so to the detriment of individual rights, in particular the right to bodily integrity. Part of the problem is that the law does not distinguish between preventative medicine and medical 'treatment' in the strict sense of the word — vaccines are considered under the broad umbrella of 'medical treatment' without regard for the nuances associated with this term in medical, ethical, and social sciences literature.[22] This nuance needs to be acknowledged in the law given that vaccination is both an individual clinical intervention and a public health tool.[23]

The puzzle becomes further complicated when a public health emergency is added to the mix. The COVID-19 pandemic saw the emergence of an intractable clash between these interests, and 'dissonance between the aims of respect for autonomy on the one hand and the law of consent on the other'.[24] There is some scholarship about the meaning of the right to bodily integrity in the context of consent to medical treatment as it is traditionally understood,[25] although some still argue that the right to bodily integrity is 'seriously under analysed' in the

[21] *Johnston* (n 19) [440].
[22] Angus Dawson, 'Vaccination and the Prevention Problem' (2004) 18(6) *Bioethics* 515, 516–7.
[23] Parmet (n 13) 75.
[24] McLean (n 8) 4.
[25] See, eg, Jonathan Herring and Jesse Wall, 'The Nature and Significance of the Right to Bodily Integrity' (2017) 76(3) *Cambridge Law Journal* 566; Elizabeth Wicks, *The State and the Body* (Hart Publishing, 2019) ch 1; Jesse Wall, *Being and Owning: The Body, Bodily Material and the Law* (Oxford, 2015).

literature.[26] This is surprising given that bodily integrity is a fundamental right, one that is not only 'at the heart of the relationship between the state and the individual, but also the concept of informed consent that is deeply embedded in the principles of medical ethics and practice'.[27] The notion that courts vacillate between 'the individualistic and the relational models of autonomy … to achieve policy-based objectives'[28] is particularly evident in judgments about vaccine mandates. There is little legal scholarship analysing this reasoning and what it means to consent to vaccination specifically in the face of coercive policies made in the context of a public health emergency. This article focuses on the right to bodily integrity given its prominence in the cases challenging COVID-19 vaccine mandates and the comparative lack of consideration in the literature, but other individual rights are of course engaged by mandates.[29] The language of medical treatment is also used in this article to refer to vaccination given its treatment as such in the relevant case law.

This article is part of a broader project that aims to better understand the impact of mandatory vaccination policies on the legal meaning and understanding of consent, and whether there are ways to improve decision-making in responding to the tension between collective and individual interests during a public health emergency. Indeed, some public health policymakers have suggested that we do away with informed consent during public health emergencies, it being seen as 'cumbersome' in situations where 'time is of the essence'.[30] In the context of school-based vaccine mandates in the United States, others have observed that the idea of informed consent is paradoxical.[31]

Mandatory vaccination may be justified to some degree in both emergency and non-emergency settings,[32] but the scale to which such policies were introduced during the pandemic warrants consideration. A vaccine mandate may be more or less justified depending on its effectiveness in preventing transmission and

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[26] Herring and Wall (n 25) 566.
[27] *NZDSOS Inc v Minister for COVID-19 Response* [2022] NZHC 716 [53] ('*NZDSOS*').
[28] McLean (n 8) ii.
[29] For example, freedom of movement, as argued in *Kassam and Others v Hazzard and Others* (2021) 393 ALR 664 [9].
[30] Parmet (n 13) 72, citing The Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities, 'The Model State Emergency Health Powers Act' (Discussion Paper, Georgetown University, 21 December 2001) 26–7 <https://publichealth.jhu.edu/sites/default/files/2023-06/msehpa.pdf>.
[31] *Allison v Merck*, 878 P 2d 948, 954–5 (Nev, 1994).
[32] For example, many government and private employers of healthcare and early education workers require vaccination against influenza: see, eg, *Barber v Goodstart Early Learning* [2021] FWC 2156.

severe disease.[33] More broadly, mandates need to be justified against specific criteria and understood in their relevant context — indeed the term 'mandate' has been criticised for its failure to distinguish between diverse policies.[34] For example, school-based mandates in the United States aim to shift norms around childhood vaccination and shape the context in which decisions about vaccination are made.[35] Conversely, a vaccine mandate in an emergency 'cannot work by shifting customs and creating an alternative environment in which vaccination becomes normalized'.[36]

The reliance on compulsion in an emergency, rather than building legitimacy over time, can be more readily perceived as coercive, eroding trust in public health at the very moment that trust is needed to encourage vaccination to the requisite level.[37] There is some emerging research that attempts to reconcile the tension between mandatory vaccination policies and informed consent from an ethical perspective, arguing that consent may be valid if *motivated* by coercion, as opposed to being *obtained* by coercion.[38] In the context of mandatory vaccination, the person administering the vaccine (ie, the consent-receiver) is not exerting coercion, a third party is — for example, an employer where vaccination is a condition of employment.[39] In this scenario, the consent-receiver has not wronged the consent-giver in any way and accordingly consent is not invalidated (as 'third parties cannot directly negate the voluntariness of consent'), argue Maxwell Smith and Evan Mackie.[40] While I do not intend to interrogate the validity of Smith and Mackie's argument from a legal perspective in this article, it perhaps unduly focuses on the individual who is administering the vaccine and ignores the broader coercive context in which the vaccination takes place. For the purpose of this article, it remains necessary to consider the legal status of vaccine mandates in the context of a public health emergency, and whether there are opportunities to create an improved and more transparent decision-making process that enhances legitimacy and public trust.

This article begins in Part II and Part III with a detailed consideration of the different courts' reasoning regarding the interaction between coercive

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[33] Alberto Giubilini, 'Vaccination Ethics' (2021) 137(1) *British Medical Bulletin* 4, 10.
[34] Attwell and Navin (n 6) 980.
[35] Parmet (n 13) 104.
[36] Ibid 105.
[37] Ibid.
[38] See, eg, Maxwell J Smith and Evan Mackie, 'Do Vaccine Mandates Impair the Voluntariness of Informed Consent?' (2025) *Journal of Medical Ethics* 0:1–5, 3.
[39] Ibid.
[40] Ibid 4.

vaccination requirements and consent in *Kassam, Falconer*, and *Johnston*. This will necessarily involve an explanation of the different legal rules as they relate to consent to medical treatment. Part II focuses on the right to bodily integrity and its lacklustre protection through the principle of legality. Part III considers the closest expression of the right to bodily integrity in human rights legislation — the right not to be subject to medical treatment without consent.[41] Part IV examines the legal status of a person's so-called right to consent to medical treatment in its various forms, and argues for internal logic and consistency in how it is understood and treated by the law, particularly in the context of a future public health emergency. This is best achieved in Australia through (1) the introduction of legislation protecting human rights (either at a federal or state and territory level) that provides: (a) a right to refuse medical treatment (similar to s 11 of the *New Zealand Bill of Rights Act 1990* (NZ) ('*NZBORA*')), rather than a requirement that a person not to be subject to medical treatment without full, free and informed consent; and (b) a direct cause of action for an alleged breach of human rights; and (2) amendments to public health legislation in each state and territory to provide a mandate-specific decision-making framework.

Elsewhere, the introduction of legislation protecting human rights has caused 'shifts in the methodology and intensity of judicial review of administrative action, largely focusing on the apparent shift from the unreasonableness standard to proportionality'.[42] Given Australia's constitutional settings and specifically the lack of a federal or constitutionally entrenched bill of rights, it is more appropriate to legislate human rights, and provide for a direct right of action, than to try to work protections into existing legal frameworks. It is hoped that these changes would better embed human rights in decision-making processes, even in emergency settings; provide consistent and transparent criteria for making a mandate; and ensure adequate scrutiny of decision-making after the fact.

II The Right to Bodily Integrity, Battery, and the Principle of Legality

The principle of legality is an interpretative tool that 'favours a construction, if one be available, which avoids or minimises the statute's encroachment upon fundamental principles, rights and freedoms at common law'.[43] When expressed

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[41] *HRA* (Qld) (n 20) s 17(c).
[42] Janina Boughey, *Human Rights and Judicial Review in Australia and Canada: The Newest Despotism?* (Bloomsbury Publishing, 2017) 2.
[43] *North Australian Aboriginal Justice Agency Limited v Northern Territory* (2015) 256 CLR 569, 581 [11].

as a presumption, it is that parliament does not intend to infringe on fundamental common law rights. The principle of legality is in part codified in human rights legislation[44] and was historically considered by some scholars to be a 'quasi-constitutional common law bill of rights',[45] improving transparency and promoting democracy and the rule of law.[46] The principle has also been criticised for its elusive scope and variable formulation.[47] It must be borne in mind that the principle of legality will never be the sole basis for a finding of invalidity, or even the only applicable interpretative tool. The principle of legality exists within a broader body of statutory interpretation law and is subject to the overarching requirement to consider legislative text, context and purpose.[48] Accordingly, while the principle of legality may help determine the meaning of an empowering provision, and in turn whether delegated legislation is within the scope of the empowering provision, it is not a basis for determining the validity of delegated legislation. Many applicants in court challenges to vaccine mandates called the principle of legality to their aid, exposing the variability and 'methodological problems that arise with the application of the principle of legality as clear statement rule' in the process.[49] Most relevantly, and as will become evident in the ensuing discussion, reasoning in vaccine mandate challenges made clear the problems that can arise when 'the 'content' of a right (ie, what it guarantees in the relevant context) is determined or divined by judges at the point of legislative application'.[50] In the context of the court challenges discussed below, the principle of legality has not operated 'coherently or legitimately as a clear statement rule'.[51]

In this part, I adopt McBride's categorisation of the principle of legality.[52] Having analysed cases emerging from the COVID-19 pandemic in England, Australia and New Zealand, McBride finds that courts have used four techniques to limit the utility of the principle of legality in challenges to governmental decisions aimed at addressing COVID-19.[53] These techniques are: (1) reading down fundamental

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[44] *Human Rights Act 2004* (ACT) s 30 ('*HRA* (ACT)'); *Charter of Human Rights and Responsibilities Act 2006* (Vic) s 32; *HRA* (Qld) (n 20) s 48.
[45] Dan Meagher, 'The Principle of Legality as Clear Statement Rule: Significance and Problems' (2014) 36(3) *Sydney Law Review* 413, 442 ('Clear Statement Rule').
[46] Ibid 437–8.
[47] Ibid 414; Dan Meagher, 'The Common Law Principle of Legality in the Age of Rights' (2011) 35 *Melbourne University Law Review* 449, 456–64; Sir Philip Sales, 'Judges and Legislature: Values into Law' (2012) 71 *Cambridge Law Journal* 287, 294–5.
[48] *Falconer* (n 18) [202].
[49] Meagher, 'Clear Statement Rule' (n 45) 415.
[50] Ibid 430.
[51] Ibid 438–9.
[52] McBride (n 15).
[53] Ibid 20.

common law rights such as to deny that a measure had any impact on them, meaning that the principle of legality was not engaged at all;[54] (2) inverting the test such that only if the interference with a particular right was disproportionate was it necessary to determine whether it was authorised by express words;[55] (3) treating general words as 'express words indicating that the government has been empowered to act in ways that abridge people's fundamental rights';[56] and (4) sidelining the issue of whether the government 'has used its powers disproportionately'[57] or, put another way, whether the common law right identified has been impermissibly infringed. In the specific context of vaccine mandates, all but (2) were present in the reasoning of Australian superior courts.

Having analysed the case law challenging vaccine mandates specifically,[58] a fifth technique emerges; courts have limited the utility of the principle of legality as an interpretative tool by finding no ambiguity as to the meaning or breadth of the empowering provision in question. Accordingly, the principle of legality had no work to do as there was no constructional choice to be made, there being no ambiguity in the requirement that a measure be 'necessary' or 'reasonably necessary'. This is in some ways a particularisation of the third technique identified by McBride. While it has long been the case that the principle of legality is a tool in the interpretative task rather than determinative of the 'correct' interpretation, the type of reasoning described above as the fifth technique for limiting the usefulness of the principle renders it defunct, despite the modern approach to statutory interpretation not requiring any ambiguity to consider context.[59] The principle appears ever-weakening — at first, common law rights could only be abrogated by express words of 'irresistible clearness'.[60] Abrogation 'by necessary intendment' or 'necessary implication' is now permissible,[61] although, in theory:[62]

> General words will rarely be sufficient for that purpose. What courts will look for is a clear indication that the legislature has directed its

[54] Ibid.
[55] Ibid 21.
[56] Ibid 22.
[57] Ibid 23.
[58] McBride having looked at COVID-19 measures more generally, not just vaccine mandates.
[59] *CIC Insurance Ltd v Bankstown Football Club Ltd* (1997) 187 CLR 384, 408 affirmed in *SZTAL v Minister for Immigration and Border Protection* (2017) 262 CLR 362, 368 [14].
[60] *X7 v Australian Crime Commission* (2013) 248 CLR 92, 153.
[61] *Coco v The Queen* (1994) 179 CLR 427, 438 ('*Coco*'); *Bropho v Western Australia* (1990) 171 CLR 1, 16–17 ('*Bropho*').
[62] *Plaintiff S157/2002 v Commonwealth* (2003) 211 CLR 476 [30] ('*Plantiff S157*').

> attention to the rights or freedoms in question, and has consciously decided upon abrogation or curtailment.

As argued by McBride, it appears that despite such judicial statements, the principle of legality is in practice and application so weak that 'it might as well not exist'.[63] Rather than suggesting ways the principle of legality may be saved from obscurity — and accordingly better protect the right to bodily integrity — I instead argue that a different decision-making framework is required for vaccine mandates made during a pandemic, one modelled on s 11AA of the *COVID-19 Public Health Response Act 2020* (NZ). This should be complemented by the introduction of human rights legislation in each state and territory to provide a better path 'when dealing with future challenges to the lawfulness of government actions'.[64] First, however, it is necessary to explore how the courts have applied the principle of legality in the context of cases challenging COVID-19 vaccine mandates to establish the shortfalls of the current approach.

A *Kassam*

Kassam is a prime example of the limited utility of the principle of legality. In *Kassam*, ten applicants challenged 'public health orders' ('PHO') made by the Minister for Health and Medical Research in NSW requiring vaccination for those working in healthcare, aged care and education.[65] The applicants' primary argument was that the PHOs went beyond the scope of the empowering provision, being s 7(2) of the *Public Health Act 2010* (NSW).[66] President Bell's leading judgment in *Kassam* is replete with statements limiting the relevance of the principle of legality, including describing the principle as an 'occasionally useful, context-dependent'[67] adjunct to the interpretative task. In another part of his Honour's reasons, Bell P states that the function of the principle is limited where the interference with the fundamental right in question is 'slight or indirect or temporary'.[68] The empowering provision under challenge permits the Minister for Health and Medical Research to give any direction they consider necessary to deal with a public health risk.[69] This is undoubtedly a broadly worded provision. However, to use the language of authoritative cases establishing the nature and parameters of the principle, does that wording limit the right to bodily integrity

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[63] McBride (n 15) 24.
[64] Ibid.
[65] *Kassam* (n 17) [2].
[66] Ibid [99], [108], [110], [113], [138], [139].
[67] Ibid [86].
[68] Ibid [87].
[69] *Public Health Act 2010* (NSW) s 7(2)(b).

'by necessary implication',[70] or show 'a clear indication that the legislature has … consciously decided upon abrogation or curtailment'?[71] Suffice to say for the purpose of this article, the Court did not even reach this stage of inquiry, finding that 'nothing in any of … [the mandates] *required*, still less coerced, aged care workers or educational professionals, authorised workers or workers in the construction industry, to be vaccinated'.[72] In separate reasons, Leeming JA criticised the appellants' conception of consent and free choice, stating that 'people are influenced by incentives and burdens, which are not uncommonly put in place for the express purpose of altering behaviour',[73] but this does not mean the decision to be vaccinated was coerced or impugned free choice. Accordingly, the Court determined that the right to bodily integrity was not limited by the mandates in question, and therefore the principle of legality was not engaged.[74]

B *Applying Kassam: Dunn v Director of Public Health*

The applicant in *Dunn v Veitch*[75] sought judicial review of a PHO which required state service employees working for or on behalf of the Department of Health to be sufficiently vaccinated against COVID-19, and prohibited a person who was not sufficiently vaccinated from providing health and medical services.[76] The applicant argued, among other things but relevantly for the purpose of this article, that the administration of a vaccine in those circumstances would amount to battery at common law, as the coercive nature of the requirement and the prospect of job loss for failure to comply would undermine consent.[77] The applicant also argued that the principle of legality was infringed as the requirement limited a person's 'freedom of movement and ability to work'.[78]

The matter came before the court on an interlocutory basis, the applicant having sought an injunction suspending the operation of the PHO until his substantive application was heard.[79] Blow CJ dismissed both these contentions, in reasons that were affirmed on appeal, based on the breadth of the empowering provision

[70] *Coco* (n 61) 438; *Bropho* (n 61) 16–17.
[71] *Plaintiff S157/2002* (n 62) [30].
[72] *Kassam* (n 17) [97], [99] (emphasis in original).
[73] Ibid [170].
[74] Ibid [99].
[75] [2021] TASSC 56 ('*Dunn First Instance*').
[76] Tasmania, *Tasmanian Government Gazette*, No 22138, 12 November 2021, 1094.
[77] *Dunn First Instance* (n 75) [10]; *Dunn v Director of Public Health* [2021] TASFC 16 [14] ('*Dunn Appeal*').
[78] *Dunn Appeal* (n 77) [14].
[79] *Dunn First Instance* (n 75) [2].

in the *Public Health Act 1997* (Tas).[80] Section 16 of the *Public Health Act 1997* (Tas) permitted the Director of Public Health to 'take any action or give any directions' to manage a threat to public health while an emergency declaration was in force. The Full Court agreed with Blow CJ that there was no ambiguity as to the meaning and breadth of s 16 and accordingly the principle of legality did not arise,[81] there being no 'constructional choice' to be made.[82] The Full Court further referred to *Kassam*, noting that 'restricting the free movement of persons and free association of persons are the very type of restrictions that [s 16] authorises', similarly to the relevant directions in *Kassam*.[83] *Dunn* is therefore a further example of the first and proposed fifth technique — reading down the right to bodily integrity such that the vaccine mandate had no impact on it, and finding no ambiguity and therefore no work for the principle of legality to do.

C *Distinguishing Kassam?: Falconer v Commissioner of Police*

The mandate challenged in *Falconer* was enacted by the Commissioner of Police under the *Police Act 1892* (WA) ('*Police Act*') and required Western Australian ('WA') police officers and employees to be vaccinated as a condition of employment.[84] Conversely, the mandate challenged in *Kassam* is better characterised as a site access requirement — it did not require vaccination, but an 'authorised worker' living in an 'area of concern' could not leave their residence to attend work without having been vaccinated.[85] Further, potential disciplinary proceedings or dismissal from employment were not an explicit consequence of non-compliance with the mandate challenged in *Kassam,* whereas under the empowering statute in *Falconer* a member of the police force could be disciplined (including dismissed) for non-compliance with a direction issued by the Commissioner of Police.[86] While in practice the result of both is the same — it was necessary for the applicants in *Kassam* to attend their place of work to do their job, and they could rightly be dismissed for repeatedly failing to show up to work — the potential consequence of dismissal in *Falconer* was ultimately a significant factor in favour of finding that Mr Falconer's bodily integrity was limited by the mandate. Another key reason for this finding was that Mr Falconer did not technically have the option to resign and remain unvaccinated due to

[80] Ibid [10]; *Dunn Appeal* (n 77) [15].
[81] *Dunn Appeal* (n 77) [15]–[18].
[82] Ibid [15].
[83] Ibid [18].
[84] *Falconer* (n 18) [2].
[85] *Kassam v Hazzard; Henry v Hazzard* (2021) 393 ALR 664 [45] ('*Kassam First Instance*').
[86] *Police Act 1892* (WA) ss 9, 23(1) ('*Police Act*').

notice requirements in the *Police Act*.[87] A constable in Mr Falconer's position is required to give one month's notice of resignation, absent which they incur a penalty — the vaccine mandate to which Mr Falconer was subject required compliance in less than a week.[88]

Further, Mr Falconer made a promise in joining the police force to discharge his duties to the best of his skill and knowledge,[89] including complying with lawful orders.[90] Any member of the police force who fails to comply with a lawful order 'commits an offence against the discipline of the Force'.[91] President Buss and Vaughan JA reasoned that honouring this duty is a matter of 'conscience and personal integrity'[92] for each police officer and a 'norm of conduct' making the direction 'objectively more likely to have a compulsive effect than might otherwise be the case'.[93] Based on this, and the threat of disciplinary action for non-compliance,[94] ranging from reprimand to dismissal,[95] Buss P and Vaughan JA found that choosing — and more importantly in the context of this case, having the *ability* to choose — to resign and being dismissed for non-compliance were 'qualitatively different'.[96] Their Honours stated in this regard that dismissal 'has an adverse connotation that is likely to be detrimental … to the prospects of a police officer in the position of Mr Falconer obtaining alternate gainful employment outside of the Police Force'.[97] Each of these factors would, according to Buss P and Vaughan JA, 'naturally and probably have the effect of deterring disobedience' with the direction.[98] President Buss and Vaughan JA concluded that the effect of the direction on Mr Falconer 'went beyond mere pressure or an element of coercion'[99] and amounted 'in effect to compulsion'[100] by depriving Mr Falconer of 'a real or genuine choice as to whether to become vaccinated'.[101] The direction in question, in the view of Buss P and Vaughan JA, operated 'in effect

[87] Ibid s 12; *Falconer* (n 18) [147]–[153].
[88] *Police Act* (n 86) s 12; *Falconer* (n 18) [150], [153].
[89] *Police Act* (n 86) s 10.
[90] Christopher Taylor-Burch, 'WA Case Notes Upholding Mandatory Vaccinations for the Police Force: *Falconer v Commissioner of Police [No 2]* [2024] WASCA 47' (June 2024) *Brief* 34, 34–5.
[91] *Falconer* (n 18) [155].
[92] Ibid [157].
[93] Ibid [156].
[94] Ibid [159].
[95] Ibid [163]; *Police Act* (n 86) s 23.
[96] *Falconer* (n 18) [163].
[97] Ibid.
[98] Ibid [164].
[99] Ibid [152].
[100] Ibid [162].
[101] Ibid [152].

by way of compulsion in a manner that is incompatible with the right to bodily integrity'.[102]

This finding was prefaced by a general discussion of what 'coercion' means in the context of a mandate to vaccinate.[103] Of course, any form of vaccine mandate is directed at inducing 'action or conduct by one person that is considered desirable by another'.[104] However, the penalty for non-compliance may on some occasions move along the spectrum from pressure to coercion; even where the subject of the mandate technically has 'a choice as a matter of form', that choice may in substance be nominal.[105] In those circumstances, '[a] person may be so constrained by the possibility of the imposition of a burden that he or she becomes compelled to do what his or her free will would otherwise refuse',[106] depending on the magnitude of the burden and likelihood the burden will be imposed. President Buss and Vaughan JA considered the ultimate question to be whether the mandate infringed the right to bodily integrity in its practical operation,[107] rather than beginning with an analysis of whether any infringement was authorised by the empowering statute (as was the case in *Kassam*).

Their Honours were however careful to demonstrate that the findings and reasoning in *Kassam* were not directly applicable to *Falconer.* Having given meaning to 'coercion' in the context of vaccination, Buss P and Vaughan JA then asserted that the orders in *Kassam* operated differently from those under challenge in *Falconer*. The orders in *Kassam* limited the movement of unvaccinated people who lived in certain areas. The orders in *Falconer* 'unequivocally compelled'[108] vaccination of police officers and employees. President Buss and Vaughan JA seemingly agreed with the reasoning in *Kassam* that consent is not vitiated because a person complies with a direction 'to avoid a general prohibition on movement or to obtain entry onto a construction site'.[109] It seems the consequences of a decision not to be vaccinated, in the context of a mandate that has only the practical effect of limiting a person's movement, are, as far as their Honours are concerned, too far removed to infringe the right to bodily integrity. Their Honours concluded that only '[a]bsent a real or genuine choice as

[102] Ibid [165].
[103] Ibid [128]–[143].
[104] Ibid [131].
[105] Ibid.
[106] Ibid [132].
[107] Ibid.
[108] Ibid [141].
[109] *Kassam First Instance* (n 85) [63].

to whether to vaccinate' is the right to bodily integrity infringed.[110] This assertion was based on the individualised nature of the right itself, and its close relationship with the concept of individual autonomy.[111] Interestingly, this formulation of the right to bodily integrity bears close similarity to the concept of 'full, free and informed' consent in s 17(c) of the *Human Rights Act 2019* (Qld) ('*HRA* (Qld)') — absent a 'real or genuine choice', it is easy to see how consent would not be 'free'.

President Buss and Vaughan JA then come to make a distinction between compulsion and 'mere coercion',[112] the implicit suggestion being that the latter is permissible where the former is not. In *Kassam*, the practical implications of the mandate were largely ignored by the Court, whereas they were clearly front of mind in *Falconer*. The effect of the mandate on the individual applicants in *Kassam* was not considered in any detail, other than in establishing that they each had standing.[113] It might be thought that individual circumstances are not relevant to determining whether the principle of legality affords protection from infringement of a fundamental right — a legislative provision either infringes the bodily integrity of everyone to which it applies, or does not infringe the right for anyone. However, that ultimately depends on the starting point of the analysis, which may itself send a powerful message to claimants and the broader community. While Buss P and Vaughan JA considered the coercive effect of the mandate on each claimant first, before turning to whether the direction was beyond the authority conferred on the Commissioner of Police because it infringed on the right to bodily integrity, the Court in *Kassam* began its analysis by considering the proper construction of the empowering provision in that case, being s 7(2) of the *Public Health Act 2010* (NSW).

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[110] *Falconer* (n 18) [133].
[111] Ibid [134].
[112] Ibid [164].
[113] *Kassam First Instance* (n 85) [105]–[109].

Their Honours' reasoning did not however go without criticism from Hall JA, who wrote separate reasons.[114] While agreeing that the appeals should be dismissed,[115] Hall JA took a different view as to whether the direction infringed the right to bodily integrity.[116] Speaking to the meaning of 'real or genuine', his Honour questioned what gives a choice that character.[117] Justice Hall commented that '[a] person may still be free to make a choice even if one option is made less attractive by the imposition of consequences … the effect of the burden [on that choice] can rarely be objectively determined'.[118] His Honour then went on to refer to s 12 of the *Police Act*, which provides that the Commissioner can waive or reduce the required notice period.[119] In Hall JA's view, that was a power the Commissioner was likely to have exercised in this case, had Mr Falconer sought that the Commissioner do so.[120] Mr Falconer could have avoided breaching any lawful obligations had he sought that the Commissioner exercise this power,[121] and accordingly this meant Mr Falconer had a 'viable choice', negating the conclusion that the mandate infringed on his right to bodily integrity.[122] Justice Hall further concluded that, even if s 12 did not apply, the consequences of non-compliance did not deprive Mr Falconer of a real or genuine choice, but were 'entirely disciplinary in nature'.[123] While the consequences of non-compliance were 'undoubtedly coercive', Mr Falconer retained the ability to make a choice according to Hall JA, who cited the fact that Mr Falconer chose not to comply and did not get vaccinated (demonstrating therein that he retained a real or genuine choice).[124] This reasoning is somewhat cyclical, but it does lend support to the idea that it is difficult to describe the parameters of the right to bodily integrity, particularly in the context of a coercive instrument that is intended to exert pressure on those who may otherwise choose not to get vaccinated.

The differing approaches to the principle of legality exhibited in *Kassam* and *Falconer* (per Buss P and Vaughan JA), together with McBride's analysis, suggest that the principle of legality may in some ways be beyond redemption when it comes to rights protection in Australia. When operating in the context of vaccine

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[114] *Falconer* (n 18) [299]–[308].
[115] Ibid [299].
[116] Ibid [300].
[117] Ibid [302].
[118] Ibid.
[119] Ibid [304].
[120] Ibid [305].
[121] Ibid [306].
[122] Ibid.
[123] Ibid [307].
[124] Ibid.

mandates, the right to bodily integrity has too many imperceptible shades of grey. Manoeuvring around the margins of the principle by using variable language like 'real or genuine choice', 'pressure', 'coercion', and 'compulsion' serves to confuse and obfuscate rather than give meaning to the principle of legality in the context of the right to bodily integrity. But is the closest legislative relative of the right to bodily integrity any more capable of being defined and understood?

III THE RIGHT NOT TO BE SUBJECT TO MEDICAL TREATMENT WITHOUT CONSENT

In the absence of any meaningful protection of the common law right to bodily integrity (or a common understanding of when that right is limited) via the principle of legality, legislating human rights may be the only way to ensure consistent legal protection. While Queensland passed the *HRA* (Qld) in 2019, *Johnston* was the first time a superior court gave detailed consideration to the meaning of the right not to be subject to medical treatment without 'full, free and informed' consent.[125] This right is based on art 7 of the *International Covenant on Civil and Political Rights* ('*ICCPR*').[126] There is little scholarship on the interpretation of the prohibition on medical or scientific experimentation without free consent in art 7 of the *ICCPR*.[127] The inclusion of treatment (not just experimentation) in human rights legislation expands the scope of the right, where art 7 of the *ICCPR* was originally 'intended to prevent the recurrence of atrocities such as those committed in concentration camps during World War II'.[128] The interpretation of equivalent rights in Victoria and the Australian Capital Territory ('the ACT') has not reached a superior court.[129]

The question of whether the right not to be subject to medical treatment without full, free and informed consent was in some way different to the right to bodily integrity, or consent to common law battery, squarely arose in *Johnston* given the

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[125] *HRA* (Qld) (n 20) s 17(c); Amy Thomasson, 'Learnings from *Johnston v Carroll*: The Place of Human Rights in Legal Challenges to COVID-19 Vaccine Directions' [2025] (1) *UNSW Law Journal Forum* 1, 13.

[126] Explanatory Note, Human Rights Bill 2018 (Qld) 3.

[127] Paul M Taylor, *A Commentary on the International Covenant on Civil and Political* Rights (Cambridge University Press, 2020) 177.

[128] Secretary-General, *Draft International Covenants on Human Rights: Annotation,* UN Doc A/2929 (1 July 1955) 87 [14].

[129] The right differs in the *HRA* (ACT) where it is only qualified by the word 'free': see s 10(2). The formulation of the right in Queensland is identical to that in Victoria. While some cases have reached the Victorian Supreme Court, none have given detailed consideration to the meaning of 'full, free and informed' consent. See, eg, *PBU and NJE v Mental Health Tribunal* (2018) 56 VR 141; *JL v Mental Health Tribunal* (2021) 67 VR 426; *De Bruyn (by his litigation guardian De Bruyn) v Victorian Institute of Forensic Mental Health* (2016) 48 VR 647.

reasoning in *Kassam*. The claimants in *Kassam* argued that a person's consent to a battery in the context of medical treatment could be vitiated by 'external factors'.[130] While accepting that 'there is room for debate at the boundaries of what external factors might vitiate a consent' in this context, the primary judge in *Kassam* reasoned that such external factors did not include 'forms of societal pressure including a law or a rule, an employment condition' or a decision made 'to avoid familial or social resentment, even scorn'.[131] Accordingly, 'a consent to a vaccination is not vitiated and a person's right to bodily integrity is not violated just because a person agrees to be vaccinated to avoid a general prohibition on movement or to obtain entry onto a construction site'.[132] In *Johnston*, Martin SJA did not disagree with this reasoning[133] but found, based on Richards J's observation in *Harding v Sutton* ('*Harding*'),[134] that the common law's idea of consent to medical treatment (and the right to bodily integrity more broadly) is narrower than the formulation of the right in the *HRA* (Qld).[135]

There are many different formulations of consent in the law. Consent to sexual contact must be 'freely and voluntarily given' in Western Australia;[136] in the context of battery, a person's consent is invalid if they lack capacity,[137] do not understand what they are consenting to,[138] or their consent is not voluntary (because it was obtained by fraud, undue influence, the use or threat of physical force, or economic duress).[139] The phrase 'full, free and informed' is not defined in the *HRA* (Qld). While it imports much of the terminology familiar to the common law, particularly free and informed,[140] working out the metes and bounds of these phrases in the context of legislation protecting human rights is an invidious task. After first noting that '[t]here are no bright lines demarking where consent is and is not free',[141] Martin SJA in *Johnston* went on to find that the consequences of this particular choice — between becoming vaccinated or being dismissed from employment — were sufficient to 'peel "free" away from "full, free and informed"'.[142] This finding was largely based on legal authorities decided in

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[130] *Kassam First Instance* (n 85) [60].
[131] Ibid [63].
[132] Ibid.
[133] *Johnston* (n 19) [319].
[134] [2021] VSC 741 [161] ('*Harding*').
[135] *Johnston* (n 19) [320].
[136] *Criminal Code 1913* (WA) s 221BB(1).
[137] See generally *Re C* [1994] 1 WLR 290.
[138] See generally *R v Williams* [1923] 1 KB 340.
[139] Deryck Beyleveld and Roger Brownsword, *Consent in the Law* (Hart Publishing, 2007) 8, 158.
[140] Ibid 7.
[141] *Johnston* (n 19) [325].
[142] Ibid [332].

the context of s 51(xxiiiA) of the *Constitution* and the extent to which 'practical compulsion' could amount to 'civil conscription'.[143] I have elsewhere summarised Martin SJA's reasoning in this regard.[144] His Honour found that there was 'practical compulsion' — being the threat of someone losing their livelihood if they did not comply with the mandate — involved in the 'decision' as to whether to consent to vaccination. Such compulsion, being 'the antithesis of consent',[145] meant that the applicants' consent was not 'free', and therefore their human rights were infringed by the mandate.

This stands in stark contrast to authority in the Queensland Industrial Relations Commission ('QIRC') finding that vaccine mandates did not infringe the right in s 17(c) of the *HRA* (Qld), largely on the basis that there may well be consequences attached to a decision not to be vaccinated, including dismissal from employment, but that does not remove the freedom to refuse vaccination.[146] The QIRC is the only body that has engaged substantively with the meaning of s 17(c) of the *HRA* (Qld) in the context of vaccine mandates. For example, Industrial Commissioner Power in *Donnelly v State of Queensland (Queensland Health)*[147] seems to import and apply the standards of employment law — that employees must comply with lawful and reasonable directions — in determining whether the right in s 17(c) of the *HRA* (Qld) was infringed. There, Industrial Commissioner Power found that the vaccine mandate in question was not coercive as the applicant had a choice as to whether to comply, and a decision not to do so 'will generally have employment consequences, as with any other decision to not follow a lawful and reasonable direction of an employer'.[148] However, Martin SJA did not engage with QIRC authorities in *Johnston.*

Mandatory vaccination policies have also been broadly accepted as lawful and reasonable directions by the Fair Work Commission in an employment law context, both before and in the context of the COVID-19 pandemic.[149] However, because reasonableness is assessed on a case-by-case basis and is therefore a question of fact, it is 'difficult to predict what will be considered reasonable

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[143] *British Medical Association v Commonwealth (No 2)* (1949) 79 CLR 201, 252–3, 292–3; *Wong v Commonwealth* (2009) 236 CLR 573, 633 [207].
[144] Thomasson (n 125) 12–13.
[145] *Johnston* (n 19) [329].
[146] See, eg, *Cervenjak v State of Queensland (Department of Children, Youth Justice & Multicultural Affairs*) [2022] QIRC 363 [29]; *Donnelly v State of Queensland (Queensland Health)* [2022] QIRC 149 [33].
[147] [2022] QIRC 149.
[148] Ibid [33].
[149] *Barber v Goodstart Early Learning* [2021] FWC 2156 [303]–[359] ('*Barber*').

en masse'.[150] The Fair Work Ombudsman also provided little guidance regarding the lawfulness of mandatory COVID-19 vaccination policies, other than suggesting that a tiered approach categorising workers according to risk of transmission may be appropriate (rather than a blanket mandate that applied to all roles regardless of the associated risk of transmission).[151] The coercive nature of the policy is not therefore particularly relevant to its lawfulness or reasonableness — if an employee breaches a lawful and reasonable direction, it is grounds for disciplinary action, as with any breach of the employment contract.[152] Provided the employer has complied with their consultation obligations and the direction falls within the nature and scope of employment, it is likely to be reasonable.[153] The primary reason the direction to ambulance service employees was found unlawful in *Johnston* was that Martin SJA had no reference point against which to measure reasonableness, having been given no evidence as to the nature and scope of the applicants' employment.[154] This might explain the dearth of academic commentary in the employment law space considering the intersection between coercive policies, like mandatory vaccination requirements, and the ability of an employer to give lawful and reasonable directions.

Conflating s 17(c) of the *HRA* (Qld) — the intention of which is to protect individual rights — with the ability of employers to give lawful and reasonable directions to their employees — which protects the right of an employer to 'exert control'[155] over their employees — is therefore inconsistent with the beneficial purpose of human rights legislation. It is important that human rights legislation is interpreted in accordance with its specific context and purpose in mind, where such beneficial or remedial legislation is to be 'given a "fair, large and liberal" interpretation'.[156] Both the QIRC authorities and Martin SJA's reasoning fail to engage with the specific wording of s 17(c), where his Honour was more focussed

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[150] Ibid [309].
[151] 'COVID-19 Vaccinations: Workplace Rights and Obligations', *Fair Work Ombudsman* (Web Page, 29 June 2023) <https://www.fairwork.gov.au/find-help-for/covid-19-and-workplace-laws/covid-19-vaccinations>; Wolf, Taliadoros and Gleeson (n 4) 1011.
[152] John Wilson and Kieran Pender, 'Vaccine Mandates and "Lawful and Reasonable" Directions: What Can an Employee Be Made to Do?' [2021] (Winter) *Ethos: Law Society of the Australian Capital Territory Journal* 28, 28.
[153] Giuseppe Carabetta, 'Vaccination Mandates and the Employee's Duty to Obey Lawful and Reasonable Directions' (2023) 50(3) *Australian Business Law Review* 1, 6.
[154] *Johnston* (n 19) [220]–[225]; Thomasson (n 125) 8.
[155] *Barber* (n 149) [303]; *R v Darling Island Stevedoring and Lighterage Co Ltd; Ex parte Halliday; Ex parte Sullivan* (1938) 60 CLR 601, 621.
[156] *AB v Western Australia* (2011) 244 CLR 390, 402 [24] citing *IW v City of Perth* (1997) 191 CLR 1, 12 (Brennan CJ and McHugh J), 39 (Gummow J).

on the meaning of 'compulsion', being the 'antithesis of consent',[157] than 'full, free and informed'.

Justice Martin resorted to authorities about the meaning of practical compulsion in the context of s 51(xxiiiA) of the *Constitution* rather than engaging with *Four Aviation Security Services Employees v Minister of Covid 19 Response* ('*Four Aviation*'),[158] a case decided by the New Zealand High Court. Similar findings were made regarding the degree of 'practical pressure' involved when non-compliance with a vaccine order meant being dismissed from employment.[159] Justice Martin found that the approach in New Zealand was irrelevant, citing differences between the *NZBORA* and the *HRA* (Qld), including the 'constitutional nature of review' under the *NZBORA*.[160] The formulation of the right is, granted, different to that in the *HRA* (Qld) — s 11 of the *NZBORA* provides that '[e]veryone has the right to refuse to undergo any medical treatment'. There is no equivalent right in the *ICCPR*, or any other international human rights instrument.[161] It is also separate from the right not to be subjected to medical or scientific experimentation without consent,[162] on which s 17(c) of the *HRA* (Qld) is based.[163] Indeed, as acknowledged by Panckhurst J of the New Zealand High Court, 'New Zealand has plotted its own course, at least in terms of the emphasis it has accorded to informed consent. Counsel's researchers revealed no other country which has a provision equivalent to [s] 11, enshrining the right to refuse medical treatment'.[164] However, the difference in origin and wording does not mean that *Four Aviation* is not of *any* assistance in interpreting s 17(c) of the *HRA* (Qld) — as Martin SJA concluded[165] — particularly when the case concerned orders requiring aviation security workers interacting with international travellers to be fully vaccinated.[166] It may be, at least on face value, more persuasive than the cases relied upon by his Honour to give meaning to 'full, free and informed' consent. This is particularly the case given that the phrase 'civil

[157] *Johnston* (n 19) [329].
[158] [2022] 2 NZLR 26 ('*Four Aviation*').
[159] Ibid [30].
[160] *Johnston* (n 19) [29].
[161] New Zealand Ministry of Justice, *A Bill of Rights for New Zealand,* White Paper (1985) 109 [10.166] <https://www.austlii.edu.au/nz/other/NZAHGovRp/1985/1.pdf >.
[162] *New Zealand Bill of Rights Act 1990* (NZ) s 10.
[163] Explanatory Note, Human Rights Bill 2018 (Qld) 3.
[164] *Department of Corrections v All Means All* [2014] 3 NZLR 404 [46] ('*All Means All*').
[165] *Johnston* (n 19) [312].
[166] *Four Aviation* (n 158) [1].

conscription' has a unique meaning that is specific to s 51(xxiiiA) of the *Constitution*.[167]

That said, the respondents in *Four Aviation* conceded that the applicants' rights under s 11 of the *NZBORA* were limited by the vaccine mandate,[168] whereas this issue was contentious in *Johnston*.[169] Section 11 of the *NZBORA* is also more straightforward than s 17(c) of the *HRA* (Qld), despite the relevance of similar considerations. Section 11 simply gives a right to refuse medical treatment, whereas s 17(c) states that a person must not be subjected to medical treatment unless certain conditions are met. In that sense, the right in s 11 of the *NZBORA* is unqualified, although still 'subject to demonstrably justified limits'.[170] The interpretative process is therefore not as complex with respect to s 11. In *Four Aviation* at least, there was an acceptance that the right is limited when the 'practical pressure' applied to a person is such that they feel unable to exercise their right to refuse vaccination.[171] This shifts the focus of the inquiry to the arguably more substantive (and consequential) question of whether the limit is reasonable and demonstrably justified. Deciding whether a person has given 'full, free and informed' consent is trickier.

For the above reasons, human rights legislation should enshrine a separate right to refuse medical treatment, similar to s 11 of the *NZBORA*. In fact, the New Zealand Parliament deliberately separated out this right from 'other more generally expressed rights' such as the right not to be subjected to medical or scientific experimentation without consent.[172] This establishes a clean interpretative slate and avoids the issues associated with giving meaning to both the right to bodily integrity and 'full, free and informed' consent. Absent such an independent right to refuse medical treatment, 'full, free and informed' consent will continue to be interpreted by reference to other more general fundamental rights[173] and even unrelated employment law rules. To defer to employment law principles or apply constitution-specific interpretations is to fall short of the interpretative task. This is particularly the case when there is already a vast amount of different terminology being used — from coercion to compulsion to

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[167] *British Medical Association in Australia v Commonwealth* (1949) 79 CLR 201, 255 (Rich J) ('*British Medical Association*').
[168] *Four Aviation* (n 158) [28].
[169] The Crown also accepted that the applicants' s 11 right was limited in *Yardley v Minister for Workplace Relations and Safety* [2022] NZHC 291, a subsequent case of the High Court of New Zealand in which Cooke J found that the limitation on that right *was not* demonstrably justified.
[170] *NZDSOS* (n 27) [46].
[171] *Four Aviation* (n 158) [30].
[172] *NZDSOS* (n 27) [48].
[173] *All Means All* (n 164) [46].

'real or genuine choice'.[174] I acknowledge that the introduction of a right to refuse medical treatment may have implications beyond vaccination.[175] This, together with careful consideration of what constitutes medical treatment, should be explored in future scholarship.

IV Is There a Way to Better Ensure Legal Consistency and Coherence in Response to this Issue?

It is clear from the foregoing that attempts to mould the principle of legality into a 'quasi-constitutional' bill of rights have been unsuccessful. Given the strict separation of powers in Australia,[176] that seems appropriate. Left without recourse to the principle of legality, this article suggests that the best way to scrutinise decision-making in the Australian context is through human rights legislation that provides a direct right of action. Further, an improved, mandate-specific decision-making framework is needed to complement these enhanced human rights protections. At a point in time where only three Australian jurisdictions have passed legislation protecting human rights — Victoria, Queensland and the ACT — analysing its application to the COVID-19 pandemic provides a unique opportunity to consider how legislative settings could be maximised to ensure consistency and better protect human rights. This could also provide a clearer framework for policymakers in setting expectations about the consideration of human rights in decision-making.

A *The Waning Significance of the Principle of Legality in Rights-Based Challenges*

While the principle of legality had a role to play in protecting the right to bodily integrity in *Falconer*, the subject of the inquiry was not the decision to impose the mandate, or the relevant decision-making process. The focus was on the 'legal and practical operation'[177] of the direction in the context of the empowering statute — it is clear from this that something more than the principle of legality is needed to ensure adequate scrutiny of decisions and decision-making processes. Further, the power of the executive in particular has grown, meaning we can no longer rely on the safeguards of responsible government to protect rights in the way we have historically.[178] This is particularly evident in the fact that the relevant

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[174] *Falconer* (n 18) [133].
[175] For example, mental health law, the fluoridation of water, and drug testing in sport.
[176] Meagher, 'Clear Statement Rule' (n 45) 442.
[177] *Falconer* (n 18) [133].
[178] Brian Galligan, Rainer Knopff and John Uhr, 'Australian Federalism and the Debate Over a Bill of Rights' (1990) 20(4) *Publius* 53, 54.

decision-maker did not give oral evidence in either *Kassam*[179] or *Falconer*[180] but did in *Johnston*.[181] In *Kassam*, the primary judge acknowledged that this 'left the Court with an incomplete set of materials to establish what was and was not considered by the Minister in making the impugned orders'.[182] Conversely, the evidence of the Commissioner of Police was scrutinised in detail over the course of almost 60 paragraphs in *Johnston*.

In any event, it is inappropriate to expand judicial review to address the deficits in accountability and decision-making identified in this article.[183] This is the vacuum, or, as Beech-Jones CJ referred to it in *Kassam,* the 'evidentiary lacuna',[184] that only a specific decision-making framework complemented by human rights legislation can fill.[185] Human rights legislation acknowledges and partly codifies the principle of legality[186] but provides a separate pathway of challenge, suggesting that primacy should be given to the active and participatory aspects of human rights protections rather than trying to make the principle of legality something that it is not. Broadly speaking, two questions need to be answered in a human rights claim: (1) is a protected right 'limited' by the provision under challenge; and (2) if a right is limited, is that limitation 'reasonable and demonstrably justifiable' in a free and democratic society?[187] The latter stage is essentially a proportionality test where courts are required to balance competing interests, something which 'lies at the very heart of human rights law'.[188] The application of the proportionality test is the closest courts have come to evaluating the policy choices that underpinned vaccine mandates — it requires close attention to the limitation imposed and the object or purpose sought to be achieved.[189] As argued by Janina Boughey, '[i]f the legislature expressly required decision-makers to exercise their statutory discretions in a manner that only

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[179] *Kassam First Instance* (n 85) [110], [129]. The Minister did not even provide affidavit evidence in *Kassam.*

[180] *Falconer v Commissioner of Police [No 4]* [2022] WASC 271 [40]; *Falconer v Chief Health Officer [No 3]* [2022] WASC 270 [32].

[181] *Johnston* (n 19) [84]–[140]. The Commissioner for Police gave evidence but the Director-General of Queensland Health did not, although the Director-General's material and reasoning relied on to make the decision to implement a vaccine mandate was scrutinised (see [241]–[265]).

[182] *Kassam First Instance* (n 85) [129].

[183] Boughey (n 42) 224–5, 230.

[184] *Kassam First Instance* (n 85) [130].

[185] Boughey (n 42) 230.

[186] See above n 30.

[187] *HRA* (Qld) (n 20) ss 8(b), 13.

[188] Kylie Evans and Nicholas Petrie, 'COVID-19 and the Australian Human Rights Acts' (2020) 45(3) *Alternative Law Journal* 175, 176.

[189] Ibid; John Mark Keyes, 'Judicial Review of COVID-19 Legislation: How Have the Courts Performed?' (2023) 30(2) *Australian Journal of Administrative Law* 115, 137.

imposed proportionate limits on rights, then proportionality arguably becomes a question of law rather than one of merits'.[190] This approach negates the argument that engaging in an assessment of proportionality necessarily usurps parliamentary supremacy.[191]

Even if a right is found to be limited justifiably, the two-pronged test is much clearer and more appropriate than how the principle of legality was applied in *Kassam,* for example. In *Kassam*, the Court found that the measures under challenge did not limit the right to bodily integrity,[192] and that freedom of movement 'is not necessarily some form of positive right' at common law.[193] Under human rights legislation, this limitation may at the very least be acknowledged, if not interrogated. There remains much debate about the nature of the proportionality test set out in the human rights legislation in Victoria, the ACT and Queensland,[194] as well as the role such legislation has to play in scrutinising laws implemented during a public health emergency.[195] It is clear however that when operating in the sphere of human rights legislation, courts are not 'confined to questions of power and the legality of its exercise'[196] in the same way they are when exercising powers of judicial review and applying the principle of legality.

While it is not the purpose of this article to examine how human rights protections should be legislated (ie, by which level of government), this could be an opportunity to legislate rights at a federal level. There have long been calls for, and even failed attempts to,[197] legislate nationalised standards for the protection of human rights.[198] Debate remains around whether those rights should apply only to federal public authorities or be imposed on states and territories as

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[190] Boughey (n 42) 230.
[191] Ibid 231.
[192] *Kassam* (n 17) [97], [99].
[193] *Kassam First Instance* (n 85) [70].
[194] See, eg, Kent Blore, 'Six Unexplored Aspects of Proportionality under Human Rights Legislation in Australia' [2022] (105) *Australian Institute of Administrative Law Forum* 42.
[195] See, eg, Evans and Petrie (n 188) 175.
[196] Christopher Taylor-Burch, 'Upholding Mandatory Vaccinations for the Police Force: *Falconer v Commissioner of Police [No 2]* [2024] WASCA 47' (June 2024) *Brief* 34, 35.
[197] Galligan, Knopff and Uhr (n 178).
[198] See, eg, National Human Rights Consultation Committee, *National Human Rights Consultation Report* (September 2009) <https://alhr.org.au/wp/wp-content/uploads/2018/02/National-Human-Rights-Consultation-Report-2009-copy.pdf>; Australian Human Rights Commission, *Free & Equal: A Human Rights Act for Australia* (Position Paper, 2022) <https://humanrights.gov.au/sites/default/files/free_equal_hra_2022_-_main_report_rgb_0_0.pdf>.

well.[199] If the framework proposed in Part IV(C) regarding pandemic management was implemented at a federal level, then it may make most sense to implement federal human rights protections. On the other hand, if pandemic management remains within the purview of the states and territories, then human rights protections should be legislated at a state and territory level. Perhaps ultimately the preferable approach is that recommended by Anne Twomey, an 'entrenched but non-constitutional'[200] model where the federal and all state and territory parliaments legislate a uniform set of rights protections.[201] This is a model that may also work for the reforms suggested in Part IV(C). It goes without saying that the matters discussed in this article will require governmental 'bravery and ambition'.[202]

B *Amendments to Human Rights Legislation*

This section considers the amendments necessary to bolster existing human rights legislation. It seems unnecessary to tie human rights challenges to another ground of review as is currently required in Queensland and Victoria. The ACT is currently the only Australian jurisdiction where a person can bring proceedings for an alleged contravention of the *Human Rights Act 2004* (ACT) ('*HRA* (ACT)') without needing to 'piggy back' another cause of action.[203] Further, even in Queensland and Victoria where such piggy backing is necessary, the human rights ground can succeed even if the primary cause of action fails,[204] as was the case in *Johnston*.[205] The concern that providing a direct right of action might lead to opening the floodgate of litigation has proven unfounded in other jurisdictions.[206]

It should also be noted that a direct right of action, as it is often referred to, was not included in the *HRA* (ACT) until 2008.[207] A direct right of action was not

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[199] National Human Rights Consultation Committee (n 198); Justin Gleeson, 'A Federal Human Rights Act: What Implications for the States and Territories?' (2010) 33(1) *UNSW Law Journal* 110.
[200] Anne Twomey, Submission to the National Human Rights Consultation Committee, *National Human Rights Consultation*, 5 May 2009, 20–1.
[201] Gleeson (n 199) 111.
[202] Ibid 112.
[203] Where the proposed legal proceedings are in relation to an act or decision of a public authority, as defined in the *HRA* (ACT). See s 40C(2)(a).
[204] *HRA* (Qld) (n 20) s 59(1), (2).
[205] Where the judicial review grounds (including unreasonableness) and the argument that the relevant decision-makers did not have the power to make the directions failed, but the argument based on s 58(1)(b) of the *HRA* (Qld) was successful.
[206] Rosalind Croucher, 'A New National Human Rights Framework for Australia' (Speech, Annual Castan Centre for Human Rights Law Conference, 21 July 2023) <https://humanrights.gov.au/about/news/speeches/new-national-human-rights-framework-australia>.
[207] Effective from 1 January 2009.

included when the legislation was first introduced in 2004, despite being included in the ACT Bill of Rights Consultative Committee's model bill (which itself was based on legislative models in New Zealand and the United Kingdom). The decision to omit a direct right of action was made to give government decision-makers time to adapt their policies and processes.[208] This is consistent with the historically cautious approach to human rights protection in Australia.[209] As a compromise, a provision requiring courts and other decision-making bodies to interpret laws consistently with human rights was included.[210] As mentioned earlier, this interpretative provision is essentially a codification of the principle of legality in its strongest form.

Public authorities in both Victoria and Queensland have now had time to implement the necessary policies and processes to safeguard human rights. Accordingly, consideration is now being given to the introduction of a direct right of action in those jurisdictions. As observed by Rosalind Croucher in her former role as President of the Australian Human Rights Commission, the inclusion of a direct right of action is becoming best practice.[211] The importance of such a right is hopefully evident from the foregoing analysis — where other legal tools have failed to provide scrutiny and accountability, human rights legislation may be the best way to ensure that decision-makers have seriously turned their minds to the potential impact their decision will have on human rights.

If human rights legislation is to be the way forward, thought should be given to the addition of a right to refuse medical treatment in line with s 11 of the *NZBORA*. The interpretation of the phrase 'full, free and informed' consent is a difficult judicial exercise. The only word in the phrase in s 17(c) of the *HRA* (Qld) that appears in art 7 of the *ICCPR* is 'free'; 'full' and 'informed' (as well as the addition of treatment, not just experimentation) were added by the Queensland Parliament. The Explanatory Note that accompanied the Human Rights Bill 2018 does not shed light on the reason for their addition. Framing s 17(c) as a positive right, or including a separate right to refuse medical treatment in the same way as s 11 of the *NZBORA,* simplifies the interpretative task. This is particularly the case given that reasonable minds may always differ as to where on the spectrum the 'burden of non-compliance is such as to deprive a person of a real or genuine choice',[212] to use the words of Buss P and Vaughan JA in *Falconer*.

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[208] Australian Capital Territory, *Parliamentary Debates*, Legislative Council, 6 December 2007, 4028 (Simon Corbell, Attorney-General).
[209] Gleeson (n 199) 111.
[210] Ibid; *HRA* (ACT) (n 44) s 30.
[211] Croucher (n 206).
[212] *Falconer* (n 18) [301].

However, there may be some issues with this approach. Noting the concession made by the respondents in *Four Aviation* and *Yardley v Minister for Workplace Relations and Safety* ('*Yardley*')[213] that the right in s 11 was limited by the relevant mandates, it may be the case that awareness of, and judicial discourse about, human rights is better embedded in New Zealand. Indeed, Cooke J acknowledged in *NZDSOS Inc v Minister for COVID-19 Response*[214] that the fundamental nature of the right in s 11 of the *NZBORA* meant that there was a 'very significant evidential burden' on the respondent to demonstrate that the mandate was reasonable, and demonstrably justified.[215] There are no statements made to this effect in Australian superior court decisions, particularly where the relevant jurisdiction did not have human rights protections. The *NZBORA* was passed in 1990 — conversations about human rights in a political and legal sense long pre-date the introduction of human rights legislation in Australia. The *NZBORA* is also considered to be one of New Zealand's constitutional documents,[216] whereas human rights legislation in Australia does not have constitutional footing. Further, New Zealand does not need to contend with the issues Australia's federal structure poses for consistency in legislation across states and territories. It is clear, however, that consistency and coherency in how the right is interpreted and applied is beneficial to everyone, the public and decision-makers alike. As more Australian jurisdictions consider the introduction of legislation protecting human rights, this will be all the more critical.[217]

C *Reconsidering Australia's Legal Approach to Public Health and Pandemic Management*

As noted in the introduction, public health legislation has in recent times been used to respond to threats posed by individuals or small groups rather than a pandemic.[218] The COVID-19 Response Inquiry found that a not insignificant portion of the public felt there was a lack of transparency from government, and

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[213] Above n 169.
[214] [2022] NZHC 716.
[215] Ibid [54].
[216] New Zealand's constitution is not made up of one document but several, including the NZBORA: *NZDSOS* (n 27) [63]; 'New Zealand's Constitution', *Office of the Governor-General* (Web Page) <https://gg.govt.nz/office-governor-general/roles-and-functions-governor-general/constitutional-role/constitution/constitution>; '30th Anniversary of the NZ Bill of Rights Act', *New Zealand Parliament* (Web Page, 28 August 2020) <https://www3.parliament.nz/en/get-involved/features/30th-anniversary-of-the-nz-bill-of-rights-act>.
[217] Taylor-Burch (n 90); Zak Vidor Staub, 'Human Rights Acts around Australia', *UNSW Australian Human Rights Institute* (Web Page) <https://www.humanrights.unsw.edu.au/news/human-rights-acts-around-australia>.
[218] David J Carter, 'The Use of Coercive Public Health and Human Biosecurity Law in Australia: An Empirical Analysis' (2020) 43(1) *UNSW Law Journal* 117, 117–8, 123.

limited supporting evidence for the decisions being made.[219] In relation to vaccine mandates specifically,

> [f]ocus groups revealed that many people had strong negative feelings about vaccine mandates and that these feelings had a strong correlation to mistrust in government and medical science. In a community input survey conducted for the Inquiry in 2024, 21 per cent of respondents said they would not get a vaccine offered by the government in a future public health emergency, and 17 per cent said they might or might not.[220]

Research is emerging as to the reasons for such mistrust.[221] In such research, consideration should be given to the role played by the exercise of broad-ranging powers with no specific reference point or the application of clear and consistent criteria. Public health is 'created, defined and re-shaped by law'.[222] It is therefore important to heed the lessons of the pandemic and devise a clear framework for future pandemic management, one that helps not only the public but also decision-makers understand the legality of vaccine mandates, with one pre-pandemic study finding that a 'substantial number' of public health respondents perceived laws as 'unclear'.[223] In the same study, the author called for 'legal amendments … to clarify the extent, scope and context of legal authority' held by public decision-makers.[224] Indeed even in superior court cases, the purpose of mandates was described variously as:

- 'to minimise the risks of transmission of COVID-19 throughout the [Queensland Police Service] and between police staff and members of the community and to ensure that [Queensland Police Service] employees were "frontline- ready and available for deployment"',[225]
- to protect the vulnerable;[226] and

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[219] Commonwealth of Australia (n 12) 116.
[220] Ibid 117.
[221] See, eg, Thomas Aechtner, *Antivaccination and Vaccine Hesitancy: A Professional Guide to Foster Trust and Tackle Misinformation* (Routledge, 2024); Hibah Khan, 'Who Doesn't Want to be Vaccinated? Determinants of Vaccine Hesitancy During COVID-19' [2021] (130) *IMF Working Papers* 1.
[222] Anda Botoseneanu et al, 'Achieving Public Health Legal Preparedness: How Dissonant Views on Public Health Law Threaten Emergency Preparedness and Response' (2011) 33(3) *Journal of Public Health* 361, 361.
[223] Ibid 363.
[224] Ibid 366.
[225] Regarding the police service mandate challenged in *Johnston* (n 19) [438].
[226] With respect to the ambulance service mandate challenged in *Johnston* (n 19) [439].

- 'to put in place some measures to address the unique risks posed by COVID-19 from the WA Police workforce for the purpose of preventing the spread of COVID-19 to vulnerable groups and the general community in Western Australia and to ensure that the WA Police Force can continue to provide critical services to the community'.[227]

This speaks to the need for a clear, mandate-specific lawmaking framework. The New Zealand Parliament recognised this need and introduced amendments to existing COVID-19 response legislation in November 2021 to create a mandate-specific framework. Now repealed, s 11AA of the *COVID-19 Public Health Response Act 2020* (NZ) set out the prerequisites for the making of a vaccine mandate under s 11AB. This framework had four key elements. Firstly, the Minister was responsible for making the mandate.[228] To ensure democratic legitimacy and maintain parliamentary sovereignty, it is important that decision-makers who are accountable to parliament, rather than unelected officials, are making these decisions (which may of course be on the advice of the relevant technocrat — for example, the Chief Health Officer).[229] Secondly, the *NZBORA* was foregrounded — the Minister had to be satisfied the order either did not limit or justifiably limited human rights.[230]

Thirdly, the Minister was expressly required to consider the public interest (as defined) and had to be satisfied that the mandate was 'appropriate to achieve the purpose' of the Act.[231] The 'public interest' was then given a multi-factorial definition, with the requirement that the Minister consider not only the importance of supporting essential services, but also 'maintaining trust in public services', among other matters.[232] It goes without saying that the public interest includes protecting the public from preventable disease, but that is not the only relevant factor in making the decision to implement a vaccine mandate. Providing a multi-factorial definition makes it clear that making decisions in the public interest is a balancing exercise, where the calculus may change depending on how effective a vaccine is in preventing transmission or reducing the severity of the disease.[233] The aim is not necessarily to change the considerations that are

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[227] The preamble to the police force direction challenged in *Falconer* (n 18) [13].
[228] *COVID-19 Public Health Response Act 2020* (NZ) s 11AA(1).
[229] Eric L Windholz, 'Governing in a Pandemic: From Parliamentary Sovereignty to Autocratic Technocracy' (2020) 8(1) *The Theory and Practice of Legislation* 93, 94.
[230] *COVID-19 Public Health Response Act 2020* (NZ) s 11AA(1)(a).
[231] Ibid s 11AA(1)(c)(ii).
[232] Ibid s 11AA(2).
[233] Anja Krasser, 'Compulsory Vaccination in a Fundamental Rights Perspective: Lessons from the ECtHr' (2021) 15(2) *Vienna Journal on International Constitutional Law* 207, 232.

relevant when deciding whether to implement a mandate, but to make them explicit from the outset and at least somewhat consistent across jurisdictions. This provides a set of reference criteria against which the public and ultimately courts can evaluate vaccine mandates — it must be remembered that transparency and accountability are also in the public interest.[234]

Finally, the Minister was required to keep the orders under review.[235] This was ultimately one of the primary reasons the vaccine mandate challenged in *Yardley*[236] was found by the New Zealand High Court not to be a reasonable and demonstrably justified limit on the applicants' human rights and therefore held to be unlawful.[237] Justice Cooke essentially reasoned that the rapid spread of the Omicron variant throughout the community meant that there was no real threat to the continuity of essential services that the mandate materially addressed.[238] If we are to work within the bounds of Australia's current state-based approach to public health, this framework could be introduced in Australia either as separate uniform legislation (repealing the existing legislation) or in the form of amendments to existing public health legislation in each state and territory. Some scholars have argued that the federal government could, if it chose, make laws with respect to public health using various heads of power in the *Constitution*.[239] It may be that a federal public health or pandemic management act could be supported by the external affairs power, in the same way as some have suggested a federal human rights act could be supported.[240] If this is correct, the suggested framework could be implemented at a Commonwealth level. On the face of it, this would certainly make sense when the risk posed is a national pandemic where states and territories are similarly impacted. Indeed, in a similar way to rights protection,[241] pandemic management and public health 'lie at the heart of arrangements for the governance of the federation' and therefore should be dealt

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[234] Carter (n 218) 117.
[235] *COVID-19 Public Health Response Act 2020* (NZ) s 14(5).
[236] [2022] NZHC 291.
[237] Ibid [80], [104]–[108].
[238] Ibid [97].
[239] Christopher Reynolds, 'Public Health and the Australian Constitution' (1995) 19(3) *Australian Journal of Public Health* 225, 225, 248–9.
[240] Gleeson (n 199) 115 citing Stephen Gageler and Henry Burmester, *In the Matter of Constitutional Issues Concerning a Charter of Rights: Supplementary Opinion*, Solicitor-General Opinion Nos 40, 68 (2009).
[241] Cheryl Saunders, 'Protecting Rights in the Australian Federation' (2004) 25 *Adelaide Law Review* 177, 183–93.

with according to a national uniform standard.[242] The appropriateness and feasibility of such an approach is a matter for future research.

V CONCLUSION

This article has developed an argument for some drastic changes to both public health law and the protection of human rights in Australia, having identified deficiencies in the current legal treatment of the right to bodily integrity. In doing so, it demonstrated that coercion in pursuit of the collective interest in public health can be acknowledged without consent necessarily being undermined. The superior court cases emerging from the pandemic have made clear that the principle of legality does not now (if it ever did) provide sufficient or consistent protection of human rights in Australia. There is a need to better embed human rights in emergency decision-making in Australia through a transparent, mandate-specific decision-making framework supplemented by human rights legislation providing a direct right of action. Absent the *HRA* (Qld), the Commissioner of Police's decision to implement a mandate would not have been scrutinised and the ultimate finding of unlawfulness in *Johnston* would not have been made. A more transparent and consistent decision-making framework would not only promote accountability but also guide decision-makers attempting to address the inherent tension between individual rights and public health in emergency settings. Such a framework acknowledges the uniqueness of vaccination as a medical treatment that serves a collective interest. It is also important, as a corollary, that those who feel aggrieved by a decision are given the opportunity to understand the reasoning process and take direct action to determine whether there were deficiencies in that process. The public has a right to understand why decisions that so intimately impact their lives were made and on what basis. Human rights legislation provides access to that information, and the proposed framework ensures consistency in decision-making, with a view to enhancing trust in government and, where a pandemic is concerned, public health.

[242] Gleeson (n 199) 111.

POLICING PUBLIC HEALTH: THE JUSTIFIABLE LIMITS OF COVID-RELATED OFFENCES IN WESTERN AUSTRALIA

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The COVID-19 pandemic reminded the world of the significant burden of infectious diseases on individuals, families, communities and health systems. Compliance with public health measures was regarded as central to a successful response to the pandemic and, like other jurisdictions, Western Australia utilised the criminal law as a way of achieving this compliance. While a common tactical response, the utilisation of the criminal law in response to a public health crisis raises significant theoretical, regulatory and practical questions about the role of criminal sanctions in this context. This article unpacks the legal frameworks imposing these restrictions and the associated criminal penalties on Western Australians during the height of the pandemic and subjects these to a normative analysis, focusing on the harm principle, and the systemic consequences of risk-based offences more generally. It then undertakes a review of the relevant case law associated with the sentencing of persons convicted of the offences in Western Australia to explore judicial attitudes and sentencing patterns. The article concludes that, in light of both the normative and the explanatory inquiry, there is a place for criminal law in the regulation of communicable diseases, but such a response must be tailored on the basis of need and proportionality given the significant human rights concerns with criminal responses to public health threats.

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INTRODUCTION

Novel infectious diseases are emerging, and previously controlled endemic diseases are re-emerging, at an increasing rate.[1] With over 777 million cases and over seven million deaths reported globally, the COVID-19 pandemic reminded nations of the significant burden of infectious disease on individuals, families, communities and health systems.[2] Public Health and Social Measures ('PHSMs') including physical distancing, mask-wearing and quarantine reduced transmission, morbidity and mortality.[3] As successful pandemic responses

[1] Michael Madigan et al, *Brock Biology of Microorganisms* (Pearson, 14th ed, 2015) 864. Emerging infectious diseases include endemic diseases that 'were previously under control but suddenly … re-emerge in epidemic or pandemic forms': at 839–41.

[2] 'Coronavirus Disease (COVID-19) Pandemic', *World Health Organisation* (Web Page, 11 May 2025) <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>. COVID-19 or 'coronavirus disease' is caused by the SARS-CoV-2 virus: 'Coronavirus Disease (COVID-19)', *World Health Organisation* (Web Page) <https://www.who.int/health-topics/coronavirus>. We acknowledge that infectious diseases are a constant, rather than sporadic, concern in developing countries: see, eg, Gaëtan Gavazzi, Francois Herrmann and Karl-Heinz Krause, 'Aging and Infectious Diseases in the Developing World' (2004) 39(1) *Clinical Infectious Diseases* 83, 84–7.

[3] Kwadwo Agyapon-Ntra and Patrick E McSharry, 'A Global Analysis of the Effectiveness of Policy Responses to COVID-19' (2023) 13(1) *Scientific Reports* 5629; 'Overview of Public Health and Social Measures in the Context of COVID-19: Interim Guidance', *World Health Organisation* (Web Page, 18 May 2020) 1 <https://apps.who.int/iris/bitstream/handle/10665/332115/WHO-2019-nCoV-PHSM_Overview-2020.1-eng.pdf?sequence=1&isAllowed=y>.

depend on substantial compliance with such measures,[4] a number of jurisdictions resorted to using the criminal law to sanction non-compliance.[5]

In Western Australia ('WA') COVID-related offences arose in relation to three pieces of legislation: the *Public Health Act 2016* (WA) ('*PHA*');[6] the *Emergency Management Act 2005* (WA) ('*EMA*');[7] and the *Criminal Code Act Compilation Act 1913* (WA) ('*Criminal Code*').[8] This article focuses on 'failure to comply'[9] offences under the *EMA*–*PHA* framework ('the offences') and is, therefore, concerned with the criminalisation of behaviours that create a risk of transmission of COVID-19 rather than with transmission itself. The *EMA*–*PHA* framework imposed a range of restrictions on the WA population. Many of the restrictions replicated those adopted elsewhere in Australia, although the adoption of WA's 'hard border' was a unique and controversial measure.[10] We focus on the offences to evaluate critically whether the criminal sanctions they imposed were a justifiable and appropriate means of enforcing PHSMs, and thereby effecting communicable[11] disease control, in the context of the COVID-19 pandemic and in WA specifically. The focus on risk-based criminalisation positions our analysis in the jurisprudential realm of preventive harm.

While there were clear social and health benefits which flowed from the WA government's approach, particularly for those at increased risk of severe disease and mortality, we remain conscious of the distinct harmful social consequences which can flow from the use of punitive measures. For these reasons the article is

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[4] See generally Kristina Murphy et al, 'Why People Comply With COVID-19 Social Distancing Restrictions: Self-Interest or Duty?' (2020) 53(4) *Australian & New Zealand Journal of Criminology* 477, 478.

[5] See, eg, *Public Health Act 2010* (NSW) s 10; *Public Health and Wellbeing Act 2008* (Vic) ss 209, 232; *Emergency Management Act 2004* (SA) s 28(1); *Public Health Act 2005* (Qld) ss 99–102, 362D; *Public Health Act 1997* (Tas) s 53; *Public Health Act 1997* (ACT) s 120(4); *Public and Environmental Health Act 2011* (NT) s 56; *COVID-19 Public Health Response Act 2020* (NZ) s 26. See generally Nina Sun et al, 'Human Rights in Pandemics: Criminal and Punitive Approaches to COVID-19' (2022) 7(2) *BMJ Global Health* e008232:1–7, 2–3.

[6] *Public Health Act 2016* (WA) ('*PHA*').

[7] *Emergency Management Act 2005* (WA) ('*EMA*').

[8] *Criminal Code Act Compilation Act 1913* (WA) ('*Criminal Code*').

[9] 'Failure to comply' offences involve the breach of public health directions made under either the *EMA* or *PHA*. Cf ibid ss 1(4)(a)–(d), 294, 297, 304, 317.

[10] 'WA's Hard Border Lifted', *Government of Western Australia* (Web Page, 3 March 2022) <https://www.wa.gov.au/government/announcements/was-hard-border-lifted>; 'Controlled Interstate Border', *Government of Western Australia* (Web Page, 30 October 2020) <https://www.wa.gov.au/government/announcements/controlled-interstate-border>.

[11] 'A communicable disease is an infectious disease that can be transmitted from person-to-person': Joanne M Willey, Linda M Sherwood and Christopher J Woolverton, *Prescott's Microbiology* (McGraw-Hill, 9th ed, 2014) 836.

underpinned by a contextual approach,[12] consistent with the Australian approach to criminalisation scholarship which argues that the criminal justice system and, specifically criminalisation, must be assessed in its socio-political context.[13] Our analysis proceeds in four parts.

First, we set out the offences and their role in the *EMA–PHA* framework, explain their substantive elements and associated penalties, and demonstrate that the process of law-making in the pandemic context was intrinsically executive-led.

Second, we engage in a normative critique of the offences. This part of the article interrogates the theoretical justifications for the offences by reference to the harm principle, noting that the elastic nature of this concept provides a useful framework to analyse risk-based offences and identify the competing interests at play. The normative critique of the offences continues with the identification of the systemic issues they raise, specifically those associated with executive law-making and the disproportionate enforcement of the offences against already marginalised societal groups.[14] In relation to the latter issue, we focus on the lessons learned from the human immunodeficiency virus ('HIV') experience which provides a historical foundation for issues that arise with respect to using the criminal law to manage a public health emergency.[15] This analysis concludes by referencing one aspect of the State's obligation to the community, particularly

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[12] See generally David Brown, 'Criminalisation and Normative Theory' (2013) 25(2) *Current Issues in Criminal Justice* 605, 607: the contextual approach adopted still recognises the value in identifying normative principles to guide criminalisation decisions.

[13] See generally Luke McNamara and Julia Quilter, 'Public Intoxication in NSW: The Contours of Criminalisation' (2015) 37 *Sydney Law Review* 1.

[14] See, eg, Julia Quilter and Luke McNamara, 'Guest Editors' Introduction Special Edition: Hidden Criminalisation — Punitiveness at the Edges' (2018) 7(3) *International Journal for Crime, Justice and Social Democracy* 1, 1. Also see the detailed discussion in Chapter 7 of Belinda Bennett, Ian Freckleton and Gabrielle Wolf, *COVID-19, Law and Regulation: Rights, Freedoms and Obligations in a Pandemic* (Oxford University Press, 2023) in which the authors explore the 'risk, impact and disadvantage' of the COVID-19 pandemic on different sectors and analyse the role of the law in managing this.

[15] HIV refers to the positive-strand, enveloped RNA retrovirus that is a human immunodeficiency virus. Persistent replication of HIV results in the progressive decline of CD4 T cell numbers and the clinical disease, acquired immune deficiency syndrome ('AIDS'), which leaves individuals vulnerable to life-threatening complications: Madigan et al (n 1) 866. We choose to refer to HIV as a pandemic to indicate its global reach, whilst the virus may have become 'endemic' the disease remains a significant global health issue: 'Epidemic, Endemic, Pandemic: What are the Differences?', *Columbia University Mailman School of Public Health* (Web Page, 19 February 2021) <https://www.publichealth.columbia.edu/news/epidemic-endemic-pandemic-what-are-differences>; Peter Sands, 'Why Aren't Diseases like HIV and Malaria, Which Still Kill Millions of People a Year, Called Pandemics?', *STAT* (Web Page, 6 July 2021) <https://www.statnews.com/2021/07/06/why-arent-diseases-like-hiv-and-malaria-which-still-kill-millions-of-people-a-year-called-pandemics/>.

those most vulnerable to infection, and assessing the role of the offences in connection with this obligation.

Third, we provide a qualitative and textual analysis of available case law associated with the offences, including high-profile magistrate and appeal decisions.[16] Transcripts of sentencing decisions in the Magistrates Court were obtained by application.[17] The language of judgments is closely analysed to distil judicial approaches to and trends in sentencing.[18]

In the final part of the article, we analyse patterns of judicial interpretation and sentencing in the context of our normative critique in Part II. The qualitative data collected in Part III is supplemented with official sentencing statistics to contextualise our findings and assess the operation of the offences:[19] noting that empirical research is still needed to assess efficacy. Ultimately, our article suggests there is a time and place for criminalisation in communicable disease control and that in the WA context, the offences were an appropriate response to the threats COVID-19 posed to our community and health system. We conclude that if criminal sanctions are found to be an effective means of generating compliance with PHSMs, criminalisation of this kind is justified in the most critical stages of a legal response to a respiratory pathogen with pandemic potential, provided discriminatory impacts are actively mitigated.

PART I: THE REGULATORY FRAMEWORK

The WA Government's 'executive-led response'[20] to COVID-19 relied on twin emergency declarations under the *EMA* and *PHA* to enliven emergency management powers.[21] Following WHO's pandemic declaration on 11 March

[16] See generally Terry Hutchinson and Nigel Duncan, 'Defining and Describing What We Do: Doctrinal Legal Research' (2012) 17(1) *Deakin Law Review* 83, 116.
[17] Google searches were conducted with the terms 'WA COVID-19 breaches' to obtain the names of defendants and date of hearings to file a Form 3A with a supporting affidavit.
[18] See Nicola Lacey, 'Legal Constructions of Crime' in Mike Maguire, Rod Morgan and Robert Reiner (eds), *The Oxford Handbook of Criminology* (Oxford University Press, 3rd ed, 2002) 179, 190; Hutchinson and Duncan (n 16) 111, 118. See also Katerina Linos and Melissa Carlson, 'Qualitative Methods for Law Review Writing' (2017) 84(1) *The University of Chicago Law Review* 213, 214; John H Farrar, *Legal Reasoning* (Thomson Reuters, 2010) 91; Christopher Enright, *Legal Reasoning* (Maitland Press, 2011) ch 6.
[19] See generally Kylie Burns and Terry Hutchinson, 'The Impact of "Empirical Facts" on Legal Scholarship and Legal Research Training' (2009) 43(2) *Law Teacher* 153, 159, 167.
[20] Tamara Tulich and Sarah Murray, 'Executive Accountability and Oversight in Australia During The COVID-19 Pandemic' (2022) 30(2) *Michigan State International Law Review* 283, 285.
[21] Western Australia, *Parliamentary Debates,* Legislative Assembly, 17 March 2020 (Mark McGowan, Premier).

2020,[22] the Minister for Emergency Services declared a 'State of Emergency' ('SOE') under s 56 of the *EMA* on 15 March 2020; and the Minister for Health subsequently declared a 'Public Health State of Emergency' ('PHSOE') under s 167 of the *PHA* on 16 March 2020.[23] Both were continuously extended under s 58 of the *EMA* and s 170 of the *PHA* respectively, until their revocation on 4 November 2022.[24] Penalties incurred under this *EMA*–*PHA* framework, while the emergency declarations were in force, were unaffected by those declarations being subsequently revoked.[25]

A *Emergency Declarations*

These declarations, given the expansive powers conferred, were intended to be temporary. Under the then statutory regime, the powers remained in force for three and six days under the *EMA* and *PHA* respectively, unless sooner revoked.[26] Further, each extension was confined to 14 days,[27] suggesting that these provisions anticipated emergency responses of short duration. Although the requirement to review circumstances every 14 days to assess the necessity of the measures[28] spoke to the emergency response character, the long-term management of the pandemic exposed the shortcomings of this approach.

This is evidenced through the parliamentary consideration of the *EMA* — although it contemplates plagues and epidemics,[29] the second reading speech focussed on terrorism preparedness and 'frequently occurring and predictable' natural disasters.[30] In reality, pandemics typically continue for many months and are, comparatively, infrequent and variable.[31] Moreover, while pts 4, 11 and 12 of

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[22] 'WHO Director-General's Opening Remarks at the Media Briefing on COVID-19: 11 March 2020', *World Health Organisation* (Web Page, 11 March 2020) <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>.

[23] Discussed in Marco Rizzi and Tamara Tulich, 'All Bets on the Executive(s)! The Australian Response to COVID-19' in Joelle Grogan and Alice Donald (eds), *Routledge Handbook on Law and the COVID-19 Pandemic* (Routledge, 2022) 457, 458–9.

[24] 'Revocation of Western Australia Declaration (No. 3) of Public Health State of Emergency: 3 November 2022', *Government of Western Australia* (Web Page, 4 November 2022) <https://www.wa.gov.au/government/publications/revocation-of-western-australia-declaration-no3-of-public-health-state-of-emergency-3-november-2022>.

[25] See, eg, *EMA* (n 7) s 59(4).

[26] *EMA* (n 7) ss 57(b), 59; *PHA* (n 6) ss 168, 170.

[27] *EMA* (n 7) s 58(4); *PHA* (n 6) s 170(5).

[28] See the preconditions in s 56 of the *EMA* and s 167 of the *PHA*.

[29] *EMA* (n 7) s 3.

[30] See Western Australia, *Parliamentary Debates,* Legislative Assembly, 17 August 2005, 4120b–4125a [1]–[2] (Michelle Roberts).

[31] See generally on the nature of pandemics Nita Madhav et al, 'Pandemics: Risks, Impacts, and Mitigation' in DY Jamison et al (eds), *Disease Control Priorities: Improving Health and Reducing*

the *PHA* were designed for 'emerging risks', including bioterrorism and 'rapidly spreading epidemics',[32] equivalent issues arise given the provisions that enable the PHSOE largely mirror the content and structure of s 56 of the *EMA*.[33]

B *Implementation of PHSMs*

Both declarations facilitated the implementation of PHSMs through executive directions while the SOE and PHSOE were in force.[34] Over the course of the pandemic, the majority of directions were implemented under the *EMA*,[35] by the State Emergency Coordinator who had 'overall responsibility' for coordinating the emergency response.[36] The primacy of the *EMA* is consistent with the *PHA*'s second reading speech, which contemplated using the *EMA* when 'a coordinated interagency response is required'.[37] In the relevant parliamentary debates, reliance on the *EMA* was attributed to the key role of the police in any emergency response;[38] and the benefits of the *EMA*'s '[establishment of] a comprehensive emergency management framework'[39] between the State Disaster Council, the State Emergency Coordinator and the Hazard Management Agency.[40] Inherent deficits of the *PHA* were proffered, including, implementation and enforcement

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Poverty (The International Bank for Reconstruction and Development, The World Bank, 3rd ed, 2017). Also note that the *EMA* did not feature in parliamentary debates during the influenza A (H1N1) pandemic of 2009. The following searches were conducted in Hansard: 'Swine flu' AND 'Emergency Management Act'; 'Swine flu'; 'H1N1'; 'SARS' AND 'Emergency Management Act'; 'Severe Acute Respiratory Syndrome' AND 'Emergency Management Act'; 'SARS'; 'Severe Acute Respiratory Syndrome'.

[32] Western Australia, *Parliamentary Debates,* Legislative Assembly, 17 August 2005, 4120b–4125a [1]–[2] (Michelle Roberts).

[33] Cf *PHA* (n 6) s 202D: the infectious disease extreme circumstances declaration introduced by pt 12A remains in force for 3 months unless extended or revoked.

[34] See *EMA* (n 7) pt 6 div 1; *PHA* (n 6) pt 12 div 5.

[35] Western Australia, *Parliamentary Debates,* Legislative Council, 19 October 2022, 4658c–4695a [2] (Stephen Dawson).

[36] Western Australia, *Parliamentary Debates,* Legislative Council, 18 November 2021, 5670c (Sue Ellery).

[37] See Western Australia, *Parliamentary Debates,* Legislative Assembly, 26 November 2014, 8833b–8836a [3] (Kim Hames). See also, *PHA* (n 6) s 164(1)–(2): these provisions make clear that a SOE and PHSOE can run concurrently.

[38] Western Australia, *Parliamentary Debates,* Legislative Council, 19 October 2022, 4658c–4695a [4] (Stephen Dawson).

[39] Western Australia, *Parliamentary Debates,* Legislative Council, 18 May 2022, 2402b–2416a [7] (Martin Aldridge).

[40] Western Australia, *Parliamentary Debates,* Legislative Council, 19 October 2022, 4658c–4695a [2] (Stephen Dawson).

difficulties,[41] and no 'legislative mechanism' to effect a whole-of-government response.[42] Further, the Hon Stephen Dawson commented:

> Given that the [CHO] is the main operational authority for the [*PHA*], holistic COVID-19 coordination, management and enforcement by the WA Police Force under the [*EMA*] is preferable so that the [CHO] may focus on underlying public health considerations and individual COVID-19 cases.[43]

One particular limitation in the *PHA* for implementing COVID-related PHSMs that was discussed was the requirement for 24-hour quarantine review.[44] To overcome this limitation the *Public Health Amendment (COVID-19 Response) Act 2020* (WA) ('*PHA Amendment*')[45] introduced 'infectious disease extreme circumstances declarations' ('IDEC-declarations') to allow the CHO to issue quarantine directions without daily review when an IDEC-declaration is in force.[46] Notably, these provisions were not utilised after their enactment as the government continued to implement the quarantine regime under the *EMA*.[47] The continued reliance on the *EMA* appears to have been based on the practicality of police enforcement of PHSMs.

The directions that were issued by the CHO under the *PHA* appear to have been targeted at coordination of the pandemic response and vaccination mandates: for example the Rapid Antigen Test (Restrictions on Sale and Supply) Directions (No 2); the Wastewater COVID testing at WA Laboratories Reporting Directions (No 2); and the Health Worker (Restrictions on Access) Directions (No 4).[48] These PHSMs were not enforced by police.[49]

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[41] Ibid.
[42] Western Australia, *Parliamentary Debates,* Legislative Council, 18 May 2022, 2402b–2416a [15] (Stephen Dawson).
[43] Ibid.
[44] See, eg, Western Australia, *Parliamentary Debates,* Legislative Council, 18 August 2020, 5056c–5073a.
[45] *Public Health Amendment (COVID-19 Response) Act 2020* (WA).
[46] *PHA* (n 6) ss 160(3), 187(3).
[47] See generally Western Australia, *Parliamentary Debates,* Legislative Assembly, 11 August 2020, 4608b–4632a [2], [18]–[20] (Roger Cook).
[48] For a list of directions in force under the *PHA* in March 2022: see Western Australia, *Parliamentary Debates,* Legislative Council, 16 March 2022, 918a–919a (Sue Ellery).
[49] Western Australia, *Parliamentary Debates,* Legislative Council, 18 May 2022, 2402b–2416a [16] (Stephen Dawson).

C *Offences*

At the outset it should be noted that the range of offences associated with the *EMA–PHA* framework do not involve proof of fault on the part of the alleged offender — these are offences which do not require proof of intention, recklessness or negligence. Under the *Criminal Code*, however, s 36 of ch V applies all excuses within that Chapter to 'all persons charged against the statute law of Western Australia'.[50]

Part 8 of the *EMA* concerns offences, all with an associated pecuniary penalty of $50,000.[51] The *Emergency Management Amendment (COVID-19 Response) Act 2020* (WA) sought to 'strengthen' WA's legislative response by amending s 86 and inserting s 70A(6)–(7), which introduced imprisonment as a sentencing option for breach of emergency management directions.[52] Section 86 now provides:

> (1) [a] person given a direction under section 47, 67, 70, 71, 72A or 75(1)(i) must comply with the direction.
>
> Penalty:
>
> (a) Imprisonment for 12 months or a fine of $50,000;
>
> (b) For each separate and further offence committed by the person under the *Interpretation Act 1984* section 71, a fine of $5,000.
>
> (2) a person must comply with a direction referred to in subsection (1) despite the provisions of any other written law, and the person does not commit an offence by reason of that compliance.
>
> (3) it is a defence to a charge of an offence under subsection (1) for the person to prove that the person had a reasonable excuse for failing to comply with the direction.[53]

[50] *Criminal Code* (n 8) s 36.
[51] *EMA* (n 7) ss 85, 86(1)(a), 87–90.
[52] Explanatory Memorandum, Emergency Management Amendment (COVID-19 Response) Bill 2020 (WA) 5.
[53] *EMA* (n 7) s 86 (emphasis added).

Significantly, imprisonment was not until this amendment a penalty under the *EMA*.[54] The stated purpose of the amendment was to 'improve compliance with directions … during an emergency' and to expand sentencing options.[55] These amendments remain in force.

The *PHA* provides for an extensive penalty framework ranging from a fine of $1,000,[56] to a fine of $250,000 *and* imprisonment for 3 years.[57] The most severe penalties relate to serious and material public health risks.[58] These are aimed at deterrence and offer a 'tiered approach' to '[capture] known and emerging risks'.[59] Section 41 provides a list of factors that the court must consider in determining appropriate penalties for these offences, including the degree of risk created; 'practical measures' that could have reduced that risk; foreseeability; and control.[60]

Significantly, it was the penalty of 12 months imprisonment which already existed under s 122 of the *PHA* for breach of personal public health orders that was introduced into the *EMA* to mandate individual PHSMs. As such, it appears that it was intended for the threat of imprisonment to generate compliance. Failure to comply with a direction issued under the *PHA*, for example attending a restricted workplace when unvaccinated, was captured by the offence provisions in ss 202 and 162.

The temporary scheme introduced by the *Emergency Management Amendment (Temporary COVID-19 Provisions) Act 2022* (WA), which amended the *EMA* (with consequential amendments to the *PHA*), was designed to enable the State Emergency Coordinator to make a 3-month COVID-19 declaration. This declaration, once made, would then confer expansive powers on 'authorised COVID-19 officers' for the purposes of COVID-19 management.[61] Relevantly, the offence contained in s 86(1) of the *EMA* was expanded to capture directions

[54] Excluding s 95 of the *EMA*, which involves breach of confidentiality by persons authorised by the act and has an associated penalty of a fine of $12,000 *and* imprisonment for 12 months.
[55] Explanatory Memorandum, Emergency Management Amendment (COVID-19 Response) Bill 2020 (WA) 5.
[56] *PHA* (n 6) s 32(2).
[57] Ibid s 37(1).
[58] Ibid s 4: a 'material public health risk' involves 'potential harm to public health that is neither trivial nor negligible'.
[59] Western Australia, *Parliamentary Debates,* Legislative Council, 3 December 2015, 9401b–9404a [2] (Alyssa Hayden).
[60] *PHA* (n 6) s 41(1).
[61] See generally Explanatory Memorandum, Emergency Management Amendment (Temporary COVID-19 Provisions) Bill 2022 (WA).

issued under those new COVID-19 declaration powers.[62] While this scheme only remained in force for a two year period, it is arguably indicative of the approach to the regulation of future pandemics, one which is likely to be governed almost entirely by the *EMA* provisions and accordingly accompanied by a reliance on punitive measures to manage the associated public health threats.

PART II: A NORMATIVE CRITIQUE OF THE REGULATORY FRAMEWORK

Questions involving the rationale for and philosophical foundations of criminalisation remain some of the most elusive and challenging aspects of criminal law theory. There is a growing recognition in critical scholarship of the theoretical incoherence and fragmented nature of criminal law,[63] its dependence on criminalisation as a social practice,[64] and the pressing need for 'shared conceptual tools and language'[65] to progress scholarship.[66] While we acknowledge the complexity and depth of criminalisation theory, we do not, understandably, attempt in this article to engage broadly with the jurisprudence nor to promote a theory of criminalisation. Rather, our normative inquiry focusses on the harm principle to situate the offences within their jurisprudential landscape for the purposes of subsequent analysis. In doing so, we explore theoretical justifications for the offences as well as the broader systemic issues they raise for the administration of criminal justice, including executive law-making and the possible exacerbation of existing social and economic inequities.

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[62] See especially *EMA* (n 7) ss 77L, 77M(4), 77N, 77O and 77Q.

[63] Simon Bronitt and Bernadette McSherry, *Principles of Criminal Law* (Thomson Reuters, 4th ed, 2017) 90.

[64] Nicola Lacey, 'Theorising Criminalisation Through the Modalities Approach: A Critical Appreciation' (2018) 7(3) *International Journal for Crime, Justice and Social Democracy* 122, 122. See also Celia Wells and Oliver Quick, *Lacey, Wells and Quick: Reconstructing Criminal Law* (Cambridge University Press, 4th ed, 2010) 4.

[65] Luke McNamara et al, 'Theorising Criminalisation: The Value of a Modalities Approach' (2018) 7(3) *International Journal for Crime, Justice and Social Democracy* 91, 92.

[66] Ngaire Naffine, 'Human Agents in Criminal Law and its Scholarship: A Review Essay' (2011) 35(1) *Criminal Law Journal* 51, 53; Nicola Lacey, 'Historicising Criminalisation: Conceptual and Empirical Issues' (2009) 72(6) *Modern Law Review* 936, 956, 960 ('Historicising Criminalisation'). See also Nicola Lacey, 'The Rule of Law and the Political Economy of Criminalisation: An Agenda for Research' (2013) 15(4) *Punishment & Society* 349, 361; McNamara et al (n 65) 92. See also Simon Bronitt, 'Towards a Universal Theory of Criminal Law: Rethinking the Comparative and International Project' (2008) 27(1) *Criminal Justice Ethics* 53, 53.

A *Theoretical Justifications: The Harm Principle and the Criminalisation of Risk*

Arguably the most influential concept shaping philosophical debate on the appropriate contours of criminal law is the harm principle.[67] Derived from John Stuart Mill's *On Liberty*,[68] Mill's original formulation only permits restrictions on individual autonomy to prevent *harm to others*: thereby prohibiting criminalisation on the basis of moral or paternalistic grounds.[69] While harm to others has been supported, modified, and critiqued, the concept does, in its various forms, permeate the literature as central to whether conduct should be criminalised.[70]

Despite its influence, application of the harm principle encounters difficulties that limit its ability to adequately guide and explain criminalisation.[71] Most notably for present purposes, the concept of 'harm' is subjective, culturally dependent, and influenced by 'prevailing [societal] power structures'.[72] It is, therefore, context dependent and challenged by the difficulty of identifying societal values. To account for these limitations, the principle is best viewed 'neither as an ideal nor as an explanation but rather, as an ideological framework in terms of which policy debate about criminal law is expressed'.[73] That view of the principle is consistent with scholarship which has expressed concern with the increasing

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[67] R A Duff et al, *The Boundaries of the Criminal Law* (Oxford University Press, 2010) 23; Wells and Quick (n 64) 9; Hamish Stewart, 'The Limits of the Harm Principle' (2009) 4(1) *Criminal Law and Philosophy* 17, 18.

[68] 'The only purpose for which power can be rightfully exercised over any member of a civilised community, against [their] will, is to prevent harm to others': John Stuart Mill, *On Liberty* (Penguin, 1974) ch 1, par 9. But see Steven Debbaut, 'The Legitimacy of Criminalizing Drugs: Applying the "Harm Principle" of John Stuart Mill to Contemporary Decision-Making' (2022) 68 *International Journal of Law, Crime and Justice* 1, 1–2: other passages in *On Liberty* have sparked debate as to whether Mill supported criminalisation on the basis of 'offence'. As the offence principle primarily concerns affronts to public decency and is therefore not relevant to the offences, which concern risk of harm, it is beyond the scope of this article.

[69] John Stanton-Ife, 'What is the Harm Principle For?' (2014) 10(2) *Criminal Law and Philosophy* 329, 331.

[70] See especially HLA Hart, *Law, Liberty, and Morality* (Stanford University Press, 1963); Patrick Devlin, *The Enforcement of Morals* (Oxford University Press, 1965); Joel Feinberg, *Harm to Others* (Oxford University Press, 1984). For commentary see also Bernard E Harcourt, 'The Collapse of the Harm Principle' (1999) 90(1) *The Journal of Criminal Law & Criminology* 109.

[71] Wells and Quick (n 64) 10.

[72] Historicising Criminalisation (n 66) 940; Andrew Ashworth and Lucia Zedner, *Preventive Justice* (Oxford University Press, 2014) 104. See generally Bernard E Harcourt, 'The Collapse of the Harm Principle' (1999) 90(1) *Journal of Criminal Law & Criminology* 109; Ted Honderich, 'On Liberty and Morality-Dependent Harms' (1982) 30 *Political Studies* 504; Paddy Hillyard et al (eds), *Beyond Criminology: Taking Harm Seriously* (Pluto Press, 2004).

[73] Wells and Quick (n 64) 10.

reliance on criminalisation as a regulatory tool and reflex response to social problems.[74]

Standard application of the harm principle weighs 'the extent and likelihood' of harm to others against the countervailing consequences of criminalisation.[75] In doing so, an analysis focussed on harm reflects the tension between individual and collective interests that underlies the criminal law. The debate in relation to the role of harm as a justification for criminalisation is particularly relevant for an analysis of risk-based offences such as those created pursuant to the *EMA–PHA* framework. As already noted, by criminalising breaches of public health directions the offences operate to criminalise *risk of transmission* of a communicable disease not *transmission* itself. In doing so, they share the preventive rationale of both inchoate and regulatory offences, which pre-emptively criminalise behaviour that risks causing harm.[76] Offences of this kind have proliferated in the anti-terrorism, organised crime and public order spheres.[77] While the precautionary principle is well established in environmental and public health legislation,[78] it remains a contentious basis for criminalisation

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[74] See, eg, Andrew Ashworth, 'Is the Criminal Law a Lost Cause?' (2000) 116(Apr) *Law Quarterly Review* 225; Douglas Husak, *Overcriminalisation* (Oxford University Press, 2007); Victor Tadros, 'Justice and Terrorism' (2007) 10 *New Criminal Law Review* 658; Lucia Zedner, *Security* (Routledge, 2009); Andrew Ashworth and Lucia Zedner, 'Defending the Criminal Law: Reflections on the Changing Character of Crime, Procedure and Sanctions' (2008) 2 *Criminal Law and Philosophy* 21; Lucia Zedner, 'Security, the State and the Citizen: The Changing Architecture of Crime Control' (2010) 13(2) *New Criminal Law Review* 379; Bernadette McSherry, Alan Norrie and Simon Bronitt (eds), *Regulating Deviance: The Redirection of Criminalisation and the Futures of Criminal Law* (Hart Publishing, 2009). But see Jeremy Horder, *Ashworth's Principles of Criminal Law* (Oxford University Press, 9th ed, 2019) 33–4: 'contrary to the impression often given by scholars, penal regulation has always existed in some form. It is not the regulatory aspect but the pre-emptive criminalisation of harmless conduct that is the main concern.'

[75] A P Simester and Andreas von Hirsch, *Crimes, Harms, and Wrongs: On the Principles of Criminalisation* (Hart Publishing, 2011) 45, 55 ('*Crimes, Harms, and Wrongs*').

[76] See Larry Alexander and Kimberly Kessler Ferzan, 'Risk and Inchoate Crimes: Retribution or Prevention?' in G R Sullivan and Ian Dennis (eds), *Seeking Security: Pre-Empting the Commission of Criminal Harms* (Hart Publishing, 2012) 103.

[77] Lucia Zedner, 'Fixing the Future? The Pre-Emptive Turn in Criminal Justice' in Bernadette McSherry, Alan Norrie and Simon Bronitt (eds), *Regulating Deviance: The Redirection of Criminalisation and the Futures of Criminal Law* (Hart Publishing, 2009) 35, 37. In relation to anti-terrorism orders in an Australian context see especially Tim Matthews, 'Under Control, but Out of Proportion: Proportionality in Sentencing for Control Order Violations' (2017) 40(4) *University of New South Wales Law Journal* 1422; Susan Donkin, *Preventing Terrorism and Controlling Risk: A Comparative Analysis of Control Orders in the UK and Australia* (Springer, 2014). See also Bernadette McSherry, Alan Norrie and Simon Bronitt (eds), *Regulating Deviance: The Redirection of Criminalisation and the Futures of Criminal Law* (Hart Publishing, 2009) 5.

[78] Ashworth and Zedner (n 72) 120, discussing Principle 15 of the United Nations Rio Declaration on Environment and Development; Elizabeth Fisher, 'Precaution, Precaution Everywhere: Developing a "Common Understanding" of the Precautionary Principle in the European

given *harm to others* need not eventuate for criminal sanctions to be imposed.[79] These preventive, risk-based regimes necessarily privilege collective interests over the autonomy of individuals.[80] Being concerned with risk, they are also challenged by the uncertainties in quantifying and predicting the harm they seek to prevent and because of this, need to accord with scientific or other expert advice.[81]

Ashworth and Zedner, in their taxonomy of criminal offences which are primarily preventive in nature, include crimes of 'concrete' and 'abstract' endangerment.[82] Endangerment offences expand the harm principle beyond realised harms to include the mitigation of risk.[83] To ensure such expansions are justified, scholars have proposed normative limits on the scale and likelihood of the targeted harm. Simester and von Hirsch argue that the harm principle is easily satisfied where the prohibited conduct creates a genuine risk of immediate harm, as with concrete endangerment.[84] Abstract endangerment is more controversial as the conduct prohibited 'only generates risk if certain contingencies are present'.[85] The offences resemble offences of 'concrete' or 'abstract' endangerment.[86] If an individual receives an isolation direction due to a positive COVID-19 test and breaches that direction, their conduct is criminalised for the 'concrete', 'actual or likely endangerment' of transmission to others. The basis for criminalising breach of a travel-based quarantine order, by way of distinction, is 'abstract endangerment' because the individual's travel history 'creates an unacceptable risk of harm'.

The greater the extent and likelihood of predicted harm, the greater the case for criminalisation.[87] Ashworth and Zedner propose further normative limits to justify endangerment offences, including that such offences must target 'a

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Community' (2002) 9(1) *Maastricht Journal of European and Comparative Law* 7, 9. See also Zedner 'Fixing the Future?' (n 77) 57–8.

[79] Ashworth and Zedner, *Preventive Justice* (n 72) 120. See also Horder (n 74) 34, quoting AP Simester, 'Prophylactic Crimes' in G R Sullivan and Ian Dennis (eds), *Seeking Security: Pre-empting the Commission of Criminal Harms* (2012) 59.

[80] McSherry, Norrie and Bronitt (eds) (n 77) 3. See also R A Duff et al, *The Boundaries of Criminal Law* (Oxford University Press, 2010) 2–3.

[81] Catherine Bennett and Meru Steel, 'Advancing Evidence to Enable Optimal Communicable Disease Control' (2025) 35(2) *Public Health Research and Practice* 1.

[82] Ashworth and Zedner, *Preventive Justice* (n 72) 120.

[83] *Crimes, Harms, and Wrongs* (n 75) 75.

[84] Ibid.

[85] Ibid 76, cited in Horder (n 74) 34.

[86] See Ashworth and Zedner, *Preventive Justice* (n 72) 102; A P Simester and Andrew Von Hirsch, 'Remote Harms and Non-Constitutive Crimes' (2009) 28(1) *Criminal Justice Ethics* 89, 93.

[87] See Ashworth and Zedner, *Preventive Justice* (n 72) 122.

significant risk of serious harm'; and that the creation of risk must also be wrongful 'in the sense that [offenders have] failed to show appropriate concern for the interests of others'.[88]

Reliance on harm as the rationale for criminalisation also, inevitably, raises the concept of proportionality as an associated limit guiding the justifiable use of criminal law.[89] While it is recognised as a central concept in the criminal justice system, the challenges associated with achieving this in practice have long been recognised.[90] It is nonetheless contended that proportionality has particular relevance for the subject of this article in two respects. First, criminalisation must be a proportionate legislative response to an identified "harm";[91] and second, any punishment imposed must be proportionate to the seriousness of the offending conduct.[92] The latter aspect is enshrined in s 6(1) of the *Sentencing Act 1995* (WA) ('*Sentencing Act*')[93] as a key sentencing principle. Jurisprudence further suggests that sentencing must be proportionate to both culpability and gravity of harm caused.[94] This requires that sentences for abstract endangerment are lower than concrete endangerment,[95] and by extension, that risk-based offences receive lower sentences than harm-based offences.

In the height of the COVID-19 pandemic in WA, the State Government aligned itself with health advice that inadequate compliance with PHSMs at that time would have resulted in uncontrolled community transmission, with significant morbidity and mortality falling disproportionately on 'vulnerable'[96] members of

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[88] Ibid 116.

[89] See generally Andrew von Hirsch, 'Proportionality in the Philosophy of Punishment' (1992) 16 *Crime and Justice* 55, 55–56. See also Tim Matthews, 'Under Control, but Out of Proportion' (2017) 40(4) *University of New South Wales Law Journal* 1422, 1429, citing Carol Steiker, 'Proportionality as a Limit on Preventive Justice' in Andrew Ashworth, Lucia Zedner and Patrick Tomlin (eds), *Prevention and the Limits of the Criminal Law* (Oxford University Press, 2013) 194, 195.

[90] See, eg, Joel Goh, 'Proportionality: An Unattainable Ideal in the Criminal Justice System' (2013) 2 *Manchester Review of Law, Crime and Ethics* 41.

[91] See generally Andrew von Hirsch, 'Proportionality in the Philosophy of Punishment' (1992) 16 *Crime and Justice* 55, 55–6; Ashworth and Zedner, *Preventive Justice* (n 72) 86, citing Victor Tadros, 'Controlling Risk' in Andrew Ashworth, Lucia Zedner and Patrick Tomlin (eds), *Prevention and the Limits of the Criminal Law* (Oxford University Press, 2013) 110.

[92] On this distinction see also Sarah J Summers, *Sentencing and Human Rights: The Limits on Punishment* (Oxford University Press, 2023) 91.

[93] *Sentencing Act 1995* (WA) ('*Sentencing Act*').

[94] Bronitt and McSherry (n 63) 18–19, 21. See generally Richard G Fox, 'The Meaning of Proportionality in Sentencing' (1994) 19(3) *Melbourne University Law Review* 489.

[95] Ashworth and Zedner, *Preventive Justice* (n 72) 102.

[96] This term is used to refer to all people at an increased risk of severe illness or complications following infection.

the community;[97] increased pressure on health systems leading to the rationing of resources,[98] disruption of health services and deferred treatment;[99] mental health harms associated with prolonged lockdowns and increased morbidity and mortality rates;[100] increased risk of new, more transmissible, and potentially more virulent, variants of concern;[101] and numerous other, negative, economic and social consequences.[102] In considering the precise harms that the offences sought to prevent or manage, then, those harms included the significant, and potentially catastrophic, direct and indirect harms to the health and welfare of individuals and to the continued functioning of our health system as a whole.

As the offences effectively operated to criminalise usually permissible human behaviour they extensively interfered with ordinary civil and social behaviours. Directions such as quarantine orders greatly restrict socialisation and freedom of movement, conduct at the very heart of the human experience. We note that the nature and extent of their impact on how we live also aligns the offences with scholarship tackling moral questions of when and why the criminal law should be used to regulate human behaviour, over other methods.[103] These observations underpin the analysis that follows of the systemic implications raised by the offences, which we suggest need to be considered to evaluate whether criminalisation in this instance was justified.

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[97] See generally 'Monitoring and Reporting on COVID-19', *Australian Government: Department of Health, Disability and Ageing* (Web Page, 2 November 2025) <https://www.health.gov.au/topics/covid-19/monitoring-and-reporting>.

[98] See, eg, Michelle A Gunn and Fiona J McDonald, 'COVID-19, Rationing and the Right to Health: Can Patients Bring Legal Actions if They Are Denied Access to Care?' (2021) 214(5) *Medical Journal of Australia* 207, 207.

[99] 'COVID-19 and the Social Determinants of Health and Health Equity: Evidence Brief', *World Health Organisation* (Web Page, October 2021) 9 <https://www.who.int/publications/i/item/9789240038387>.

[100] See, eg, Chip Le Grand, 'Melbourne Ground Zero for Lockdown Harms, Says Health Expert' *The Age* (online, 24 September 2022) <https://www.theage.com.au/national/victoria/melbourne-ground-zero-for-lockdown-harms-says-health-expert-20220922-p5bkcc.html>.

[101] World Health Organisation (n 99) v, 13. See also 'Why Does COVID Mutate and Will We See More Variants?', *University of Western Australia* (Web Page, 21 March 2022) <https://www.uwa.edu.au/news/Article/2022/March/Why-does-COVID-mutate-and-will-we-see-more-variants>.

[102] 'Overview of Public Health and Social Measures in the Context of COVID-19: Interim Guidance', *World Health Organisation* (Web Page, 18 May 2020) 1 <https://apps.who.int/iris/bitstream/handle/10665/332115/WHO-2019-nCoV-PHSM_Overview-2020.1-eng.pdf?sequence=1&isAllowed=y>.

[103] See generally *Crimes, Harms, and Wrongs* (n 75) 3.

B *Systemic Implications*

1 *Executive Law-Making*

Given it is the breach of a public health direction that incurs criminal sanction, the offences invoke a two-step criminalisation process that allows the criminal law to intervene and criminalise conduct that, without the pandemic context, would not be criminal. This method of criminalisation is characteristic of many civil preventive orders, often associated with criminalisation that circumvents standard criminal processes that safeguard the rights of the accused. This is because conviction and the imposition of a penalty occurs as an administrative process, absent the involvement of a court or tribunal.[104]

Although providing a flexible response to the fluctuating circumstances of the pandemic brought benefits,[105] one consequence of the two-step structure of the offences is that the question of whether criminalisation is justified depends on the specific nature of the directions themselves. PHSMs significantly curtail individual freedoms, including by restricting movement and positively requiring COVID-testing and mask-wearing, and as such they raise questions of the proportionality of the measures and their necessity in controlling the risk of transmission.[106] While evaluating the directions is beyond the scope of this article and requires interdisciplinary expertise, it is noted here that infringements on individual rights for public health purposes raise questions around the consistency of such instruments with democratic processes.[107]

This method of criminalisation is often associated with the exercise of wide and discretionary executive powers. As noted earlier, the declaration of successive states of emergency in WA (and indeed in other Australian jurisdictions) triggered these powers, enabling the introduction of the various Directions (and related offences).[108] The parliamentary scrutiny which ordinarily accompanies

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[104] Andrew Ashworth, 'Criminal Law, Human Rights and Preventative Justice' in Bernadette McSherry, Alan Norrie and Simon Bronitt (eds), *Regulating Deviance: The Redirection of Criminalisation and the Futures of Criminal Law* (Hart Publishing, 2009) 87, 95, 97; Lucia Zedner, 'Penal Subversions: When is a Punishment Not Punishment, Who Decides and on What Grounds?' (2016) 20(1) *Theoretical Criminology* 3, 11 citing Andrew Ashworth, 'Four Threats to the Presumption of Innocence' (2006) 10(4) *International Journal of Evidence and Proof* 241.

[105] See also Transcript of Proceedings, *Western Australia Police v Burbank* (Magistrates Court of Western Australia, 40621–40623, Magistrate Holgate, 13 October 2021) 20 (Magistrate Holgate) ('*Burbank*').

[106] See Bernadette McSherry, '"Dangerousness" and Public Health' (1998) 23(6) *Alternative Law Journal* 276, 279.

[107] Michael Kirby, 'The Right to Health Fifty Years on: Still Sceptical?' (1999) 4(1) *Health and Human Rights* 6, 16–17.

[108] *EMA* (n 7) pts 5–6; *PHA* (n 6) pt 12.

the introduction of criminal offences was therefore absent,[109] raising distinct concerns around the transparency of decision-making and accountability of governmental action. As the Directions implemented under the *EMA–PHA* framework are examples of delegated legislation, they were made 'without parliamentary enactment'.[110] Moreover, much delegated legislation made in response to the pandemic bypassed the usual avenues that provide proper parliamentary scrutiny.[111] Relatedly the *EMA–PHA* framework authorised the executive to create offences to manage emergencies;[112] the dependence of these offences on 'fast-tracked' delegated legislation accordingly raised related issues of government accountability and concerns that the process was fundamentally flawed.[113] While the Directions were the subject of external scrutiny in the courts,[114] judicial commentary demonstrates considerable deference to public health advice,[115] and supports the executive's precautionary response to the pandemic emergency.[116] Although this deference is appropriate given the need for epidemiology and virology expertise in assessing the legitimacy of the directions, it dilutes the scrutiny provided by the judiciary. The sheer scope conferred by emergency powers contained in the *EMA* and *PHA* further questions the ability of the courts to temper the use of executive power.[117] As transparency

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[109] Tulich and Murray (n 20) 285.
[110] Ibid 309.
[111] Ibid discussing the *Interpretation Act 1984* (WA), pts III–V.
[112] *EMA* (n 7) pt 5; *PHA* (n 6) pts 11–12.
[113] Julie Falck, Jessica Kerr and Marco Rizzi, 'I Sought the Law and the Law Is Gone: Revoked COVID-19 Directions in Western Australia', *Australian Public Law* (Blog Post, 12 May 2023) <https://www.auspublaw.org/blog/2023/5/i-sought-the-law-and-the-law-is-gone-revoked-covid-19-directions-in-western-australia>.
[114] State challenges include: *Falconer v Chief Health Officer* [2022] WASC 3; *Falconer v Commissioner of Police [No 4]* [2022] WASC 271; *Falconer v Chief Health Officer [No 3]* [2022] WASC 270; *Falconer v Chief Health Officer [No 2]* [2022] WASC 29; *Falconer v Commissioner of Police [No 3]* [2022] WASC 30; *Falconer v Commissioner of Police (WA)* [2022] WASCA 157; *Falconer v Commissioner of Police (WA)* [2021] WASC 481. See also, eg, *Palmer v Western Australia* (2021) 95 ALJR 229; *Palmer v Western Australia (No 4)* [2020] FCA 1221; *Newman v Minister for Health and Aged Care* [2021] FCA 517; *Loielo v Giles* [2020] VSC 722. Although not a court but an Ombudsman review, see also Victorian Ombudsman, *Investigation into the Detention and Treatment of Public Housing Residents Arising from a COVID-19 Hard Lockdown* (Report, 17 December 2020).
[115] See especially Transcript of Proceedings, *Western Australia Police v Babbage* (Magistrates Court of Western Australia, 40618–40620, Magistrate Holgate, 13 October 2021) 26 (Magistrate Holgate) ('*Babbage*'). See also, eg, *Palmer v Western Australia* (2021) 95 ALJR 229 [77]–[79] (Kiefel CJ and Keane J).
[116] *Palmer v Western Australia (No 4)* [2020] FCA 1221 [315], [366] (Rangiah J); *Palmer v Western Australia* (2021) 95 ALJR 229 [77] (Kiefel CJ and Keane J), cited in Tulich and Murray (n 20) 314.
[117] See especially *PHA* (n 6) ss 158, 185: these provisions empower authorised officers to enforce directions with reasonable force if necessary, including to effect medical examination, treatment, or vaccination (see ss 158(2)(c), 185(2)(c)).

and accountability engender trust in government action,[118] mechanisms that promote these qualities may improve the overall effectiveness of the *EMA–PHA* framework in generating compliance. To this end it has been suggested that human rights compatibility statements should be explored to strengthen this legislative framework and justification of criminalisation.[119]

2 *Inequality Exacerbation and Stigmatisation: Lessons from HIV*

Infectious diseases generally exacerbate pre-existing inequalities within our society.[120] Given the law's pivotal role in protecting vulnerable people and marginalised groups,[121] any legal response to an infectious disease should mitigate, not aggravate, discriminatory outcomes.

A significant risk associated with criminalisation and the offences was the potential for the regulatory framework to disproportionately impact some members of our community.[122] The HIV experience is a cautionary tale of the risks associated with criminalisation. For 'those vulnerable to HIV, the law is neither abstract nor distant. It is police harassment or clean needles, prison cells or self-help groups — the law is the torturer's fist or the healer's hand.'[123] It is, therefore, important for us to engage with the extensive scholarship on

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[118] See Maria Cucciniello and Greta Nasi, 'Transparency for Trust in Government: How Effective is Formal Transparency?' (2014) 37(13) *International Journal of Public Administration* 911.

[119] Tulich and Murray (n 20) 312–13, quoting Kylie Evans and Nicholas Petrie, 'COVID-19 and The Australian Human Rights Acts' (2020) 45 *Alternative Law Journal* 175.

[120] See, eg, Philip M Alberti, Paula M Lantz and Consuelo H Wilkins, 'Equitable Pandemic Preparedness and Rapid Response: Lessons from COVID-19 for Pandemic Health Equity' (2020) 45(6) *Journal of Health Politics, Policy and Law* 921, 923; Clare Bambra et al, 'The COVID-19 Pandemic and Health Inequalities' (2020) 74 *Journal Epidemiology Community Health* 964, 964. See also, Clare Bambra, Julia Lynch and Katherine E Smith, *The Unequal Pandemic: COVID-19 and Health Inequalities* (Policy Press, 2021) ch 2; Paul D Rutter et al, 'Socio-Economic Disparities in Mortality Due to Pandemic Influenza in England' (2012) 57(4) *International Journal of Public Health* 745.

[121] See, eg, *Convention on the Rights of Persons with Disabilities*, opened for signature 13 December 2006, 2515 UNTS 3 (entered into force 3 May 2008) ('*CRPD*').

[122] See Joseph Lelliott, Andreas Schloenhardt, and Ruby Ioannou, 'Pandemics, Punishment, and Public Health: COVID-19 and Criminal Law in Australia' (2021) 44(1) *University of New South Wales Law Journal* 167, 190, citing '5 Concerns with Australia's Policing During COVID-19', *Amnesty International* (Web Page, 27 April 2020) <https://www.amnesty.org.au/policing-during-covid-19/>; Jarni Blakkarly, 'Concerns Police Using Coronavirus Powers to Target Marginalised Communities in Australia', *SBS News* (online, 12 April 2020) <https://www.sbs.com.au/news/concerns-police-using-coronavirus-powers-to-target-marginalised-communities-in-australia>; Matt Dennien, 'Concerned Human Rights Groups Call for COVID-19 Fine Data', *Brisbane Times* (online, 14 June 2020) <https://www.brisbanetimes.com.au/national/queensland/concerned-human-rights-groups-call-for-covid-19-fine-data-20200608-p550ih.html>.

[123] Global Commission on HIV and the Law, *Risks, Rights & Health* (Final Report, July 2012) 12 <https://hivlawcommission.org/wp-content/uploads/2017/06/FinalReport-RisksRightsHealth-EN.pdf>.

HIV-specific criminalisation ('HIV-criminalisation'), which refers to laws that specifically and expressly target people living with or at risk of HIV and intend to regulate their behaviour.[124] This scholarship has developed in the context of communicable disease control and in this sense is particularly aligned with the concerns raised in relation to the offences under examination.

Because Australia has largely steered away from criminalisation in the HIV context and limited the criminal law to respond to assault-based crimes, much of the contemporary literature relied upon concerns other jurisdictions.[125] The scholarship is, unsurprisingly, focused on criminalisation theories associated with endangerment offences. Notably, the weight of the literature largely falls against criminalising risk behaviours.[126] It is accordingly one site of criminalisation where empirical and theoretical scholarship indicate that the counter-productive and discriminatory consequences of criminalisation significantly outweigh the benefits.[127] While there is a reasonable body of historical scholarship which has expressed support for the criminalisation of HIV in limited circumstances,[128] this article accepts more recent scholarship which points to evidence that the criminalisation of HIV disproportionately impacts already marginalised groups by effectively criminalising behaviour 'legal for others'.[129] In the United States and Canada, there is empirical evidence that

[124] See generally 'Global HIV Criminalisation Database', *HIV Justice Network* (Web Page) <https://www.hivjustice.net/global-hiv-criminalisation-database/>. On the two ways these laws regulate behaviour see especially Joshua D Blecher-Cohen, 'Disability Law and HIV Criminalisation' (2021) 130 *Yale Law Journal* 1560, 1569.

[125] See generally Michael Kirby, 'The Never-Ending Paradoxes of HIV/AIDS and Human Rights' (2004) 4(2) *African Human Rights Law Journal* 163, 168, citing William Bowtell, 'HIV/AIDS: Present at the Creation' (Presentation to the HIV/AIDS, Hepatitis C and Related Diseases Social Research Conference, Sydney, 18 May 2004).

[126] Eric Mykhalovskiy, 'The Public Health Implications of HIV Criminalization: Past, Current, and Future Research Directions' (2015) 25(4) *Critical Public Health* 373, 374.

[127] See generally 'Save Lives: Decriminalise', *UNAIDS* (Web Page) <https://www.unaids.org/en/topic/decriminalization>. See generally Kirby (n 125) 164.

[128] See, eg, Simon H Bronitt, 'Criminal Liability for the Transmission of HIV/AIDS' (1992) 16(2) *Criminal Law Journal* 85; Simon Bronitt, 'Spreading Disease and the Criminal Law' (1994) Jan *Criminal Law Review* 21; Simon Bronitt, 'Controlling Disease and the Criminal Law: A New Regulatory Strategy' in R Smith (ed), *Health Care, Crime and Regulatory Control* (Hawkins Press, 1998) 167.

[129] See, eg, Amy R Baugher et al, 'Black Men Who Have Sex with Men Living in States with HIV Criminalisation Laws Report High Stigma, 23 U.S. Cities, 2017' (2021) 35(10) *AIDS (London)* 1637, 1638.

HIV-criminalisation disproportionately impacts people of colour and African immigrants, likely due to racial bias and increased policing.[130]

Public health and human rights-based concerns emerge from this complex 'medico-legal borderland'[131] including the misaligning of objectives and outcomes of public health and criminal law.[132] HIV-criminalisation, in targeting people living with or at risk of HIV, significantly undermines public health efforts aimed at reducing transmission of the virus.[133] The HIV literature particularly emphasises that the 'blunt'[134] and 'punitive'[135] nature of criminalisation is ill-equipped to regulate the complex issues that arise around disclosure of infection.[136] Relatedly, the stigmatising effects of criminalisation[137] construct a psychological barrier to HIV-testing and treatment initiatives.[138]

More generally, criminal regulation of risk behaviours and the lives of those living with HIV harmfully magnifies existing stigma of the virus itself and those people perceived to be at increased risk of infection.[139] These individuals most frequently

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[130] Trevor Hoppe, Alexander McClelland and Kenneth Pass, 'Beyond Criminalisation: Reconsidering HIV Criminalisation in an Era of Reform' (2022) 17(2) *Current Opinion in HIV & AIDS* 100, 100.

[131] Stefan Timmermans and Jonathan Gabe, 'Introduction: Connecting Criminology and Sociology of Health and Illness' (2002) 24(5) *Sociology of Health & Illness* 501, 506–9, cited in, 'The Public Health Implications of HIV Criminalization: Past, Current, and Future Research Directions' (n 128) 379.

[132] Leslie Pickering Francis and John G Francis, 'Criminalising Health-Related Behaviours Dangerous to Others? Disease Transmission, Transmission-Facilitation, and the Importance of Trust' (2012) 6 *Criminal Law and Philosophy* 47, 48–9.

[133] See, eg, Mykhalovskiy, 'The Public Health Implications of HIV Criminalisation: Past, Current, and Future Research' (n 126) 377.

[134] Ibid 375. See also Pickering Francis and Francis (n 132) 47: these authors also discuss the 'potential misalignment between static criminal law and the changing nature of infectious disease'.

[135] See also Pickering Francis and Francis (n 132) 54.

[136] Mykhalovskiy, 'The Public Health Implications of HIV Criminalization: Past, Current, and Future Research Directions' (n 126) 375.

[137] On the particular relationship between stigma and health see Daniel S Goldberg, 'On Stigma & Health' (2018) 45(4) *Journal of Law, Medicine and Ethics* 475.

[138] See, eg, Daniel Grace, 'Criminalising HIV Transmission Using Model Law: Troubling Best Practice Standardisations in the Global HIV/AIDS Response' (2015) 25(4) *Critical Public Health* 441, 442; Elena Jeffreys, Kane Matthews and Alina Thomas, 'HIV criminalisation and sex work in Australia' (2010) 18(35) *Reproductive Health Matters* 129, 134; Lydia Kapiriri et al, '"…They Should Understand Why…" The Knowledge, Attitudes and Impact of the HIV Criminalisation Law on a Sample of HIV+ Women Living in Ontario' (2016) 11(10) *Global Public Health* 1231, 1231; Amy R Baugher et al (n 129) 1643; Mykhalovskiy, 'The Public Health Implications of HIV Criminalisation: Past, Current, and Future Research' (n 126) 377; Hoppe, McClelland and Pass (n 130) 101.

[139] See Mykhalovskiy, 'The Public Health Implications of HIV Criminalisation: Past, Current, and Future Research' (n 126) 378 and the scholarship cited therein.

include men who have sex with men, injecting drug users, sex workers, and some immigrants.[140] While COVID-19 did not emerge in quite the same way, epidemics and pandemics have a long history of generating xenophobic attitudes.[141] In relation to COVID-19, attempts were made to address this issue in the public health space, through a deliberate decision to take away the geographic origin of the SARS-CoV-2 virus;[142] and to focus on care-driven messaging and education.[143]

It is also worth noting that HIV-related stigma has been, and continues to be exacerbated by, often 'gendered and racialized' media reports that portray HIV-positive defendants as hypersexual, blameworthy predators.[144] Although

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[140] Pierre Somse and Patrick M Eba, 'Lessons from HIV to Guide COVID-19 Responses in the Central African Republic' (2022) 22(1) *Health and Human Rights* 371, 371, citing G M Herek, 'Thinking About AIDS and Stigma: A Psychologist's Perspective' (2003) 30(4) *Journal of Law, Medicine & Ethics* 594.

[141] See, eg, Carmen H Logie and Janet M Turan, 'How Do We Balance Tensions Between COVID-19 Public Health Responses and Stigma Mitigation? Learning from HIV Research' (2020) 24(7) *AIDS and Behaviour* 2003, 2003.

[142] See especially *World Health Organisation,* 'WHO Director-General's Remarks at the Media Briefing on 2019-nCoV on 11 February 2020' (Web Page, 11 February 2020) <https://www.who.int/director-general/speeches/detail/who-director-general-s-remarks-at-the-media-briefing-on-2019-ncov-on-11-february-2020>. See also Marietta Vazquez 'Calling COVID-19 the "Wuhan Virus" or "China Virus" is Inaccurate and Xenophobic', *Yale School of Medicine* (Web Page, 12 March 2020) <https://medicine.yale.edu/news-article/calling-covid-19-the-wuhan-virus-or-china-virus-is-inaccurate-and-xenophobic/>; Mari Webel, 'Calling COVID-19 a 'Chinese Virus' is Wrong and Dangerous — The Pandemic is Global' *The Conversation* (online, 25 March 2020) <https://theconversation.com/calling-covid-19-a-chinese-virus-is-wrong-and-dangerous-the-pandemic-is-global-134307>.

[143] Australian Council of Human Rights Authorities, 'Australian Council of Human Rights Authorities Statement' (Media Release, Equal Opportunity Commission, 16 September 2020) <https://www.wa.gov.au/government/announcements/australian-council-of-human-rights-authorities-statement>; Logie and Turan (n 141) 2004. For COVID-related examples of "care-driven" messaging see, eg, World Health Organisation's 'Small acts save lives' comics: who, 'Keep your distance' (Instagram, 26 December 2022) <https://www.instagram.com/p/CmoTJJuj39n/?igshid=YmMyMTA2M2Y=>; who, 'Wear a mask' (Instagram, 27 December 2022) <https://www.instagram.com/p/Cmqrw4_D5n_/?igshid=YmMyMTA2M2Y=>; who, 'Cover up a cough or sneeze' (Instagram, 29 December 2022) <https://www.instagram.com/p/CmudpS4DAYU/?igshid=YmMyMTA2M2Y=>; who, 'Protect yourself today' (Instagram, 30 December 2022) <https://www.instagram.com/p/Cmw6g0PDw7C/?igshid=YmMyMTA2M2Y=>; who, 'Open a window' (Instagram, 3 January 2023) <https://www.instagram.com/p/Cm69gosDxjG/?igshid=YmMyMTA2M2Y=>; who, 'Wash your hands' (Instagram, 4 January 2023) <https://www.instagram.com/p/Cm-EtFkDvod/?igshid=YmMyMTA2M2Y=>.

[144] Hoppe, McClelland and Pass (n 130) 102, citing Jennifer M Kilty and Katarina Bogosavljevic, 'Emotional Storytelling: Sensational Media and the Creation of the HIV Sexual Predator' (2019) 15(2) *Crime, Media, Culture* 279. See, eg, Colin Hastings et al, 'Prairie Fantasy and Constructing Racial Otherness: An Analysis of News Media Coverage of Trevis Smith's Criminal Non-Disclosure Case' (2020) 45(1) *Canadian Journal of Sociology* 22; Eric Mykhalovskiy et al, 'Explicitly Racialised and Extraordinarily Over-represented: Black Immigrant Men in 25 Years of News Reports on HIV Non-disclosure Criminal Cases in Canada' (2021) 23(6) *Culture, Health and Sexuality* 788; Jenny Roth and Chris Sanders, '"Incorrigible Slag," the Case of Jennifer Murphy's HIV Non-Disclosure:

constructions of "otherness"[145] were not as obviously apparent in press coverage of the offences analysed,[146] there were instances of racial abuse following media reports of border breaches in other jurisdictions.[147] What remains clear is that the stigmatising effects of criminalisation cannot be overlooked, and must be proactively addressed by government, communities and individuals.[148] It is also important to recognise that communicable diseases can be associated with stigma in and of themselves;[149] HIV-related stigma is arguably entwined with the stigma already faced by marginalised groups.

While these difficulties associated with HIV-criminalisation reveal the need for flexibility in legislative pandemic responses, their connection to mode of transmission, length of incubation period, and nature of infection should also be acknowledged. In contrast to COVID-19, an acute respiratory virus, HIV is a chronic infection transmitted by direct contact with specific bodily fluids and also perinatally.[150] As such, HIV risk behaviours are limited, usually involving private,

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Gender Norm Policing and the Production of Gender-Class-Race Categories in Canadian News Coverage' (2018) 68 *Women's Studies International Forum* 113. For an Australian example see Elena Jeffreys, Kane Matthews and Alina Thomas (n 138) 130–1.

[145] Logie and Turan (n 141) 2003: 'Blaming a foreign other for epidemics is commonplace throughout history'; to conceptualise illness in this way harmfully and unproductively, promulgates fear and xenophobia.

[146] See, eg, Heather McNeill, Lucy Manly and Gary Adshead, 'Demons fans charged in WA after illegally entering state for AFL grant final' *WAtoday* (online, 28 September 2021) <https://www.watoday.com.au/national/western-australia/melbourne-demon-fans-arrested-in-regional-wa-after-sneaking-into-state-to-attend-grand-final-20210928-p58vhe.html>. Also note that none of the offenders had COVID-19.

[147] See Lelliott, Schloenhardt, and Ioannou (n 122) 191, discussing Jessica Marszalek, 'Enemies of the State', *The Courier Mail* (Brisbane, 30 July 2020) 1; Queensland Human Rights Commission, 'Commission Urges Focus on Safety, Not Scapegoating' (Press Release, 30 July 2020) <https://www.qhrc.qld.gov.au/__data/assets/pdf_file/0020/27434/2020.07.30-Media-statement-re-new-Queensland-COVID-cases.pdf>; Ahmed Yussuf, 'Media Reporting of Two Queensland Teens: "A Form of Doxxing"', *SBS News* (online, 31 July 2020) <https://www.sbs.com.au/news/the-feed/article/media-reporting-of-two-queensland-teens-a-form-of-doxxing/y9fq5mgtk>.

[148] On the importance of community led action see generally Winnie Byanyima, Karl Lauterback and Matthew M Kavanagh, 'Community Pandemic Response: The Importance of Action led by Communities and the Public Sector' (2022) 401(10373) *The Lancet (British edition)* 253.

[149] See generally Joan L Williams, Diego J Gonzalez-Medina and Quan Vu Le, 'Infectious Diseases and Social Stigma' (2011) 7 *Medical and Health Science Journal* 2.

[150] 'Coronavirus disease (COVID-19): How is it transmitted?', *World Health Organisation* (Web Page, 23 December 2021) <https://www.who.int/news-room/questions-and-answers/item/coronavirus-disease-covid-19-how-is-it-transmitted>. 'Global HIV Programme: Mother-to-child transmission of HIV', *World Health Organisation* (Web Page) <https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/prevention/mother-to-child-transmission-of-hiv>. Perinatal transmission is also known as 'mother-to-child' or 'vertical' transmission.

human-to-human interactions entwined with issues of consent and disclosure.[151] The offences, although targeting various social behaviours, were most concerned with an individual's interaction with the wider public for a limited period of time, either while infectious or when in quarantine.[152] These virological differences are significant because the reasons why criminalisation is ineffective in reducing HIV-transmission do not necessarily translate to the COVID-19 pandemic.

A study of 90 reports of people's experiences of COVID-related policing throughout Australia in 2020 confirmed that these disproportionate impacts manifested during the pandemic. In that study, the authors identified that people's experiences of this policing were influenced by their 'race, age, gender, disability or illness'.[153] We argue that the offences raised concerns in relation to three particular categories: people who were disproportionately impacted by PHSMs; people who were more likely to be exposed to COVID-19 and therefore, more frequently subject to isolation and quarantine requirements;[154] and people who were at increased risk of severe illness and complications from COVID-19. There are numerous vulnerable populations upon which PHSMs placed a disproportionate burden, including, but not limited, to people experiencing homelessness, family violence, disability, drug or alcohol dependencies, and mental illness.[155] People from low socio-economic and culturally and linguistically diverse ('CaLD') backgrounds may additionally have been at increased risk of infection due to overcrowded housing and employment in

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[151] See generally Kirby (n 125) 164. On the intersection of consent and disclosure see Wells and Quick (n 64) 256-257, citing Andrew Ashworth, *Principles of Criminal Law* (Oxford University Press, 5th ed, 2006) 319. Also on the complexities of consent consider people living with HIV who may be vulnerable to circumstances of coercion and intimate partner violence: Pickering Francis and Francis (n 132) 49; Grace (n 138) 442; Scott Burris and Edwin Cameron, 'The Case Against Criminalization of HIV Transmission' (2008) 300(5) *Journal of the American Medical Association* 578, 580. Pragna Patel et al, 'Estimating Per-Act HIV Transmission Risk: A Systematic Review' (2014) 28(10) *AIDS* 1509, 1513–16.

[152] All cases except for Transcript of Proceedings, *Western Australia Police v Parihar* (Magistrates Court of Western Australia, 853–4, Chief Magistrate Heath, 27 April 2022) ('*Parihar*') involved interstate travel-based quarantine breaches.

[153] Vicki Sentas and Louise Boon-Kuo, 'People's Experiences of Pandemic Policing: Why Criminalisation is Bad for the Social Determinants of Health', (2023) 46(4) *University of New South Wales Law Journal* 1356, 1375.

[154] Isolation separates people with an infectious disease from the community, whereas quarantine 'separates and restricts the movement of people who were exposed to a contagious disease' in case they were infected: US Centres for Disease Control and Prevention, 'Port Health' *Centres for Disease Control and Prevention* (Web Page) <https://www.cdc.gov/port-health/about/?CDC_AAref_Val=https://www.cdc.gov/quarantine/quarantineisolation.html>.

[155] For a more detailed list see National COVID-19 Health and Research Advisory Committee, *Mental Health Impacts of Quarantine and Self-Isolation* (Report, 19 May 2020) 9.

service professions.[156] It must be recognised that for some individuals, particularly those experiencing mental illness and abuse, the threat of criminal sanctions may well have harmfully intensified their distress more than other measures of social regulation.[157]

Although the abovementioned unequal impacts are not necessarily reflected in the cases analysed in the next part of this article, there is evidence of discriminatory enforcement in other jurisdictions. Both the "hard lockdown" of the Public Housing Towers in Melbourne and the highly visible police presence in Fairfield LGA in Sydney disproportionally impacted people from low socio-economic and CaLD backgrounds.[158] Data on fines issued during Melbourne's first lockdown similarly suggested an over-policing of Aboriginal and Torres Strait Islander peoples and migrant Australians.[159] A Victorian Parliamentary inquiry in 2021 confirmed that people from lower socio-economic areas in Victoria were disproportionately fined by police for COVID-related breaches during this time.[160] A more recent study has found that the imposition of COVID fines was influenced by racial profiling.[161] While the issue of on-the-spot fines in WA by police has not been scrutinised, one observation of the WA approach is that PHSMs were primarily aimed at interstate travellers and it was, therefore, people voluntarily entering the state who were policed rather than the WA resident community.

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[156] See also George Williams and Sophie Rigney, 'Human Rights in a Pandemic' in Belinda Bennett and Ian Freckelton (eds), *Pandemics, Public Health Emergencies and Government Powers: Perspectives on Australian Law* (The Federation Press, 2021) 134–149, 142, citing Aryati Yashadhana et al, 'Indigenous Australians at Increased Risk of COVID-19 due to Existing Health and Socioeconomic Inequities' (2020) 1 *The Lancet Regional Health — Western Pacific* 100007, 100007.

[157] See, eg, UNAIDS, *Rights in the Time of COVID-19: Lessons from HIV for an Effective, Community-Led Response* (Report, 20 March 2020) 9.

[158] See, eg, Osman Faruqui, 'As Police Enforce COVID-19 Health Orders, a Disproportionate Number of Fines Have Been Issued in Areas Largely Populated by Indigenous or Migrant Australians', *The Saturday Paper* (online, 18 April 2020) <https://www.thesaturdaypaper.com.au/news/health/2020/04/18/compliance-fines-under-the-microscope/15871320009710#hrd>: noting the drastically different approach to fines in the Northern Beaches and Waverley; Duc Dau and Katie Ellis, 'From Bondi to Fairfield: NSW COVID-19 press conferences, health messaging, and social inequality' (2022) 188(1) *Media International Australia* 12.

[159] Williams and Rigney (n 156) 145, citing J Taylor, 'Sudanese and Aboriginal People Overrepresented in Fines from Victoria Police During First Lockdown', *The Guardian* (online, 28 September 2020) <https://www.theguardian.com/australia-news/2020/sep/28/sudanese-and-aboriginal-people-overrepresented-in-fines-from-victoria-police-during-first-lockdown>.

[160] Public Accounts and Estimates Committee, Parliament of Victoria, *Inquiry into the Victorian Government's Response to the COVID-19 Pandemic* (Parliamentary Paper No 203, February 2021) 266-7.

[161] Tamar Hopkins and Gordana Popovic, *Policing COVID-19 in Victoria: Exploring the Impact of Perceived Race in the Issuing of COVID-19 Fines during 2020* (Report, 2023).

Since pecuniary penalties are intrinsically more burdensome on people in low socio-economic circumstances,[162] the policing of these offences needs to be reviewed to ensure that, in future public health emergencies, police enforcement does not penalise disadvantage and desperation, but rather targets deliberate wrongdoing.[163]

As 'trust and equity'[164] are evidenced to be factors which greatly contribute to the efficacy of public health responses, it is critical that, going forward, over-policing and discrimination are not just minimised but actively avoided.[165] Indeed, it has been argued that many of the police actions during the height of the pandemic 'sabotaged public health by criminalising health-positive behaviour'[166] and that in this respect 'pandemic policing has demonstrated it is incapable of preserving public health'.[167]

In addition to mitigating the discriminatory effects detailed above, the law has an integral role in supporting the welfare of those at increased risk of serious illness and complications from COVID-19. Australia has obligations under international law to respect 'the dignity, autonomy and liberty' of all persons.[168] Out of the 14 treaties of which Australia is a party, the *Convention on the Rights of Persons with Disabilities*[169] is especially emblematic of the role of the law in supporting those considered "vulnerable".[170] While human rights protections in Australia are complex and difficult to enforce, particularly given the absence of national human rights guarantees, it is submitted that legal responses should fulfil human rights

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[162] Gaye Lansdell et al, 'Infringement Systems in Australia: A Precarious Blurring of Civil and Criminal Sanctions?' (2012) 37(1) *Alternative Law Journal* 41, 41. See generally Andrew Ashworth, *Sentencing and Criminal Justice* (Cambridge University Press, 5th ed, 2010) 240–59 for an overview and discussion of equality before the law issues that arise in sentencing.

[163] See, eg, the cases concerning breaches associated with attendance at Australian Rules Football ('AFL') games.

[164] Winnie Byanyima, Karl Lauterback and Matthew M Kavanagh, 'Community Pandemic Response: The Importance of Action led by Communities and the Public Sector' (2022) 401(10373) *The Lancet (British edition)* 253, 253.

[165] Pickering Francis and Francis (n 132) 48.

[166] Sentas and Boon-Kuo (n 153) 1356.

[167] Ibid 1384.

[168] See Belinda Bennett et al, 'Australian Law During COVID-19: Meeting the Needs of Older Australians?' (2022) 41(2) *University of Queensland Law Journal* 127, 137.

[169] *CRPD* (n 121).

[170] See also Bennett et al (n 168) 137. But see 133, citing Majse Lind, Susan Bluck, and Dan P McAdams, 'More Vulnerable? The Life Story Approach Highlights Older People's Potential for Strength during the Pandemic' (2021) 76(2) *Journals of Gerontology: Psychological Sciences* 45: these commentators recognise the negative connotations associated with "vulnerability" that undermine the resilience and 'psychosocial strength' of older members of the community and generate ageist attitudes.

obligations and operate consistently with anti-discrimination legislation.[171] People at increased risk of serious illness and complications from COVID-19 include older persons, people with some disabilities, immune deficiencies, chronic illnesses and co-morbidities, those receiving immunosuppressive therapies, and Indigenous populations.[172]

It is important to emphasise that many of these individuals are also impacted by discrimination and stigmatisation as discussed above. For example, many older persons and people with disabilities experienced prolonged isolation; disruption to essential care services; and increased social stigma, ageism and ableism as a result of PHSMs.[173] They were and remain at increased risk of exposure to COVID-19 due to a reliance on care services and physical difficulties with implementing some PHSMs.[174] It has also been observed that:[175]

> While the COVID-19 pandemic was associated with increased severe disease and mortality amongst older persons with COVID-19, the pandemic was also characterized by increased ageism, negative stereotypes of older persons, and a devaluing of the lives of older persons …

The difficulties experienced by older people, particularly those in aged care facilities, also demonstrated the fragility of the health system, and speak to the risk which the pandemic posed to its fundamental integrity, one that has been identified and discussed in recent scholarship.[176] The evidence and scholarship presents a 'complex picture of risk for older persons [and other vulnerable groups], comprising the physical risk of severe disease, the risks of [and associated with] social isolation, and the risks of ageism [and other forms of discrimination]'.[177] Given this complexity, fashioning a supportive rather than

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[171] See especially the *Age Discrimination Act 2004* (Cth) s 10(7); *Disability Discrimination Act 2004* (Cth) s 12(8); *Equal Opportunity Act 1984* (WA) ss 66A, 66V.
[172] Williams and Rigney (n 156) 134–49.
[173] Ivanka Antova, 'Disability Rights During COVID-19: Emergency Law and Guidelines England' (2020) 28(4) *Medical Law Review* 804, 805, discussing A Ruddock and A Gkiouleka, 'I Feel Forgotten: The Impact of COVID-19 on People with Chronic Illness' (online, 2020) <https://citizen-network.org/library/i-feel-forgotten.html>. See also UN News, 'Preventing Discrimination Against People with Disabilities in COVID-19 Response' (online, 2020) <https://news.un.org/en/story/2020/03/1059762>.
[174] See also Ivanka Antova, 'Disability Rights During COVID-19: Emergency Law and Guidelines England' (2020) 28(4) *Medical Law Review* 804.
[175] Belinda Bennett, Ian Freckelton and Gabrielle Wolf, *COVID-19 Law & Regulation: Rights, Freedoms, and Obligations in a Pandemic* (Oxford University Press, 2023) 284.
[176] Stephen Bottomley and Simon Bronitt, *Law in Context* (Federation Press, 5th ed, 2023) 356.
[177] Bennett et al (n 168) 133.

discriminatory role for the law involves a thorough balancing exercise of the interests that different individuals in society have in their health and freedoms.[178]

PART III: THE CASE LAW AND APPROACHES TO SENTENCING

The next section of the article moves to examine the way in which the offences have been approached by the courts. It examines judicial commentary on the relevance of the pandemic context to the criminalisation of the conduct in question and the exercise of sentencing discretion as a further dimension of our critique of the offences. Several key themes identified in the canvassing of the relevant cases are now explored.

A *Compliance with Fundamental Sentencing Principles*

The language and outcomes of appeal decisions convey the importance of fundamental sentencing principles and warn that the circumstances of the pandemic must not override their consistent application. In *Johnson v Vander Sanden* ('*Johnson*'),[179] the Full Court of Appeal held:

> [T]he sentencing of persons under the [*EMA*], in times of emergency such as the COVID-19 pandemic, does not involve some special category of case in which the law is to be applied differently than in other times. The rule of law remains unaffected and the fundamental principles of the criminal law continue unaltered.[180]

In upholding the decision of Hill J in *Vander Sanden v Johnson* ('*Vander Sanden*'),[181] the Court emphasised imprisonment as a penalty of last resort despite the public interest underlying the directions.[182] Similarly in *RDS v Luplau* ('*RDS*'),[183] McGrath J emphasised the universal application of both principles, having stated that they 'have application to all offences *including* offences under the [*EMA*]'.[184] Both Hill and McGrath JJ held that the sentences in question were 'manifestly

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[178] See, eg, *Universal Declaration of Human Rights,* GA Res 217A (III), UN GAOR, UN Doc A/810 (10 December 1948) art 1; *International Covenant on Civil and Political Rights*, opened for signature 16 December 1966, 999 UNTS 171 (entered into force 23 March 1976) art 4(1), 4(2), 6.
[179] [2021] WASCA 27; (2021) 57 WAR 209 ('*Johnson*').
[180] Ibid [3] (Quinlan CJ, Buss P and Mazza JA), quoted in *Tonkin v Busby* [2021] WASC 61 [35] (Allanson J) ('*Tonkin*'); Transcript of Proceedings, *Western Australia Police v Cox* (Magistrates Court of Western Australia, 40528–40530, Magistrate Harries, 25 October 2021) 12 ('*Cox*'), discussed *Babbage* (n 115) 26.
[181] See *Vander Sanden v Johnson* [2020] WASC 331 ('*Vander Sanden*').
[182] *Johnson* (n 179) [4] (Quinlan CJ, Buss P and Mazza JA), discussing *Sentencing Act* (n 93) ss 6(4), 39(3). See also *Dinsdale v The Queen* (2000) 202 CLR 321, 328 [14] (Gleeson CJ and Hayne J) ('*Dinsdale'*).
[183] [2021] WASC 280 ('*RDS*').
[184] Ibid [78] (McGrath J) (emphasis added).

excessive',[185] and resentenced the appellants to a 6-month community-based order and a $1000 fine, respectively. Importantly, in *Vander Sanden*, it was the learned magistrate's failure to consider suspension that was found to be in error.[186] Hill J considered a partly or wholly suspended sentence would have been appropriate. A community-based order was only imposed due to time spent in custody and 'should not … ordinarily be imposed for an offence … where the offender has avoided the quarantine regime'.[187]

Arguably a "trend" of reduced sentences on appeal highlights the risk for the pandemic context and public interest underlying the offences to result in harsher penalties than ordinarily appropriate.[188] In *Tonkin v Busby* ('*Tonkin*'),[189] Allanson J overturned a sentence of 7 months imprisonment, 5 months suspended, again on grounds of excessiveness.[190] The magistrate's comments indicate an attitude that the need to communicate 'to the community that [PHSMs] must be adhered to'[191] warranted a custodial sentence.[192] While not necessarily representative of sentencing practices more broadly, it is an example of where the pursuit of general deterrence was found to have generated a disproportionate sentence.

More recently, in the Tasmanian case of *Gunn v Reardon and Rogers*,[193] the Court referenced the Western Australian decisions, noting that 'the facts on each of the cases decided in that jurisdiction all differ greatly from one another'. The magistrate in that case, in dealing with a breach of public health directions in entering Tasmania in circumstances where the applicant had provided false information in knowingly breaching the directions stated that '[t]he instant case lacks the mitigation and reasons for sympathy and leniency present in most of these cases, including those that, somewhat surprisingly, were dealt with quite

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[185] 'A sentence may be excessive 'because the wrong type of sentence has been imposed (for example, custodial rather than non-custodial) or because the sentence imposed is manifestly too long': *Tonkin* (n 180) [57], citing *Dinsdale* (n 182) [6].
[186] *Johnson* (n 179) [5] (Quinlan CJ, Buss P and Mazza JA).
[187] *Vander Sanden* (n 181) [65] (Hill J).
[188] For example, *AAN v Butterfield* [2021] WASC 228 ('*AAN*'); *Tonkin* (n 180); *RDS* (n 182). But see *AAN* (n 188) [28]–[31] (Tottle J): although the initial sentence of 7 months, 5 months suspended, was not expressly found to be manifestly excessive, Tottle J found that a more lenient sentence was appropriate.
[189] *Tonkin* (n 180).
[190] Ibid [76] (Allanson J).
[191] Ibid [28] (Allanson J), quoting ts 5.
[192] Ibid [76] (Allanson J): '[t]he sentencing magistrate expressly found that imprisonment was the only appropriate sentence'.
[193] [2022] TASSC 10.

harshly'.[194] The original sentence for the offences — a term of imprisonment of five months with two months suspended — was upheld by the Supreme Court, which found that sentence to be well within the magistrate's discretion and that '[c]ompletely irrespective of the applicant ultimately testing positive to COVID-19, the sentence was justified on grounds of general deterrence and denunciation'.[195]

This sentence has not been appealed, but, by way of contextualisation, the conduct of the applicant involved a level of determination to breach the directions, involving deceit, and which necessitated a significant effort in contact tracing and the imposition of a three-day lockdown in southern Tasmania.

B *The Pandemic Context*

Notwithstanding the maintenance of the fundamental principles referenced above, the pandemic context informed the courts' approach to sentencing with respect to the prioritisation of sentencing aims, along with the view of the relative seriousness of the offending conduct. It is important to note at this juncture that the vast majority of prosecutions occurred at the summary level, with the superior courts only involved in the occasional appeal. The implications of hearings at the summary level have been the subject of critique, notably in connection with the 'ideology of triviality' associated with summary level proceedings.[196] Exploration of the specific ramifications in relation to the offences are beyond the scope of this article but this point is noted as a characteristic of the pattern of prosecution.

The case law indicates that judicial consideration of the purpose of the directions to limit transmission, the public interest in uniform compliance, and the role of these offences in generating compliance gave weight to a prioritisation of deterrence.[197] As Hall J stated in *Phillips v Wroe* ('*Phillips*'):[198]

> Offences against the [*EMA*] of failing to comply with directions must be seen in light of the context in which they occur. Where directions are given, as here, in the context of a pandemic, public safety depends

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[194] Ibid [55].
[195] Ibid [87]. Note Bennett, Freckelton and Wolf (n 175) 458 where the authors note that in Germany the sentence imposed was harsher where a person's violation of quarantine resulted in someone else being infected.
[196] Doreen McBarnet, 'Magistrate's Courts and the Ideology of Justice' (1981) 8(2) *British Journal of Law and Society* 181, 189.
[197] *Burbank* (n 105) 19–20; *Vander Sanden* (n 181) [39] (Hill J).
[198] [2022] WASC 48 ('*Phillips*').

> upon uniform compliance. Personal and general deterrence is a significant factor in sentencing for such offences.[199]

This prioritisation of deterrence is consistent with all cases citing personal and general deterrence as important sentencing considerations.[200] Personal circumstances, 'although not irrelevant', were accordingly given less weight.[201]

Secondly, the ever-evolving circumstances of the pandemic provided the context within which seriousness was assessed.[202] In *Western Australia Police v Burbank* ('*Burbank*'),[203] circulation of the more virulent Delta Variant of Concern ('VOC') elevated the risk of the defendant's conduct and aggravated the seriousness of the offence.[204] Magistrate Holgate also considered that the emergence and circulation of the Delta VOC distinguished the cases in which breaches had occurred in the context of attendance at Australian Rules Football ('AFL') games from earlier appeal decisions.[205] Similarly, in *Western Australia Police v Parihar* ('*Parihar*'),[206] Chief Magistrate Heath discussed the circumstances that had led to the introduction of the breached directions, particularly the Mess Hall cluster and resulting concern that cases were circulating in the community.[207] These circumstances increased *both* risk of harm and culpability, as the defendant's knowledge of the local outbreak, coupled with his failure to act, knowingly risked creating a "super-spreader" event.[208]

The court assesses seriousness in light of aggravating and mitigating factors.[209] The cases, therefore, provide insight into the influence of specific factual

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[199] *Phillips* (n 198) [43] (Hall J).
[200] *Vander Sanden* (n 181) [42] (Hill J); *RDS* (n 182) [66] (McGrath J); *Tonkin* (n 180) [74] (Allanson J); *Babbage* (n 115) 25 (Magistrate Holgate).
[201] *Tonkin* (n 180) [53] (Allanson J).
[202] *AAN* (n 188) [35] (Tottle J).
[203] *Burbank* (n 105).
[204] Ibid 19–20 (Magistrate Holgate). See also *Cox* (n 180) 9 (Magistrate Harries).
[205] *Burbank* (n 105) 20 (Magistrate Holgate). See also *Babbage* (n 115) 25, 27 (Magistrate Holgate).
[206] *Parihar* (n 152).
[207] Ibid 6 (Chief Magistrate Heath). See, eg, Charlotte Elton, 'COVID-19 WA: Woman charged after allegedly travelling to South West after Perth Mess Hall rave', *PerthNow* (online, 25 December 2021) <https://www.perthnow.com.au/news/coronavirus/covid-19-wa-woman-charged-after-allegedly-travelling-to-south-west-after-perth-mess-hall-rave-c-5082968>; Jessica Warriner, 'Two new WA COVID-19 cases in Perth outbreak as Mark McGowan warns close contacts unlikely to be found', *ABC News* (online, 29 December 2021) <https://www.abc.net.au/news/2021-12-29/two-new-local-covid-19-cases-recorded-in-wa-outbreak/100729632>; Department of Health (WA), 'COVID-19 update 26 December 2021' (Media Release, 26 December 2021).
[208] *Parihar* (n 152) 6 (Chief Magistrate Heath).
[209] *Phillips* (n 198) [37] (Hall J); *RDS* (n 182) [57] (McGrath J), discussing ss 6(1) and 6(2) of the *Sentencing Act* (n 93).

circumstances on sentencing outcomes. Hall J outlined factors considered in the proceeding appeal decisions as follows: 'the degree of risk of the offender introducing this disease in [WA], whether deception was involved … the extent to which the offender sought to avoid the quarantine regime and the extent to which the offender complied with the regime'.[210] While these factors are interconnected and wide-ranging, ultimately, the courts considered factual circumstances that increased *risk of transmission* and *culpability*.

Risk-relevant factual circumstances identified in the cases included vaccination;[211] mask-wearing;[212] state or territory travelled from;[213] timing and result of COVID-19 tests;[214] duration of offending conduct;[215] and degree of public exposure.[216] Judicial consideration of these factors provides insight into the court's interpretation of the purpose and scope of the offences. For example, the fact that testing negative after committing the offence was not a mitigating factor indicates that these offences only targeted the creation of risk. As Hill J in *Vander Sanden* wrote:

> [T]he Directions seek to address the *risk* of COVID-19 being reintroduced into [WA], and how this risk can best be managed. The Directions are not solely aimed at the management of people who have the virus.[217]

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[210] *Phillips* (n 198) [47] (Hall J).

[211] Ibid [45] (Hall J); *Cox* (n 180) 10 (Magistrate Harries); *Babbage* (n 115) 26 (Magistrate Holgate); *Burbank* (n 105) 19, 22 (Magistrate Holgate). Although vaccination is mentioned as a relevant consideration, it is unclear how much weight it is given, particularly as no cases involved wholly unvaccinated offenders. Further, in *Cox,* vaccination appears to be considered as a factor that mitigates risk, whilst one dose only reduces risk minimally: *Cox* (n 180) 6 (T M Andrews), 10 (Magistrate Harries).

[212] *Phillips* (n 198) [45] (Hall J).

[213] Ibid; *Vander Sanden* (n 181) [41] (Hill J); *Babbage* (n 115) 25 (Magistrate Holgate); *Burbank* (n 105) 22 (Magistrate Holgate); *Cox* (n 180) 9 (Magistrate Harries).

[214] *Vander Sanden* (n 181) [46] (Hill J); *Babbage* (n 115) 26 (Magistrate Holgate); *Burbank* (n 105) 19, 22 (Magistrate Holgate); *Cox* (n 180) 9, 14 (Magistrate Harries); *Tonkin* (n 180) [27]–[29], [71], [76] (Allanson J).

[215] *Phillips* (n 198) [38], [44] (Hall J); *Tonkin* (n 180) [72] (Allanson J).

[216] *Vander Sanden* (n 181) [45] (Hill J); *Babbage* (n 115) 26, 28 (Magistrate Holgate); *Burbank* (n 105) 21, 23–4 (Magistrate Holgate); *Cox* (n 180) 9 (Magistrate Harries); *Phillips* (n 198) [45] (Hall J).

[217] *Vander Sanden* (n 181) [46] (Hill J), quoted in *Tonkin* (n 180) [28] (Allanson J) (original emphasis). See also *Burbank* (n 105) [19] (Magistrate Holgate); *Babbage* (n 115); *Cox* (n 180) 6, 11 (Magistrate Harries): Burbank and Babbage were tested on 15 September 2021 and arrived in Perth a week later on 22 September, those tests were irrelevant as they did not indicate risk at the time of breach. Cox, by contrast, was tested on 11 September 2021 and arrived on 23 September 2021; the test appears to have been taken into account as a step towards mitigating risk.

In *Tonkin*, Allanson J distinguished from this the receipt of a negative test pre-breach on the basis that it reduced risk.[218] The appellant had tested negative for a second time on day 11 of his 14-day quarantine before breaching quarantine on day 12.[219] His Honour gave considerable weight to the timing of this second test result in determining that the initial custodial sentence was inappropriate.[220] Importantly, it was the receipt and knowledge of the negative test, after 11 days of compliance, that proved significant.[221] Allanson J's commentary implies that an offender's attitude, at least to the extent demonstrated by conduct, influenced how these factual circumstances were considered. Conduct indicating indifference or a deliberate, rather than spontaneous, attempt to circumvent requirements increased culpability.[222] Being a close contact, receiving a positive test result pre-breach, or being symptomatic might have therefore featured as significant aggravating factors.

Deception and public exposure emerged as the most serious aggravating factors. In the AFL cases, the deception demonstrated by the offenders in entering WA and the number of people they could have exposed elevated the seriousness of these offences to the worst category of case.[223] In *Babbage* and *Burbank,* Melbourne-based offenders obtained Northern Territory drivers' licences, changed their banking addresses, and produced fraudulent documents including a property lease to falsely represent they had been living in a "low-risk" jurisdiction prior to arrival.[224] Their method of entry was considered the most serious charge as it facilitated their avoidance of all PHSMs.[225] The degree of public exposure was extensive given the offenders attended cafes, the AFL grand final with 61,000 people, after-parties, and even travelled to other regions of the state while in WA.[226] Accordingly, only a partial 10% s 9AA discount was awarded for their early plea, which reduced their total custodial sentence from 11 to 10

[218] *Tonkin* (n 180) [29] (Allanson J).
[219] Cf *AAN* (n 188) [9] (Tottle J) where the appellant had been tested but was unaware of the result at the time of the breach.
[220] *Tonkin* (n 180) [76] (Allanson J).
[221] Ibid [71] (Allanson J).
[222] For an example of disregard, the offender in *AAN* breached without knowing the results of his COVID-19 test: *AAN* (n 188) [9] (Tottle J).
[223] *Babbage* (n 115) 28 (Magistrate Holgate); *Burbank* (n 105) 21, 23 (Magistrate Holgate).
[224] *Babbage* (n 115) 25 (Magistrate Holgate) ('*Babbage*').
[225] *Burbank* (n 105) 23 (Magistrate Holgate).
[226] Ibid 19 (Magistrate Holgate).

months.[227] Their conduct was deemed too serious to wholly suspend their sentences.[228]

Another compelling factor in the cases analysed was the offender's state of mind at the time of, and motivation behind, the offending. In *AAN v Butterfield* ('*AAN*')[229] and *Tonkin,* there were express statements in each decision concerning motivation, which included that selfishness aggravated the seriousness of the offence;[230] and that the appellant had had 'no good reason' for breaching quarantine.[231] In *Babbage* and *Burbank*, Magistrate Harries similarly emphasised that the sole motivation of the offenders was to attend the AFL grand final.[232] Such conduct sits in stark contrast to RDS, whose visit to her critically ill father in breach of the restrictions occurred 'in the most extenuating of circumstances';[233] and to the offender's emotional distress in *Phillips*.[234] While there was no discussion of the statutory 'reasonable excuse' defence under s 86 of the *EMA* in the case law, its existence supports the relevance of the circumstances that contribute to or cause an offender's breach.[235]

C *Range of Sentences*

Table 1: Range of sentences

Defendant/conduct	*First instance*	*Appeal*
Vander Sanden Deception	Imprisonment for 6 months and 1 day	6-month community-based order
Tonkin Quarantine breach High risk public exposure Negative test result	7 months imprisonment, 2 months to serve, 5 months suspended for 12 months	$6000 fine

[227] *Babbage* (n 115) 29 (Magistrate Holgate).
[228] Ibid (Magistrate Holgate).
[229] *AAN* (n 188).
[230] Ibid [35]. But see *Tonkin* (n 180) [73] (Allanson J): although the appellant had 'no good reason' for breaching quarantine, substantial compliance suggests a sudden, spontaneous breach on day 12.
[231] *Tonkin* (n 180) [73] (Allanson J).
[232] Cf *Cox* (n 180).
[233] *RDS* (n 182) [20], [25], [99] (McGrath J).
[234] See especially *Phillips* (n 198) [38] (Hall J). See also [20] (Hall J).
[235] See *EMA* (n 7) s 86(3).

AAN Quarantine breach Potentially exposed two people	7 months imprisonment, 2 months to serve, balance suspended for 12 months	6-month community-based order and spent conviction order
RDS Quarantine breach in extenuating circumstances Low risk public exposure	Imprisonment for 6 months and 1 day, wholly suspended	$1000 fine and spent conviction order
Phillips Quarantine breach	Imprisonment for 6 months and 1 day, partially suspended after 2 months	6 months and 1 day, wholly suspended for 6 months
Babbage Avoidance of quarantine Deception High risk public exposure	10 months imprisonment, 3 months to serve, 7 months suspended for 10 months	
Burbank Avoidance of quarantine Deception High risk public exposure	10 months imprisonment, 3 months to serve, 7 months suspended for 10 months	
Cox Avoidance of quarantine Deception Public exposure	7 months imprisonment, 1 month to serve, 6 months suspended for 12 months	
Power[*]	8 months imprisonment, wholly suspended	
Parihar Deception Public exposure	7 months imprisonment, wholly suspended	

[*] Sentencing decision not obtained due to adjournment.

Where a custodial sentence was imposed these were either partially or wholly suspended.[236] While this may seem at odds with judicial commentary as to the seriousness of these offences,[237] it is clear from the language and reasoning of the judgments that even wholly suspended sentences are regarded as severe penalties of last resort.[238] In *Johnson* the Court, by reference to Kirby J's discussion of s 76 of the *Sentencing Act* in *Dinsdale v The Queen*,[239] explained that suspension requires two steps such that the Court must consider imprisonment a necessary penalty as a precondition to considering whether that sentence can then be suspended. This approach demonstrates that suspension was not regarded as a 'soft option',[240] but used to mitigate the 'effect of imprisonment' on the offender.[241]

D *Prosecutorial Approaches*

The court's view of the seriousness of the offending conduct and relative seriousness of the offences did not always reflect the compilation and presentation of the prosecution's case. At times there was a lack of precision in the prosecution's case regarding which directions applied,[242] or the specific conduct constituting each charge.[243] Notably in *Phillips,* these issues included the grounds of appeal, with the appeal judge noting that '[i]t was not apparent, either from the charges themselves or the statement of facts read by the prosecutor, what conduct related to each of the charges'.[244] The confusion led the learned magistrate to make an express factual error that one charge concerned a police direction when in fact, it related to a failure to wear a mask whilst being transported by police.[245] Hall J held that this error was so fundamental it prevented the sentencing discretion from being properly exercised.[246]

Our examination of the offences both "in the books" and "in action"[247] reveals the WA Government's primary reliance on the *EMA* to implement and enforce PHSMs. Most cases concerned interstate travel and involved either an individual's failure

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[236] *Phillips* (n 198); *Babbage* (n 115); *Burbank* (n 105); *Parihar* (n 152).
[237] See especially *RDS* (n 182) [93]–[94] (McGrath J).
[238] See, eg, *Babbage* (n 115) 29 (Magistrate Holgate).
[239] *Dinsdale* (n 182) [76] (Kirby J).
[240] *Johnson* (n 179) [76] (Quinlan CJ, Buss P and Mazza JA).
[241] *Tonkin* (n 180) [36] (Allanson J). See also *Cox* (n 180) 12 (Magistrate Harries).
[242] See *Tonkin* (n 180) [13]–[16] (Allanson J).
[243] See *Phillips* (n 198) [31] (Hall J).
[244] *Phillips* (n 198) [31] (Hall J).
[245] Ibid [31]–[34].
[246] Ibid [6], [36]–[37].
[247] See generally Roscoe Pound, 'Law in Books and Law in Action' (1910) 44 *American Law Review* 12.

to comply with quarantine directions or their avoidance of the quarantine regime entirely. The judiciary's approach to sentencing was consistent across the cases analysed. The pandemic context afforded more weight to deterrence as a sentencing aim and informed the courts' assessment of seriousness, while emphasising the need for the fundamental principles of criminal law to be maintained. While the broad range of conduct captured by these offences meant each case turned on its own facts,[248] there was consistency in the courts' identification and consideration of factors relating to *risk of transmission* and *culpability*, which revealed the deterrent purpose of these offences to generate compliance. While no express criticism nor endorsement of the criminalisation of these behaviours surfaced in the case law, there was commentary emphasising the seriousness of these offences in the pandemic context and perhaps an implicit deference to the public health interest protected. These observations are useful, although not a basis for inferring that they indicate judicial support for the criminalisation of PHSMs.

PART IV: EVALUATING THE USE OF CRIMINAL SANCTIONS IN THE WA COVID-19 RESPONSE

While the breadth of the offences may intuitively appear an overreach of the criminal law, patterns of judicial interpretation and sentencing arguably placed them within justifiable limits, in light of the theoretical justifications discussed in Part II. What emerges from the appeal decisions is that the consequentialist aim of general deterrence was fettered by the exercise of the sentencing discretion, which prioritised proportionate sentencing and reserved imprisonment as a penalty of last resort.[249] Proportionality in sentencing was addressed through the courts' consideration of factual circumstances that increased *risk of transmission* and *culpability.*[250]

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[248] See also *Vander Sanden* (n 181) [38] (Hill J); *Tonkin* (n 180) [30] (Allanson J).

[249] *Sentencing Act* (n 93) ss 3(1), 6(1)–(4); *Johnson* (n 179) [3] (Quinlan CJ, Buss P and Mazza JA); *RDS* (n 182) [78] (McGrath J). See generally Bronitt and McSherry (n 63) 18, citing Australian Law Reform Commission, *Same Crime, Same Time: Sentencing of Federal Offences* (Report, ALRC Report 103, 13 September 2006) 133, 149–51. See also Sarah J Summers, *Sentencing and Human Rights: The Limits on Punishment* (Oxford University Press, 2023) 91, 91, 93, citing Youngjae Lee, 'Why Proportionality Matters' (2012) 160(6) *University of Pennsylvania Law Review* 1835, 1836.

[250] See generally Bronitt and McSherry (n 63) 18–19, 21; Richard G Fox, 'The Meaning of Proportionality in Sentencing' (1994) 19(6) *Melbourne University Law Review* 489. Consider also the retributivist language in *Phillips* (n 200) 3 (Hall J): '… whilst the offence was serious enough to *deserve* a sentence of imprisonment, that sentence should be wholly suspended' (emphasis added).

Though s 6(1)–(3) of the *Sentencing Act* facilitates proportionate sentencing, whether criminalisation itself is a 'proportionate response'[251] depends upon the balancing of the interests at stake. Firstly, as discussed in Part II, the offences sought to prevent probable, significant, and irreparable harm. While expanding on the accepted core of harm-based crimes,[252] the gravity of the consequences anticipated was regarded as meriting the adoption of a precautionary approach which resulted in pre-emptive legal intervention.[253] Secondly, the courts' consideration of culpability in sentencing indicated the consideration of wrongdoing, such that judicial interpretation of the offences appears to satisfy Ashworth and Zedner's proposed limits for criminalising the creation of risk. We also suggest that the existence of the 'reasonable excuse' defence, though not discussed in the case law, should in theory also operate to minimise the discriminatory impacts on people for whom PHSMs placed a disproportionate burden.[254]

Despite the proposition that the *EMA–PHA* framework justifiably used the pragmatic and symbolic functions of criminalisation to manage a significant risk, it is submitted that the censure of criminal sanction could still only be regarded as appropriate if the offences fulfilled their deterrent purpose and generated substantial compliance with PHSMs.[255] Although there was no 'controlled experiment' to measure the efficacy of alternative pandemic responses in a WA context,[256] lessons from the HIV experience and statistical evidence on the application of the offences are instructive. In Part II some of the extensive literature on the HIV experience was explored. This article now turns to the available qualitative data concerning the offences in WA.[257]

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[251] See generally Andrew von Hirsch, 'Proportionality in the Philosophy of Punishment' (1992) 16 *Crime and Justice* 55, 55–6.
[252] *Crimes, Harms, and Wrongs* (n 75) 75.
[253] Ashworth and Zedner, *Preventive Justice* (n 72) 116.
[254] As discussed above in Part II.B above, this may include people experiencing homelessness, family violence, mental illness, disability and drug or alcohol dependencies.
[255] See generally Lelliott, Schloenhardt, and Ioannou (n 122) 167, citing Horder (n 74) 73–7; Douglas Husak, 'The Criminal Law as Last Resort' (2004) 24(2) *Oxford Journal of Legal Studies* 207, 208. See *Phillips* (n 198) [43] (Hall J): 'public safety depends on uniform compliance'.
[256] Heather McNeill, 'A Timeline of WA's COVID-19 Response: Was Our Success Luck, Good Management, or a Bit of Both?' *WAtoday* (online, 28 August 2020) <https://www.watoday.com.au/national/western-australia/a-timeline-of-wa-s-covid-19-response-was-our-success-luck-good-management-or-a-bit-of-both-20200827-p55q03.html>.
[257] Burns and Hutchinson (n 19) 159, 167.

In WA, 219, 746 and 1,171 people were 'proceeded against'[258] for the offences during 2019–2020, 2020–2021 and 2021–2022, respectively.[259] Over two-thirds of these were male,[260] and more than one-third nationally were aged between 20 and 29 years.[261] Given limited data and inconsistencies across jurisdictions, these statistics should be interpreted cautiously.[262] Nevertheless, it does appear that young males were sanctioned most commonly Australia-wide.[263] Empirical research on convicted persons' characteristics would assist in determining why: whether penalties were an ineffective deterrent; socio-economic circumstances presented barriers to compliance; or young males were simply more visible to police by virtue of their public behaviours. While not necessarily representative of this demographic, the offender in *AAN* failed to appreciate both the seriousness of his offence and that imprisonment was a sentencing option.[264]

Border restrictions and 'snap lockdowns'[265] enabled WA to live comparatively unaffected by the pandemic, until the arrival of the highly transmissible Omicron

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[258] Note that 'data relating to police proceedings for [WA]' is not included in publications by the Australian Bureau of Statistics: Australian Bureau of Statistics, 'Recorded Crime: Offenders methodology', *Australian Bureau of Statistics* (Web Page, 10 February 2022) 'Western Australia' <https://www.abs.gov.au/methodologies/recorded-crime-offenders-methodology/2020-21>.

[259] Australian Bureau of Statistics, 'Recorded Crime: Offenders', *Australian Bureau of Statistics* (Web Page, 11 February 2021) <https://www.abs.gov.au/statistics/people/crime-and-justice/recorded-crime-offenders/2019-20#covid-19-related-offences>; Australian Bureau of Statistics, 'Recorded Crime: Offenders', *Australian Bureau of Statistics* (Web Page, 10 February 2022) <https://www.abs.gov.au/statistics/people/crime-and-justice/recorded-crime-offenders/latest-release#cite-window2>; Australian Bureau of Statistics, 'Recorded Crime: Offenders', *Australian Bureau of Statistics* (Web Page, 9 February 2023) <https://www.abs.gov.au/statistics/people/crime-and-justice/recorded-crime-offenders/latest-release#covid-19-related-offences>.

[260] 65.8%, 62.3% and 67.7%, recorded in 2019–2020, 2020–2021 and 2021–2022, respectively.

[261] 42%, 36.4% and 34% offenders nationally were aged between 20 and 29 years in 2019–2020, 2020–2021, and 2021–2022 respectively.

[262] Australian Bureau of Statistics, 'Recorded Crime: Offenders', *Australian Bureau of Statistics* (Web Page, 9 February 2023) <https://www.abs.gov.au/statistics/people/crime-and-justice/recorded-crime-offenders/latest-release#covid-19-related-offences>.

[263] Ibid.

[264] *AAN* (n 188) [29] (Tottle J).

[265] See, eg, Government of Western Australia, '4-day Lockdown Introduced for Perth and Peel' (Media Release, 28 June 2021) <https://www.wa.gov.au/government/announcements/4-day-lockdown-introduced-perth-and-peel>; Government of Western Australia, 'Perth Metro and Peel to enter a 3-day Lockdown' (Media Release, 23 April 2021) <https://www.wa.gov.au/government/announcements/perth-metro-and-peel-enter-3-day-lockdown>; Government of Western Australia, 'Perth Metro, Peel and South West to Enter Hard Lockdown' (Media Release, 31 January 2021) <https://www.wa.gov.au/government/announcements/perth-metro-peel-and-south-west-enter-hard-lockdown>. On the efficacy of such measures compared with New South Wales and Victoria see Rizzi and Tulich (n 23) 6, discussing Aisha Dow and Melissa Cunningham, 'NSW Too Slow to Lock Down so Borders Should be Closed: Epidemiologists' (online, 28 June 2021) <https://www.theage.com.au/national/victoria/nsw-too-slow-to-lock- down-so-borders-should-be-closed-epidemiologists-20210628-p584y4.html>.

VOC in 2022.[266] While these measures were effective in preventing widespread community transmission in WA,[267] there is a lack of qualitative data around the influence of criminal sanctions on compliance and, therefore, the efficacy of the offences. Similarly, quantitative data on the effect of relaxing mandates on vaccination rates and case numbers in WA,[268] and comparative analyses of government responses, could gather further evidence of the broader public health and social effects of criminalisation.[269] As it was geographic isolation that made the "controlled border" possible,[270] it is clear that geographic, socio-economic and cultural circumstances had an impact on the efficacy of PHSMs generally. Comparative research must, therefore, be sensitive to these differences in order to be valuable.[271]

Statistics also demonstrate that the efficacy of criminalisation in generating compliance was inseparable from the way in which PHSMs were utilised. The majority of the offences occurred in Victoria:[272] a state that faced extended restrictions, including an extended lockdown of 112 days.[273] By July 2022 the Victorian Government was rejecting health advice to mandate PHSMs on the basis

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[266] Government of Western Australia, 'WA's Updated Safe Transition Plan from 5 February, 2022' (Media Release, 20 January 2022) <https://www.wa.gov.au/government/announcements/was-updated-safe-transition-plan-5-february-2022>; Government of Western Australia, 'New Public Health and Social Measures from Monday, 21 February' (Media Release, 18 February 2022) <https://www.wa.gov.au/government/announcements/new-public-health-and-social-measures-monday-21-february>; Department of Health, 'COVID-19 Update 18 January 2022' (Media Release, 18 January 2022) <https://ww2.health.wa.gov.au/Media-releases/2022/COVID19-update-18-January-2022>; Department of Health, 'COVID-19 Viral Fragments Detected in WA Wastewater' (Media Release, 28 January 2022) <https://ww2.health.wa.gov.au/Media-releases/2022/COVID-19-viral-fragments-detected-in-WA-wastewater>.

[267] *Palmer v Western Australia [No 4]* [2020] FCA 1221 (25 Aug 2020) [315], [366] (Rangiah J): 'the border restrictions presently reduce the probability of COVID-19 being imported into WA to a very substantial extent, broadly by somewhere in the region of 85%–90%. Screening and PCR testing would not have the same effectiveness in preventing importation of the virus.'

[268] Including hospitalisations, intensive care, and mortality rates.

[269] See especially Lawrence O Gostin et al, 'Human rights and the COVID-19 pandemic: a retrospective and prospective analysis' (2023) 401(10371) *The Lancet: Health Policy* 154, 155.

[270] McNeill (n 256).

[271] See, eg, Frederik E Juul et al, 'Mortality in Norway and Sweden During the COVID-19 Pandemic' (2022) 50(1) *Scandinavian Journal of Public Health* 38.

[272] 'Recorded Crime: Offenders', *Australian Bureau of Statistics* (Web Page, 10 February 2022) <https://www.abs.gov.au/statistics/people/crime-and-justice/recorded-crime-offenders/latest-release#cite-window2>.

[273] See, eg, 'Covid in Australia: Melbourne to Exit 112-Day Lockdown', *BBC NEWS* (online, 26 October 2020) <https://www.bbc.com/news/world-australia-54686812>; Chip Le Grand, 'Melbourne ground zero for lockdown harms, says health expert' *The Age* (online, 24 September 2022) <https://www.theage.com.au/national/victoria/melbourne-ground-zero-for-lockdown-harms-says-health-expert-20220922-p5bkcc.html>.

that compliance with further restrictions was predicted to be low.[274] In contrast to the high levels of public support for the "controlled border" in WA, the Melbourne experience illustrates that as sentiments of lockdown fatigue grew, PHSMs and by extension criminalisation became less effective.[275]

A further question around the efficacy of compliance with the offences arises in connection with the imposition of suspended sentences for high-profile border breaches. Although judicial commentary reveals that these sentences are the penultimate penalty before imprisonment, public perception may have differed.[276] The 8 month wholly suspended sentence imposed on Neville Power generated headlines that he 'avoid[ed]', 'dodge[d]' and was 'spared jail'.[277] Such reporting may have reflected and even encouraged a perception that suspended sentences are less serious than what actually is the case according to established approaches to sentencing. While this potential mismatch between judicial and public perception may have impacted the ability of suspended sentences to achieve general deterrence, we would also suggest that the influence on deterrence of the initial publicity surrounding criminalisation, and the consequences of successful prosecution, should not be discounted.[278]

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[274] Annika Smethurst, 'Why the Victorian Government Won't Go Harder on COVID Restrictions', *The Age* (online, 12 July 2022) <https://www.theage.com.au/national/victoria/why-the-victorian-government-won-t-go-harder-on-covid-restrictions-20220712-p5b0zz.html>.

[275] See Dau and Ellis (n 158). See also Ian Freckelton, 'Editorial: COVID-19 as a disruptor and a catalyst for change' (2021) 28(3) *Journal of Law and Medicine* 597, 599.

[276] R A Duff, *Punishment, Communication, and Community* (Oxford University Press, 2001) 4.

[277] See, eg, Peter de Kruijff, 'Neville Power Avoids Jail For COVID-19 Helicopter Border Breach', *The Sydney Morning Herald* (online, 23 March 2022) <https://www.smh.com.au/national/neville-power-avoids-jail-for-covid-19-helicopter-border-breach-20220323-p5a79n.html>; Michael Bennet, 'Nev Power And Son Dodge Jail For WA Border Breach', *Financial Review* (online, 23 March 2022) <https://www.afr.com/wealth/people/nev-power-and-son-dodge-jail-for-wa-border-breach-20220323-p5a76h>; Michael Ramsey, 'Nev Power Spared Jail Over 'Disrespectful And Foolish' COVID Breach', *The West Australian* (online, 23 March 2022) <https://www.perthnow.com.au/news/court-justice/nev-power-spared-jail-over-wa-virus-breach-c-6176855>; 'Millionaire Neville Power Avoids Jail For 'Deliberate And Disrespectful' Flouting Of WA Covid Restrictions', *The Guardian* (23 March 2022) <https://www.theguardian.com/australia-news/2022/mar/23/millionaire-neville-power-avoids-jail-for-deliberate-and-disrespectful-flouting-of-wa-covid-restrictions>.

[278] See, eg, Peter de Kruijff, 'Police Seek Prison Term for Former COVID-19 Recovery Boss After WA Border Breach' (online, 11 February 2022) <https://www.smh.com.au/national/former-national-covid-commission-boss-to-plead-guilty-over-wa-border-breach-20220211-p59vpk.html>. See especially Government of Western Australia, 'Urgent Legislation to Support State's COVID-19 Response' (Media Release, 31 March 2020) <https://www.mediastatements.wa.gov.au/Pages/McGowan/2020/03/Urgent-legislation-to-support-States-COVID-19-response.aspx>; Government of Western Australia, 'Police Squad to Enforce COVID-19 Restrictions' (Media Release, 29 March 2020) <https://www.mediastatements.wa.gov.au/Pages/McGowan/2020/03/Police-squad-to-enforce-COVID-19-restrictions.aspx>.

CONCLUSION

Criminal offences reflect the values and priorities of the society from which they stem.[279] The COVID-19 pandemic, and indeed public health crises more broadly, require governments to tackle the complex balancing of individual and collective interests and to mitigate discriminatory outcomes. In WA, these demands appear to have prompted a communitarian shift in legislative responses that saw a recalibration of what constitutes 'criminal harm'. The offences effected this shift by imposing criminal sanctions on those who, wrongfully, put their own interests above the welfare of the community. Whether criminalisation was justified requires serious consideration of whether the offences, both in word and action, reflect the central limiting concepts that underlie theories of criminalisation and the punitive regime associated with this.

As preventive offences, the offences intuitively raise concerns of overcriminalisation by expanding the traditional contours of criminal law beyond substantive harm-based crimes.[280] Further, and unusually, the offences lacked association with innately dangerous activities, instead targeting social human behaviours that we would ordinarily encourage. What emerges from our analysis is that patterns of judicial interpretation and sentencing aligned (at least at lower and appellate court levels) the operation of the offences with jurisprudence by upholding principles of proportionate sentencing and imprisonment as a penalty of last resort.

To assess efficacy and explore the social consequences of criminalisation in this instance, insights were drawn from the HIV experience and from available quantitative data on the offences. Our analysis concludes that the most significant risk with the *EMA–PHA* framework was that it may have generated disproportionate impacts, primarily through policing and the provision of on-the-spot fines. We also note that the effectiveness of criminal sanctions as a deterrent may well have waned with the prolonged exercise of immense executive power.

While scholarship concerning HIV-criminalisation provides wise counsel regarding the risks associated with using the criminal law to effect communicable disease control, it is not determinative of our assessment of the offences associated with the *EMA–PHA* framework. We conclude that while there is no place for criminalisation to facilitate PHSMs for HIV and other pathogens

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[279] See generally Bronitt and McSherry (n 63) 6, citing Herbert Packer, *The Limits of the Criminal Sanction* (Stanford University Press, 1968) 364.
[280] *Crimes, Harms, and Wrongs* (n 75) 75–76; Ashworth, 'Is the Criminal Law a Lost Cause?' (n 74) 225–6.

transmitted by direct-contact routes,[281] there is scope for its use in relation to virulent respiratory pathogens with pandemic potential.[282] When faced with the prospect of catastrophic harm, most especially when that harm falls disproportionately on particular societal groups, the nuanced and proportionate use of criminalisation is not only justified but, we would argue, necessary to fulfill human rights obligations and mitigate the unequal impacts of infectious disease outbreaks. Looking forward, if criminal sanctions are able to establish an effective quarantine or containment regime that could avoid extended lockdowns and restrictions, criminalisation itself will minimise the adverse public health and social consequences resulting from PHSMs.

While the offences sought to pragmatically manage a risk, the symbolic aspects of criminalisation functioned to communicate to the community the seriousness of the pandemic and that the failure to comply was wrongful in a criminal sense. By doing so, the offences sent a message to vulnerable members of the community that their lives mattered. The complexity of the balancing of interests demonstrated the need for legislative responses to be proportionate, fair and nuanced. Unprecedented times saw a necessary expansion of executive power, but evidence- and theory-based recommendations will improve government accountability and the overall success of future pandemic responses.

[281] Consider Mpox and viral haemorrhagic fevers: see generally Willey, Sherwood and Woolverton (n 11) 901.
[282] Such as influenza A H5N1 (avian influenza), which has appeared several times over the last decade with a mortality rate of almost 60%: Madigan et al (n 1) 874.

CIVIL LIABILITY FOR AI CLINICAL TOOLS IN WESTERN AUSTRALIA: A CRITICAL OVERVIEW

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Over the past 50 years, the use of AI clinical tools has experienced exponential growth, particularly in the realm of clinical judgements and assessment. While the use of AI clinical tools has been heralded as bringing the benefits of efficiency and accuracy to clinical practice, questions about how best to regulate the use of these tools persist, particularly in relation to the potential for patients experiencing harm. This article outlines the relevant legal frameworks in Western Australia, with a particular focus on civil liability regimes, analysing how these can adapt to the challenges of the use of AI in clinical settings. The analysis identifies possible gaps in the liability frameworks and provides an overview of select alternative liability models developed by legal scholarship, assessing their potential to address these gaps. The article concludes by highlighting the need for research into how health professionals navigate the risks of AI clinical tools, and the practical challenges they present, to inform the development of relevant liability frameworks in WA.

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I INTRODUCTION

In 1955, John McCarthy introduced the term Artificial Intelligence ('AI'), a descriptor for the domain of science and engineering responsible for the development of intelligent machines and computer programs with the capacity to mimic human cognitive abilities, including thinking, acting, and decision-making.[1] There are currently several definitions of AI, each reflecting the diverse applications and interpretations of the technology.[2] For example, some definitions emphasise AI's ability to mimic human cognition, while others focus on its capacity to learn and improve autonomously.[3] For present purposes, however, the broad definition provided by the ISO/IEC 22989:2022 standard, as referenced in the Western Australian ('WA') Government AI Policy, will be adopted. This refers to AI as:

> An engineered system that generates predictive outputs such as content, forecasts, recommendations, or decisions for a given set of human-defined objectives or parameters without explicit programming. AI systems are designed to operate with varying levels of automation.[4]

The above definition more than hints at the complex issues which arise when deploying AI tools in the context of healthcare. The ethical, legal, and social quandaries which arise in connection with the increasing role of this technology in the provision of patient care cannot and should not be minimised. Particularly

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[1] John McCarthy, 'What is Artificial Intelligence? Basic Questions', *Stanford Formal Reasoning Group* (Web Page, 12 November 2007) <http://www-formal.stanford.edu/jmc/whatisai/node1.html>.

[2] See generally Haroon Sheikh, Corien Prins and Erik Schrijvers, 'Artificial Intelligence: Definition and Background' in *Mission AI: The New System Technology* (Springer, 2023) 15, 15–16.

[3] Mara Graziani et al, 'A Global Taxonomy of Interpretable AI: Unifying the Terminology for the Technical and Social Sciences' *Artificial Intelligence Review* 56 (2023) 3473, 3474.

[4] Department of the Premier and Cabinet Office of Digital Government, *Western Australian Government Artificial Intelligence Policy* (Policy Paper, March 2024) 5.

difficult questions arise when considering the allocation of legal responsibility for patient harm, which occurs in association with the use of AI tools. These questions include, but are not limited to: who should bear the ultimate liability for any harm inflicted; and what is the most appropriate mechanism of liability allocation in the event of a patient being harmed?

These questions continue to form the focus of wide-ranging scholarship, from purely doctrinal analysis of liability to more high-level theoretical discussions, and, to a lesser extent, contextual and socio-legal aspects of the issue.[5] A full review of existing literature is beyond the scope of this article, but it is critical for legal scholarship to interrogate how liability models function in real-world settings, governed by specific and locally variable legal frameworks. This article provides a jurisdiction-specific analysis of the strengths and limitations of available liability models for health professionals who use AI clinical tools in diagnosing, treating, and advising patients, as well as a critical overview of possible alternatives.

The focus on the civil liability landscape of WA, as applied to the use of this technology in a local setting, facilitates the examination of these practical challenges. It questions whether the current legal frameworks are sufficiently nuanced and adapted to the use of AI clinical tools in the event that a patient suffers harm. The analysis underscores the need for empirical research to explore the experiences of health professionals in using AI clinical tools, particularly in connection with the identified questions of allocation of liability.

To provide clarification around terminology, the following table provides definitions of key terms used in this article.

[5] See Helen Smith and Kit Fotheringham, 'Artificial Intelligence in Clinical Decision-Making: Rethinking Liability' (2020) 20(2) *Medical Law International* 131; Megan Prictor, 'Where Does Responsibility Lie? Analysing Legal and Regulatory Responses to Flawed Clinical Decision Support Systems when Patients Suffer Harm' (2022) 31(1) *Medical Law Review* 1; Paul Nolan and Rita Matulionyte, 'Artificial Intelligence in Medicine: Issues When Determining Negligence' (2023) 30(3) *Journal of Law and Medicine* 593; Søren Holm, Catherine Stanton and Benjamin Bartlett, 'A New Argument for No-Fault Compensation in Health Care: The Introduction of Artificial Intelligence Systems' (2021) 29(3) *Health Care Analysis* 171; Frank Griffin, 'Artificial Intelligence and Liability in Health Care' (2021) 31 *Health Matrix* 66; Dane Bottomley and Donrich Thaldar, 'Liability for Harm Caused by AI in Healthcare: An Overview of the Core Legal Concepts' (2023) 14 *Frontier Pharmacology* 1.

Table 1: Definitions

Term	*Definition*
Algorithms	Refers to a 'set of instructions that is designed to accomplish a task. Algorithms usually take one or more inputs, run them systematically through a series of steps, and provide one or more outputs.'[6]
Neural networks	Refers to algorithms where the input data connects to many 'hidden layers' before ultimately connecting to the output layer.[7]
Black Box	Refers to 'systems that hide their internal logic from the user'. They have been described as 'ubiquitous decision systems'.[8]
Machine Learning ('ML')	Refers to a subfield of artificial intelligence that involves the development of algorithms that allow computers to learn from data.[9] It uses statistical models and algorithms to analyse and identify patterns in data, and make predictions or decisions based on that data.[10]
Human-in-the-loop ('HITL')	'The term human-in-the-loop generally refers to the need for human interaction, intervention, and judgment to control feedback and change the outcome of a process. It is a practice that is being increasingly emphasised in ML and generative AI.'[11]
Clinical practice	Refers to the practical execution of skills and tasks in the provision of healthcare to patients by healthcare professionals.
Health professional	Refers to professionals who are delivering healthcare services to patients in the course of providing treatment, in this context particularly diagnostic services.
AI clinical tools	In this article, this term refers to clinical tools that use AI technology. Clinical tools in this context are tools used by health professionals to diagnose patients' conditions, predict patients' risk of disease onset, progression, or complications, and suggest treatment decisions.[12]

[6] *National Library of Medicine: Data Glossary* (online at 16 November 2025) 'Algorithm' <https://www.nnlm.gov/guides/data-glossary/algorithm>.
[7] See Jenna Burrell, 'How the Machine "Thinks": Understanding Opacity in Machine Learning Algorithms' (2016) 3(1) *Big Data & Society* 1, 5-6.
[8] Riccardo Guidotti et al, 'A Survey of Methods for Explaining Black Box Models' (2018) 51(5) *ACM Computing Surveys* 1, 1.
[9] See Ally S Nyamawe et al, 'Fundamentals of Machine Learning' in *Practical Machine Learning: A Beginner's Guide with Ethical Insights* (CRC Press LLC, 2025) 16, 16.
[10] Ibid.
[11] Xiao-Li Meng, 'Data Science and Engineering with Human in the Loop, Behind the Loop, and Above the Loop' (2023) 5(2) *Harvard Data Science Review* 1, 2.
[12] See Khaled Ouanes and Nasren Farhah, 'Effectiveness of Artificial Intelligence (AI) in Clinical Decision Support Systems and Care Delivery' (2024) 48(74) *Journal of Medical Systems* 1, 1–2.

II RECALIBRATING THE RISKS IN THE AI SPACE

As noted above, this article seeks to assess the legal liability frameworks in WA by reference to health professionals who interact with AI clinical tools. In traditional clinical settings, health professionals need to evaluate the benefits and risks of a particular type of treatment, procedure, or medication, as part of their professional and legal duties to avoid foreseeable harm to the patient.[13] This involves an exercise of professional autonomy whereby the health professional assumes responsibility in relation to the patient's care, including making decisions about the patient's diagnosis and treatment options.[14] Applying this approach to the use of AI clinical tools for diagnosis and associated treatment options, health professionals should similarly assess the risks and benefits of these tools, given the possibility that the patient may suffer harm should the risk materialise. However, the complexity of the processes associated with the application of AI clinical tools adds a dimension to the traditional approach to determining liability, raising questions around fault, causation of harm, and ultimately the fair allocation of liability for patient harm.

The answers to these questions are inextricably tied to the status allocated to the AI clinical tool in the health professionals' clinical responsibilities. The scholarship reveals several approaches to this issue. One approach is to regard the use of the AI clinical tool as merely an adjunct or clinical decision support tool, implying that it is the end user of the tool, the health professional, who should bear responsibility for any harm suffered by the patient.[15] Megan Prictor argues that this is the effect of the current Australian regulatory frameworks. Her work has analysed potential forms of liability in negligence, contract, and under statutory consumer law in Australia relating to unintended harm associated with the use of AI clinical tools in healthcare.[16] Her conclusion is that the contours of legal risk still centre upon the clinician's duty to exercise decisional autonomy and to intercept flawed recommendations generated by algorithmic errors within clinical decision support systems.[17]

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[13] The requirement of foreseeability of harm is enshrined in the general legislative provision governing breach of duty: *Civil Liability Act 2002* (WA) s 5B(1)(a) ('*CLA 2002*').
[14] See Joseph Lee, 'The Standard of Medical Care under the Australian Civil Liability Acts: Ten Years On' (2014) 22 *Journal of Law and Medicine* 335, 336–9.
[15] See Prictor (n 5) 2, 7–8.
[16] Ibid 7–9.
[17] Ibid 14–15.

Another approach canvassed in the literature is to regard the relationship between the patient and the AI system as direct, since the patient's data is processed by the system itself, even if a clinician mediates the interaction.[18] This perspective resonates with the broader discourse on algorithmic contracts, which references the reliance on algorithmic decision-making and challenges the traditional place of human autonomy and responsibility. Natalie Skead and Marco Rizzi, for example, discuss the influential effect of algorithmic decision-making on contractual relationships in ways that erode free will or informed consent, raising concerns akin to undue influence.[19] In the clinical context, this would manifest through AI clinical tools shaping medical decision-making, either by subtly nudging health professionals toward particular recommendations, or by introducing a Black Box effect that obscures independent judgement. This may warrant reconsideration of liability allocation beyond the individual health professional to include AI suppliers or manufacturers.[20]

These different approaches to the essential role of AI tools in the decision-making process are implicitly bound up with risk determinants — both the degree of risk and the type of risk (the nature of the harm which may be experienced by patients). As such, it is important to outline the particular risks of harm associated with the use of AI in clinical practice before assessing the capability of current civil liability regimes available to patients in WA in dealing with these risks.

III WHAT RISKS OF WHAT HARM?

Any liability regime requires the identification of a harm of some kind as the necessary premise for the regime to be engaged. Simply put, without harm, there can be no liability.[21] Defining harm is not as easy as it may intuitively seem. What constitutes cognisable harm at law has been the subject of a long-lasting doctrinal debate in the Anglosphere.[22] If one were to cast a wider net to capture the

[18] Smith and Fotheringham (n 5) 137.
[19] Natalie Skead and Marco Rizzi, 'Algorithmic Contracts and the Equitable Doctrine of Undue Influence: Adapting Old Rules to a New Legal Landscape' (2020) 14(3) *Journal of Equity* 301.
[20] Ibid 314–16.
[21] See generally, eg, Jane Stapleton, *Three Essays on Torts* (Oxford University Press, 2021); Nicky Priaulx, 'Reproducing the Properties of Harms that Matter: The Normative Life of the Damage Concept in Negligence' (2017) 5 *Journal of Medical Law and Ethics* 17; Donal Nolan, 'Rights, Damage and Loss' (2017) 37(2) *Oxford Journal of Legal Studies* 255; Nicky Priaulx, 'Endgame: On Negligence and Reparation for Harm' in Janice Richardson and Erika Rackley (eds), *Feminist Perspectives on Tort Law* (Taylor & Francis Group, 2012) 36; Gemma Turton, *Evidential Uncertainty in Causation in Negligence* (Bloomsbury Publishing, 2016); Kumaralingam Amirthalingam, 'The Changing Face of the Gist of Negligence' in Jason Neyers et al (eds), *Emerging Issues in Tort Law* (Hart Publishing, 2007) 467.
[22] Examples of that debate can be found in the literature referenced at n 21.

European continental tradition, the results would be even more fragmented. Broadly speaking, liability regimes tend to be engaged either when the claimant has suffered a form of quantifiable loss (the dominant approach at common law), or when an identifiable right or legitimate interest has been violated (a common approach in the civil law tradition).[23] The emergence of AI is further complicating this debate, and Australian jurisdictions are not immune to the challenge. The *WA Government Artificial Intelligence Assurance Framework* identifies several potential risks of harm associated with AI technologies, noting that physical harm, psychological harm, unauthorised use of health or other sensitive information, incorrect advice or guidance, and inconvenience or delay are particularly relevant to the use of AI clinical tools.[24] Adverse health outcomes such as physical harm, for example, can result from misdiagnosis or inappropriate treatment recommendations associated with data biases embedded in AI clinical tools (discussed below).[25]

In considering how the use of AI clinical tools produces risks of these sorts of harms, it is essential to have regard to the operational premise underpinning these tools. Their function is intrinsically founded in the application of algorithms. AI algorithms in AI clinical tools are designed to enhance decision-making processes in clinical settings by analysing vast amounts of data to provide insights, predictions, and recommendations.[26] This involves using predictive analytics to identify correlations and patterns that contribute to disease development and progression.[27] This critical element of predictive analysis is inseparable from the flaws that are more generally associated with

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[23] See, eg, James Gordley, 'The Architecture of the Common and Civil Law of Torts: An Historical Survey' in Mauro Bussani and Anthony J Sebok, *Comparative Tort Law: Global Perspectives* (Edward Elgar, 2021) 160.

[24] Department of the Premier and Cabinet Office of Digital Government, *WA Government Artificial Intelligence Assurance Framework* (October 2025) <https://www.wa.gov.au/government/publications/wa-government-artificial-intelligence-policy-and-assurance-framework>. The main risk factors for individuals or communities encompass physical harm, psychological harm, environmental harm or harms to the broader community, unauthorised use of health or other sensitive information, impact on right, privilege or entitlement, unidentified identification or misidentification of an individual, misapplication of a fine or penalty, other financial or commercial impact, incorrect advice or guidance, and inconvenience or delay.

[25] For a general discussion see Cakesha Hardin, 'Data-Driven Technology Medical Malpractice: A Narrative Review on the Legal Implications in Clinical Settings' in Darrell Norman Burrell (ed), *Organizational Readiness and Research Security, Management, and Decision Making* (IGI Global, 2025) 373.

[26] Vikas Kumar Kharbas, Y R Meena and Praveen Kumar Thakur, 'Enabling Clinical Decision-Making in Smart Healthcare through AI/ML Algorithms' (Conference Paper, Proceedings of the 15th International Conference on Computing Communication and Network Technologies (ICCCNT), 24–28 June 2024) 2.

[27] Ibid 3.

system-generated decisions.[28] The conclusions offered by predictive analytic software make it nearly impossible to analyse and understand the basis for a diagnosis or treatment.[29] This inherent complexity means that the flaws are deeply embedded within the system's operation as the logic and inputs may not be fully explained to the user.[30]

Before diving into an analysis of how civil liability models in WA can (or could) respond to cases where harm may ensue for patients, the following paragraphs succinctly unpack algorithmic flaws and their related risks as explored in the literature, grouping them around three themes: bias, error, and opacity.

A *Bias*

Bias in AI is a systematic error in decision-making arising from data bias, algorithm bias, or user bias.[31] Bias here refers to the situation where people with particular characteristics such as race, gender, or socioeconomic status are disproportionately affected in the provision of healthcare. The bias underpinning the manifestation of these effects is generated by AI systems which create misleading results that compromise the accuracy of decisions in healthcare contexts.[32] For example, a study by Ziad Obermeyer et al, examining bias in a widely used United States healthcare risk-prediction algorithm, revealed that Black patients were more likely to present with higher needs on a range of common diseases such as severity of diabetes, high blood pressure, renal failure, cholesterol, and anaemia than White patients.[33] It was demonstrated that this occurred because the algorithm used past healthcare spending as a proxy for health status. This measure is influenced by structural inequities in access to care, resulting in fewer White patients being flagged for high-risk care management and revealing systemic racial bias in the tool's design.[34]

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[28] Ibid.
[29] Christophe Lazaro and Marco Rizzi, 'Predictive Analytics and Governance: A New Sociotechnical Imaginary for Uncertain Futures' (2023) 19(1) *International Journal of Law in Context* 70, 85.
[30] Ibid 73.
[31] Emilio Ferrara, 'Fairness and Bias in Artificial Intelligence: A Brief Survey of Sources, Impacts, and Mitigation Strategies' (2024) 6(3) *Sci* 1, 2.
[32] Ninareh Mehrabi et al, 'A Survey on Bias and Fairness in Machine Learning' (2021) 54(6) *ACM Computing Surveys* 115, 3–9. In the 'Taxonomy of Bias' section, where they provide detailed explanations of data bias, algorithm bias, and user bias, the descriptions often include examples and implications for fairness, specifically in real-world applications.
[33] Ziad Obermeyer et al, 'Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations' (2019) 366(6464) *Science* 447, 450.
[34] Ibid 453.

Data bias can stem from limitations in input data, such as imbalanced data sets, which fail to accurately represent real-world populations.[35] Research has established that one cause of data bias is a distributional shift, which occurs when ML systems encounter new contexts or data that differ from their training.[36] This shift is observed when systems trained on specific devices or populations perform poorly in broader applications.[37] Examples of distributional shifts can be identified in the clinical use of ML algorithms. One study in relation to Epic Sepsis — a widely used proprietary ML tool designed to predict sepsis risk in hospitalised patients — found that it performed significantly worse in real-world settings compared to its reported accuracy.[38] The model struggled to identify many sepsis cases when rolled out in clinical settings, highlighting the challenges of deploying AI-driven clinical decision support tools in a dynamic and evolving healthcare environment.[39] Another study reported bias in skin disease triage tools which classify dermatological images to prioritise which patients require urgent specialist evaluation.[40] The study revealed that these tools performed less accurately on individuals with darker skin tones and in detecting uncommon diseases like malignant skin cancer.[41]

A separate but related type of bias is algorithmic bias, which occurs as a result of biases inherent to the ML process born out of assumptions embedded in the system's design.[42] The tool which the Obermeyer et al study examined is a good example of algorithmic bias.[43] The nature of the ML process, particularly when based on artificial neural networks, poses a significant obstacle to the detection of bias (and ensuing errors), as its predictions are intrinsically opaque.[44]

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[35] Robert Challen et al, 'Artificial Intelligence, Bias and Clinical Safety' (2019) 28(3) *BMJ Quality & Safety* 231, 233.
[36] Ibid 232–3.
[37] Ibid; Larry Han, 'Addressing Distribution Shift for Robust and Trustworthy Prediction and Causal Inference in Clinical AI Settings' (2025) 8(6) *JAMA Network Open* 1, 1.
[38] Andrew Wong, Erkin Otles and John Donnelly, 'External Validation of a Widely Implemented Proprietary Sepsis Prediction Model in Hospitalised Patients' (2021) 181(8) *JAMA Intern Med* 1065, 1068–9 .
[39] See ibid 1069.
[40] See Andre Esteva et al, 'Dermatologist-Level Classification of Skin Cancer with Deep Neural Networks' (2017) 542(7639) *Nature* 115.
[41] Ibid 118.
[42] Ferrara (n 31) 2.
[43] Obermeyer et al (n 33) 453.
[44] Challen et al (n 35) 233; Adam Andreotta, Nin Kirkham and Marco Rizzi, 'AI, Big Data, and the Future of Consent' (2022) 37(4) *AI & Society* 1715, 1719.

So far, we have identified bias-affected inputs, which affect the front end of the generative process. Other forms of bias are based in the users of the tools, which arguably present more of a remedial challenge. General user bias arises when individuals interacting with AI systems introduce conscious or unconscious biases, which can influence the system's behaviour as it iteratively learns from experience.[45] Hierarchical dynamics in hospitals, disparities in access to care, and cultural norms around diagnosis and treatment all shape how users engage with AI.[46] For example, if a hierarchical dynamic in a clinical setting leads to a culture of deference to senior staff involved in the recognition of diagnostic patterns, then the AI tool, depending on its nature, may be prompted to replicate the pattern and embed whatever bias underpins it. This example reflects a view that user bias is closely linked to the sociotechnical context in which an AI tool operates, that is, the interaction between technical systems and the social, cultural, and institutional environments they are embedded in.[47] It casts general user bias as a complex and multilayered problem, emphasising the dangers of approaching the design of AI tools as a purely technical challenge. Confounding what is a sociotechnical problem as presenting a simple technological issue therefore risks overlooking the deep-seated origins of bias and the production of solutions which inadvertently sustain or worsen inequality.[48]

The forms of bias considered so far implicate, to varying degrees, the manufacturer of the AI tool. A further form of bias, automation bias, centres on the back end of the process, where the application of the tool to a dataset has resulted in specific conclusions around diagnoses.[49] It therefore arises from the use of these outputs in clinical practice. It is distinct from general user bias in that it does not stem from the user projecting their own social or cognitive biases

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[45] Ferrara (n 31) 2.

[46] Kate Crawford and Ryan Calo, 'There is a Blind Spot in AI Research' (2016) 538(7625) *Nature* 311, 312–13. As Crawford and Calo note, the performance of medical AI cannot be separated from the institutional and cultural environment in which it operates. For example, hospital guidelines and insurance practices shaped the data that led an AI system to misclassify asthma patients as low risk for pneumonia complications.

[47] Andrew Selbst et al, 'Fairness and Abstraction in Sociotechnical Systems' (Conference Paper, FAT '19: Proceedings of the Conference on Fairness, Accountability, and Transparency, 29 January 2019). The authors argue that fairness and bias are not intrinsic properties of algorithms but of the broader sociotechnical systems, ie social, cultural, and institutional, within which these tools are embedded (at 59–60). The authors also emphasise that technical interventions often reshape existing practices and power dynamics, meaning that user bias is inseparable from the social contexts in which AI systems operate (at 62–5).

[48] Ibid 63–4.

[49] Kate Goddard, Abdul Roudsari and Jeremy Wyatt, 'Automation Bias: A Hidden Issue for Clinical Decision Support System Use' in EM Borycki et al (eds), *International Perspectives in Health Informatics* (IOS Press, 2011) 17, 18.

onto the system, but rather from the user placing excessive trust in AI outputs, often leading to the acceptance of incorrect recommendations generated by the AI clinical tool.[50] Such overreliance may take the form of a failure to act on an error because of a lack of alerts, or of unquestioningly following incorrect system advice.[51] While the absence of alerts or the presence of incorrect recommendations may be attributed to system errors, the failure of clinicians to interrogate AI outputs is indicative of a user placing inordinate trust in the system's guidance. This can be particularly problematic as the output may be incorrect or incomplete.[52] The implications of this form of bias are that, in the event of patient harm associated with the AI tool, the liability lens shifts to the health professional's interaction with the tool. It squarely raises the question of how the health professional's actions and inactions could feature in the determination of civil liability for that harm.

B *Errors in, or of, the AI Clinical Tool*

The identified sources of bias in the design and use of an AI tool need to be conceptually distinguished from errors in the AI tools themselves, such as where the tool contains flawed, outdated or inaccurate source information.[53] While automation bias, where users overly rely on AI outputs, can amplify the impact of these errors, it is not the same as an intrinsic error within the tool itself. This distinction is crucial for understanding and addressing the full range of challenges associated with AI clinical tools. Evans and Snead have identified several types of errors which can manifest in AI clinical tools, noting that both errors and bias can affect the reliability and safety of such tools.[54]

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[50] Florian Kücking et al, 'Automation Bias in AI-Decision Support: Results from an Empirical Study' (2024) 30(317) *Studies in Health Technology and Informatics* 298, 303.
[51] Mark Sujan et al, 'Human Factors Challenges for the Safe Use of Artificial Intelligence in Patient Care' (2019) 26(1) *BMJ Health and Care Informatics* 1, 2.
[52] Joan Ash et al, 'Some Unintended Consequences of Clinical Decision Support Systems' (Conference Paper, AMIA Annual Symposium Proceedings 2007, 11 October 2007) 26, 27–8; Sarah Jabbour, David Fouhey and Stephanie Shepard, 'Measuring the Impact of AI in the Diagnosis of Hospitalised Patients: A Randomised Clinical Vignette Survey Study' (2023) 330(23) *JAMA Network* 2275, 2279–80; Yaëlle Bellahsen-Harrar et al, 'Exploring the Risks of Over-Reliance on AI in Diagnostic Pathology: What Lessons can be Learned to Support the Training of Young Pathologists?' (2025) 20(8) *PLoS One* 1, 8.
[53] Ash et al (n 52) 26–7.
[54] Harriet Evans and David Snead, 'Why Do Errors Arise in Artificial Intelligence Diagnostic Tools in Histopathology and How Can we Minimise Them?' (2024) 84(2) *Histopathology* 279, 281–3.

These errors are conceptually distinct from the distributional shift, which occurs when the model encounters data during deployment that differs from the data it was trained on.[55] Distributional shift, which may result in misleading outputs, is often associated with changes in population characteristics, clinical practices, or data collection procedures.[56] It can result from poor-quality data, but it is not synonymous with error. For example, low-quality data may be incomplete but still relatively representative, whereas erroneous data, such as wrong labelling of source information, can directly misinform model training and lead to systematic errors.[57]

Separate to those that are intrinsic to the AI tool, errors can also be practical manifestations of biases as described above. Lyell et al explain that errors can arise from the interactions between users and AI clinical tools. These errors are not limited to flaws in the data processed by AI tools but are also a product of how the tools are implemented, understood, and used.[58] For example, inadequate user training or the deployment of AI systems outside their intended scope can lead to erroneous outputs, particularly in high-stakes clinical environments.[59] This type of error can be the manifestation of automation bias. Lyell et al illustrate this with an example of an electronic prescribing system failing to alert a clinician about a potential drug interaction.[60] Because the clinician relied on the system's guidance, the interaction was missed, leading to a prescribing error.[61] As AI technology continues to advance, it is anticipated that new types of errors will emerge. Siontis et al have identified the possibility of AI systems generating outputs that appear plausible but are not grounded in the underlying data or clinical context, a phenomenon known in generative AI as 'hallucination'. This underscores the importance of implementing robust validation processes and ensuring that users are adequately trained to critically evaluate AI-generated outputs.

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[55] Nicolas Acevedo et al, 'Definition and Detection of Distribution Shift', *arXiv* (Preprint, 23 May 2024) 1, 1 <https://arxiv.org/abs/2405.14186>.
[56] Samuel Finlayson et al, 'The Clinician and Dataset Shift in Artificial Intelligence' (2021) 385(3) *New England Journal of Medicine* 283, 284–6.
[57] Marzyeh Ghassemi, Luke Oakden-Raynerc and Andrew Beam, 'The False Hope of Current Approaches to Explainable Artificial Intelligence in Health Care' (2021) 3(11) *Lancet Digital Health* 745, 748.
[58] David Lyell et al, 'Automation Bias in Electronic Prescribing' (2017) 17(1) *BMC Medical Informatics and Decision Making* 28, 35.
[59] See Yang Gong et al, 'Challenges and Opportunities of Artificial Intelligence in CDSS and Patient Safety' in John Mantas et al (eds), *Digital Health and Informatics Innovations for Sustainable Health Care Systems* (IOS Press, 2024) 1250, 1251.
[60] Lyell et al (n 58) 35.
[61] Ibid 37.

C *Issues with Opacity, Explainability and Interpretability*

While it is well known that bias or error can occur, identifying with any precision the how and when behind these occurrences is a significant challenge. Scholars have identified complexity, opacity (often referred to as the Black Box phenomenon), and unpredictability as the key issues associated with the use of AI operations. These factors can make it difficult to trace errors or verify decision pathways, with resulting complications in establishing accountability for adverse outcomes.[62] The Black Box has been explained as 'a system or program that allows one to see the input data and output results but gives no view of the processes and workings in between'.[63] This description identifies a lack of operational transparency which leaves even developers unable to explain how specific conclusions are drawn.

The lack of accessibility of the decision-making process, from the input of data to the output of conclusions derived from the operation of clinical tools, creates profound challenges for traditional legal liability frameworks. The next part of the article illustrates these challenges by setting out the current WA liability frameworks relevant to the production and use of AI clinical tools, as an essential precursor to addressing the question of allocation of liability for harm associated with these tools. It aims to clarify whether liability could lie with the health professional, the healthcare facility, or the developers or manufacturers of the AI clinical tool. The broad field of therapeutic goods, of which AI clinical tools are a small subset, is a heavily regulated one.[64] As such the analysis will also briefly touch on the potential liability of regulators.

IV RELEVANT LEGAL FRAMEWORKS

The focus of this section is on responses to personal injury, and the analysis therefore centres on the civil law of negligence, which in Australia is organised at a state and territory level. In WA the general law of negligence, as well as medical negligence specifically, stems from a combination of common law and statute. In addition to medical negligence, this section will also consider the role of existing

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[62] Nicholson Price II, 'Medical Malpractice and Black-Box Medicine' in Glenn Cohen et al (eds), *In Big Data, Health Law, and Bioethics* (Cambridge University Press, 2018) 295, 300.

[63] Frank Pasquale, *The Black Box Society: The Secret Algorithms that Control Money and Information* (Harvard University Press, 2015) 3.

[64] See Eimear Reynolds, 'Machine Learning-Integrated Medical Devices in Australia: Safety Defects and Regulation' (2024) 50(3) *Monash University Law Review* 496, 31–4; Marco Rizzi, Penny Gleeson and Jeannie Marie Paterson, 'Floors and Ceilings: Coordination, Coherence and Consistency in the Relationship Between Therapeutic Goods Regulation and Consumer Protection' (2024) 47(9) *Melbourne University Law Review* 466, 471–6.

consumer protection laws in providing compensation for affected patients and consumers.

A *Civil Liability Act 2002 (WA)*

Proving liability in negligence requires a plaintiff to establish that the defendant owes them a duty of care, that the defendant breached that duty, and that the breach is causative of recognisable harm.[65] In WA, as in other Australian jurisdictions, civil liability legislation governs significant aspects of negligence liability for personal injury. Several parts of the *Civil Liability Act 2002* (WA) ('*CLA*') are relevant to the issues of breach of duty and causation.[66] By way of premise, it is important to note that the issue of establishing the duty of care is largely governed by the common law.[67] There are well-established categories of duty of care between health professionals and patients, as well as between a manufacturer and consumer.[68] Conversely, no established category of duty of care exists between regulatory bodies, such as the Therapeutic Goods Administration ('TGA'), and those claiming to be harmed by their decisions. Indeed, the presence of conflicting statutory duties is often fatal to claims against public authorities.[69] The relevance of this approach for present purposes lies in its implication that the TGA and comparable regulators are unlikely to be held liable in negligence for harm arising from the exercise of their statutory functions. No challenge brought against the TGA — the most recent example being the decision of the Federal Court in the case of *Rose v Secretary of the Department of Health and Aged Care*[70] — has been successful to date.

With regard to the issues under consideration in this article, the use of AI tools in clinical practice is unlikely, in and of itself, to trigger judicial interventions for the purpose of establishing a novel category of duty — although such a development is not impossible to envisage in the future. The sticking points in cases involving the clinical use of AI, as the law of negligence currently stands, are more likely to revolve around breach of already existing categories of duty of care, as well as causation. It is to these elements that we now turn our attention.

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[65] See *Lochgelly Iron Co v M'Mullan* [1934] AC 1, [25] (Lord Wright).
[66] *CLA 2002* (n 13) pt 1A divs 2–3.
[67] See *Rogers v Whitaker* (1992) 175 CLR 479, 489; *Sullivan v Moody* (2001) 207 CLR 562, [47]–[50].
[68] *Gill v Ethicon Sàrl (No 5)* [2019] FCA 1905, [3624]–[3627] (Katzmann J) ('*Gill Trial*').
[69] See *Minister for the Environment v Sharma* (2022) 291 FCR 311, [192]–[195]. See also *Sullivan v Moody* (n 67) [50].
[70] *Rose v Secretary of the Department of Health and Aged Care* [2025] FCA 339.

1 *Breach of Duty of Care*

Section 5B(1) of the *CLA* outlines the principles for determining whether a duty of care has been breached. It specifies that a person is not negligent in failing to take precautions against a risk unless the risk was foreseeable, the risk was not insignificant, and a reasonable person in the same circumstances would have taken precautions.[71] This risk characterisation, also known as the standard of care, is the yardstick against which a court determines the fault of a defendant. A court will assess whether the conduct of a defendant has fallen below the standard and breached a duty of care by reference to the factors outlined in s 5B(2). These include (amongst other relevant things) weighing the probability of harm occurring, the likely seriousness of the harm, the burden of taking precautions against the risk of harm, and the social utility of the activity that creates the risk.

A key difficulty lies in determining how health professionals can be said to have discharged their duty to take reasonable precautions when they lack adequate information about the training dataset and the functioning of the training algorithm. Although transparency has been widely advocated for, AI developers have in recent years adopted a far more secretive stance toward their training data.[72] Many have shifted from providing detailed explanations of the data used to train a particular model to single sentence descriptions.[73] The inability to access such information makes it difficult to anticipate risks of bias or algorithmic error. In the leading case on breach of duty at common law, *Wyong Shire Council v Shirt*, the High Court held that the assessment of whether reasonable precautions were taken depends on the foreseeability of the risk and the steps available to mitigate it.[74] Similarly, the civil liability legislation requires a risk to be both foreseeable and not insignificant to attract an inquiry into a possible breach of duty.[75] Yet, where critical details are obscured by developers, the capacity of

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[71] *CLA 2002* (n 13) s 5B(1).

[72] Adam Buick, 'Copyright and AI Training Data: Transparency to the Rescue?' (2025) 20(3) *Journal of Intellectual Property Law & Practice* 182, 184.

[73] Yacine Jernite, 'Training Data Transparency in AI: Tools, Trends, and Policy Recommendations', *Hugging Face* (Blog Post, 5 December 2023) <https://huggingface.co/blog/yjernite/data-transparency>.

[74] *Wyong Shire Council v Shirt* (1980) 146 CLR 40, 47 (Mason J).

[75] *CLA 2002* (n 13) s 5B(1)(b). The statutory requirement that a risk be 'not insignificant' under civil liability legislation reflects only a subtle shift from the former common law test of a 'not far-fetched or fanciful' risk: see *Wyong Shire Council v Shirt* (n 74) 47–8. Courts have observed that while it imposes a slightly more demanding standard, the difference is largely semantic and unlikely to alter outcomes in most cases: see, eg, *Shaw v Thomas* [2010] NSWCA 169, [44] (Macfarlane, Beazley and Tobias JJA).

health professionals to foresee and respond to bias and algorithmic risks is constrained. At its core, this is a transparency problem which challenges the fair application of the negligence standard.

In addition to s 5B of the *CLA*, s 5PB specifically addresses the issues of standard of care and breach of duty in the context of the acts or omissions of health professionals.[76] In essence, the provisions establish that a health professional will not be considered negligent where they have acted 'in accordance with *a practice* that, at the time of the act or omission, is widely accepted by the health professional's peers as *competent* professional practice'.[77] For the provisions of this section to be enlivened, two key ingredients are necessary: there must be 'a widely accepted practice', and that practice must be considered 'competent' by peer professionals at the time of the events.[78]

In the clinical context, *competence* has been referred to as the 'habitual and judicious use of communication, knowledge, technical skills, fundable reasoning, emotions, value, and reflection in daily practice'.[79] Both the wording of s 5PB and established case law allow for the contemporaneous existence of more than one practice regarded as 'competent', accommodating for variation in professional approaches. At first blush, this flexibility appears particularly relevant in the context of rapid advancements in AI-driven healthcare. Given that AI clinical tools are continuously evolving, health institutions are likely to adopt different risk management strategies based on the specific tool and the extent of established medical consensus on their relative risks.

Notably, the WA Court of Appeal in *Child and Adolescent Health Service v Mabior* interpreted the existence of a practice widely accepted as competent at the time of the events very narrowly.[80] This case involved 16-month-old Sunday John Mabior who suffered severe scald burns. It was alleged that hospital doctors negligently failed to recognise and treat his sepsis and thus caused Sunday to suffer harm in the form of Systemic Inflammatory Response Syndrome ('SIRS')

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[76] Note that a section specifically limited to the standard of care of health professionals is unique to the civil liability legislation of WA. Most other jurisdictions have a general provision on professional liability, typically in the form of a defence. For a discussion of the topic, see Marco Rizzi, 'Health Professionals' Standard of Care and Breach of Duty in Western Australia: A Requiem for the 'Peer Professional' Test at a Time of Uncertainty' (2020) 26(2) *Torts Law Journal* 179.
[77] *CLA 2002* (n 13) s 5PB(1) (emphasis added).
[78] See *Child and Adolescent Health Service v Mabior* (2019) 55 WAR 208, [313]–[327].
[79] Ronald Epstein and Edward Hundert, 'Defining and Assessing Professional Competence' (2002) 287(2) *JAMA* 226, 226.
[80] *Child and Adolescent Health Service v Mabior* (n 78). In this case, the doctors failed to suspect, recognise and treat sepsis in the toddler, and did not administer antibiotics in a timely manner, which would have been a reasonable and practicable precaution.

and Acute Respiratory Distress Syndrome ('ARDS'), ultimately leading to cardiac arrest and multiple-organ failure.[81] The trial judge found the doctors negligent, concluding their actions were not in accordance with a widely accepted practice, which in this case would have required treatment for sepsis.[82] The Court of Appeal upheld this decision, providing a strict textual interpretation of s 5PB of the *CLA*. They emphasised that for s 5PB to apply, there must be an *established course of conduct* that was widely accepted as an *actual fact* at the time of the incident, rather than merely an opinion.[83]

When applied to an AI clinical tool, this requirement, for a health professional to demonstrate the existence of a widely accepted practice considered as competent by the peer professional group at the time of the incident, represents a significant challenge. The Black Box nature of algorithms, limited disclosure about training data, and the risk of automation bias create evidential obstacles in negligence claims. These factors complicate the determination of whether reliance or non-reliance on an AI clinical tool constitutes a widely accepted practice as competent by a peer professional group at the time of the incident. In traditional medical procedures, competence can be validated through peer-reviewed literature, clinical trials, and professional guidelines. However, when considering whether to accept or reject an AI clinical tool's recommendation, the assessment becomes less straightforward. If a health professional chooses not to follow the suggestion of an AI clinical tool, would that omission be regarded as a failure to follow a widely accepted practice? If the tool is not used, would that omission be regarded as incompetent practice at the relevant time, given that departmental protocol required its prior use? These questions illustrate the uncertainty in relation to how courts will assess liability in cases where AI-driven decisions either deviate from conventional practices, or where no established and widely accepted professional courses of conduct yet exist.[84]

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[81] Ibid [2].
[82] Ibid [82] referring to the primary reasons of the trial judge: see *Mabior v Child and Adolescent Health Service* [2018] WADC 12 [714].
[83] Rizzi (n 76) 8.
[84] Ibid. Note that s 5PB of the *CLA 2002* (n 13) allows for diverging views to co-exist. A widely accepted practice does not have to be the only accepted practice. It does not even have to be the dominant one — it simply must be accepted by a significant proportion of the health professional's peers and be deemed reasonable by the court.

The Australian medical community has taken steps to develop guidance documents and policies on AI clinical tools.[85] Even though these documents are non-binding, the WA and New South Wales ('NSW') courts in *Ellis v East Metropolitan Health Service*[86] and *South Western Sydney Local Health District v Gould*[87] confirmed that appropriate adherence to college, hospital, or other accepted professional guidelines constitutes persuasive evidence that the defendant health professionals were practising in accordance with widely held peer professional opinion.[88] In WA, this is likely to be relevant regardless of the applicability of s 5PB of the *CLA*. Even where the special standard of care is not enlivened by the circumstances, the normal assessment of standard of care and breach, conducted under ss 5B(1)(c) and (2), allows taking into consideration all relevant factors, which certainly can include professional guidelines.[89] Below are examples of such guidelines with an assessment as to their potential relevance in the WA civil liability context.

In 2024, the Australian Health Practitioner Regulation Agency ('AHPRA') published guidance outlining how health practitioners can meet their existing professional obligations when using AI.[90] The guidance makes it clear that individual health professionals remain ultimately responsible for the outcomes of using AI tools in their clinical practice, requiring them to critically evaluate and apply professional judgement to the outputs of such tools rather than relying solely on the generated results.[91] The guidance also outlines key professional

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[85] See, eg, Australian Medical Association ('AMA'), 'Artificial Intelligence in Healthcare' (Position Statement, 8 August 2023) <https://www.ama.com.au/sites/default/files/2023-08/Artificial%20Intelligence%20in%20Healthcare%20-%20AMA.pdf>; 'Meeting Your Professional Obligations When Using Artificial Intelligence in Healthcare', *Australian Health Practitioner Regulation Agency* ('*AHPRA*'), (Web Page, 22 August 2024) <https://www.ahpra.gov.au/Resources/Artificial-Intelligence-in-healthcare.aspx>; Australian Alliance for Artificial Intelligence in Healthcare ('AAAIH'), 'A National Policy Roadmap for Artificial Intelligence in Healthcare' (Guidelines, 2023) <https://aihealthalliance.org/wp-content/uploads/2023/11/AAAiH_NationalPolicyRoadmap_FINAL.pdf>.

[86] *Ellis v East Metropolitan Health Service* [2018] WADC 91.

[87] *South Western Sydney Local Health District v Gould* (2018) 97 NSWLR 513.

[88] David Pakchung, Morag Smith and Catherine Hughes, 'The Role of Clinical Guidelines in Establishing Competent Professional Practice' (2019) 48(1–2) *Australian Journal of General Practice* 22, 23. The authors refer to the judgment in *Ellis v East Metropolitan Health Service* (n 86) and *South Western Sydney Local Health District v Gould* (n 87), illustrating how courts use clinical guidelines as evidence of competent practice, while also recognising that guidelines are not determinative of the legal standard of care.

[89] Rizzi (n 76) 188.

[90] *AHPRA* (n 85).

[91] Ibid.

obligations including the requirements to ensure human oversight, to understand how the AI clinical tools are trained, and to recognise their inherent biases.[92]

Similarly, the Australian Medical Association emphasizes the importance of transparency and explainability in AI use within healthcare, highlighting the need for all stakeholders to understand its role in clinical decision-making, including addressing inherent biases.[93] It also includes a requirement that patients should be informed when diagnoses or treatment recommendations are determined by AI programs.[94]

The Australian Medical Council ('AMC') is the national standards body responsible for accrediting medical education and training programs, with the aim of ensuring quality and consistency across the healthcare sector in Australia.[95] It oversees 25 specialist medical colleges, each of which plays a critical role in guiding clinical practice and professional standards within their respective specialities.[96] Given the growing integration of AI in healthcare, these colleges are expected to provide leadership and guidance on its ethical and clinical implications.[97] However, among the 25 specialist medical colleges under the AMC, only four have published position statements on AI in healthcare.[98] The position statements from three colleges (Australasian College of Dermatologists,[99] Royal Australian College of

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[92] Ibid.
[93] AMA (n 85).
[94] Ibid.
[95] See 'About the Australian Medical Council', *Australian Medical Council* (Web Page) <https://www.amc.org.au/about-the-amc/>.
[96] 'List of Specialist Medical Colleges', *Australian Medical Council* (Web Page, 4 February 2025) <https://www.amc.org.au/accredited-organisations/assessment-and-accreditation-of-specialist-medical-programs/specialist-medical-colleges/>.
[97] AMA, 'AMA Calls for Expert Clinical Oversight of the Use of AI in Healthcare'(Media Release, 12 August 2025) <https://www.ama.com.au/media/ama-calls-expert-clinical-oversight-use-ai-healthcare>.
[98] See Australasian College of Dermatologists, 'Position Statement: Use of Artificial Intelligence in Dermatology in Australia' (2022); Royal Australian College of General Practitioners ('RACGP'), 'Artificial Intelligence in Primary Care' (Position Statement, 17 April 2025) ; Royal Australian and New Zealand College of Radiologists ('RANZCR'), 'Ethical Principles for AI in Medicine' (Position Statement, 15 September 2023) <https://www.ranzcr.com/whats-on/news-media/ethical-principles-for-artificial-intelligence-for-medicine-version-2>; Royal Australasian College of Medical Administrators, 'RACMA Position Statement on AI in Healthcare' (June 2025) <https://racma.edu.au/app/uploads/2025/06/RACMA-Position-Statement-on-AI-in-Healthcare-Final.pdf>.
[99] Australasian College of Dermatologists, 'Use of Artificial Intelligence in Dermatology in Australia' (Position Statement, July 2025) <https://www.dermcoll.edu.au/wp-content/uploads/2025/07/ACD-Position-Statement-Use-of-Al-in-Dermatology-in-Australia-July-2025.pdf>.

General Practitioners,[100] and Royal Australian and New Zealand College of Radiologists ('RANZCR')[101]) emphasise the importance of transparency and explainability and human oversight. The RANZCR has developed standards of practice for the use of AI in radiation oncology, providing a risk-management framework for safe and effective implementation.[102] The document outlines the standards required, among others, for training in ML and AI, consent and privacy, algorithm selection, clinical oversight, and decision-making.[103] In relation to clinical decision-making, the RANZCR has determined that ultimate responsibility rests with the radiation oncologist.[104] A full discussion of this standard is beyond the scope of this article, but it is worth noting that this kind of non-legal regulatory framework does engage with the issue of allocating responsibility.

While all professional guidelines can gain relevance in the context of a medical negligence claim through the broad reference in s 5B(2) to 'other relevant things', they have the potential to become 'a widely accepted practice', thereby determining the standard of care. Arguably, this is particularly the case for speciality-specific standards and guidelines, especially those issued by RANZCR, which may serve as a guidance for other specialist medical colleges.

2 *Causation*

Section 5C of the *CLA* addresses the requirement of causation in stating that a breach of duty must be a necessary condition for the harm suffered by the plaintiff (factual causation) and that it is appropriate for the scope of liability to extend to the harm (scope of liability).[105] The former is exclusively factual and a restatement of the well-known 'but for test'.[106] The latter is normative, and its purpose is to set limits around a defendant's liability based on policy considerations, the foreseeability of the harm, or the nature of the chain of causation.[107] Proof of causation has long been established as a challenge for

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[100] 'Artificial Intelligence in Primary Care', *RACGP* (Web Page, 17 April 2025) <https://www.racgp.org.au/advocacy/position-statements/view-all-position-statements/clinical-and-practice-management/artificial-intelligence-in-primary-care>.
[101] RANZCR, *Standards of Practice for Artificial Intelligence in Radiation Oncology* (30 October 2024).
[102] Ibid.
[103] Ibid 11–18.
[104] Ibid 11.
[105] *CLA 2002* (n 13) ss 5C(1)(a), 5C(1)(b), 5C(4).
[106] See *Adeels Palace v Moubarak* (2009) 239 CLR 420, [41]–[44]; *Strong v Woolworths Ltd* (2012) 246 CLR 182, [18].
[107] *Wallace v Kam* (2013) 250 CLR 375, [14], [24].

plaintiffs seeking compensation for harm associated with clinical settings.[108] The patient's physical condition and variables associated with predictions of the impact of a proper diagnosis or treatment have traditionally complicated the plaintiff's requirement of proving both factual causation on the balance of probabilities, and the normative allocation of causal liability.[109] In *Tabet v Gett*, the High Court ruled that loss of a chance of a better medical outcome is not a recognised form of compensable harm in negligence claims.[110] As such, a plaintiff must establish, on the balance of probability, that the defendant's negligence was a necessary condition of the actual personal injury suffered.

3 *The 'State of Negligence' with Respect to AI Clinical Tools.*

The provisions discussed so far form the basis for evaluating whether liability can be established in negligence in situations involving the use of AI clinical tools. They set out the criteria for proving that the defendant breached its duty of care, and that the breach caused the patient's harm. The relevant sections come into play by providing a framework for assessing the actions of health professionals who incorporate AI into their clinical practice. Under s 5B of the *CLA*, determining whether there has been a breach of the duty of care involves evaluating whether the medical professional appropriately used the AI clinical tool based on the foreseeable risks associated with its limitations and the accuracy of its outputs.

Making this determination requires examining if the health professional took reasonable precautions to verify the AI-generated advice, considering factors such as the likelihood of the AI's errors and the severity of potential harm to the patient. As specific courses of action with respect to the use of AI in clinical practice become well established, the alternative standard of care for health professionals under s 5PB is likely to gain relevance. Causation under s 5C is particularly challenging in AI-related cases, as the provision requires a plaintiff to establish that a health professional's reliance on the AI's recommendation was a necessary condition for the harm, distinguishing this from other causal influences such as the AI's inherent flaws, user misuse, or a combination of factors.

In situations in which the use of an AI clinical tool by a health professional is considered negligent, and harm to a plaintiff ensues because of the AI's inherent flaws rather than their misuse, interesting questions arise with respect to the allocation of liability. Under the current WA legal regime, health professionals

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[108] See, eg, ibid; *Tabet v Gett* (2010) 240 CLR 537; *Waller v James* [2013] NSWSC 497.
[109] *Tabet v Gett* (n 108) [54]–[62].
[110] Ibid [21]–[25]. See Meredith Blake, 'Loss of a Chance in Medical Negligence: A Lost Cause' (2009) 17(3) *Tort Law Review* 123, 125.

retain responsibility for clinical decision-making and cannot be fully exonerated of liability. However, where the use of an AI tool is involved, liability could arguably be jointly attributed to the AI developer, the institution adopting the AI, and potentially other stakeholders. The Black Box nature of AI discussed above, specifically its lack of transparency and predictability, complicates the fundamental questions around attribution of liability, particularly regarding the standard of care and causation. There are clear challenges for both health professionals and adjudicators in evaluating the reasoning behind AI-generated recommendations. It therefore remains unclear whether liability should rest solely with clinicians or extend to developers and institutions.[111]

This issue is of pressing concern as the risks identified in the previous part of this article are particularly alive in the clinical context. For example, the deployment of clinical decision support systems ('CDSS') is linked to increasing forms of automation bias among clinicians.[112] This is of concern at a time when health services across the world are actively integrating these systems into routine care delivery, increasing their scale of use, frequency of application, and clinician reliance.[113] For example, in the United Kingdom, the National Health Service has already deployed AI in high-volume settings such as radiology, pathology, and diagnostic decision support, where automated tools assist in detecting breast cancer, analysing chest radiographs, and prioritising high-risk patients.[114] These overseas developments have particular relevance for the WA context, where provisions specifically dedicated to the standard of care and liability of health professionals will be put to the test while 'widely accepted' practices emerge. It is worth noting that the particular legal landscape of WA creates a lack of clarity

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[111] Smith and Fotheringham (n 5) 136–7; Nicholson Price II, 'Artificial Intelligence in Health Care: Applications and Legal Issues' (2017) 14(1) *SciTech Lawyer* 10, 11.

[112] Susanne Gaube et al, 'Do as AI Say: Susceptibility in Deployment of Clinical Decision-Aids' (2021) 4(31) *NPJ Digital Medicine* 1, 4.

[113] Priya Jeyaraj, 'Role of Artificial Intelligence in Enhancing Healthcare Delivery' (2023) 11(12) *International Journal of Innovative Science and Modern Engineering* 1, 10–11.

[114] Jordan Smith et al, 'Real-World Performance of Autonomously Reporting Normal Chest Radiographs in NHS Trusts Using a Deep-Learning Algorithm on the GP Pathway', *arXiv* (Preprint, 28 June 2023) <https://arxiv.org/abs/2306.16115>; Sam Blanchard, 'AI SAY "Landmark" Moment as NHS Clinics Use AI to "Detect Breast Cancer Cases Earlier and Faster"', *The Scottish Sun* (online, 4 February 2025) <https://www.thescottishsun.co.uk/health/14275629/artificial-intelligence-ai-nhs-trial-breast-cancer-screening/>; Andrew Gregory, 'Algorithm could help prevent thousands of strokes in UK each year', *The Guardian* (online, 28 December 2024) <https://www.theguardian.com/society/2024/dec/28/algorithm-could-help-prevent-thousands-of-strokes-in-uk-each-year>.

around the standard of care expected of health professionals, which can cause uncertainty among health professionals and encourage defensive practices.[115]

4 *Expanding the Picture: Liability of the Developer?*

As previously discussed, there are two major sources of the risks of harm associated with clinical AI tools: the four types of bias identified, and errors of the AI clinical tool. Where harm has resulted to a patient because of bias or error, it is arguable that the developer has breached their duty of care, which is likely to fall within the established category owed by manufacturers to consumers.[116] This is the case notwithstanding a finding that the health professional is liable where the use of AI clinical tools is found to be in breach of their specific duty of care.

The rationale for integrating the developer of the AI clinical tool within the scope of one claim for medical negligence (as opposed to treating it as a separate instance of liability) can be summarised as follows. The development of the algorithm and the data training that informs the AI clinical tool lie within the developer's purview. While they may not always have direct control over the data source, particularly if it is provided by third parties or acquired through external datasets, they oversee critical aspects such as the selection, preprocessing, and curation of the data used for training.[117] Consequently, developers should reasonably foresee the potential for user bias in algorithms designed to continuously learn from user-provided data, as these systems inherently reflect and amplify patterns in the input data.[118] Since user-generated data can be influenced by individual behaviours, cultural norms, or systemic biases, algorithms may inadvertently adopt and reinforce these biases over time.[119] This issue is well-documented in ML literature, emphasising the need for proactive bias mitigation strategies during the algorithm's design and deployment stages to ensure fair and reliable outputs.[120]

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[115] Tom Lawton et al, 'Clinicians Risk Becoming "Liability Sinks" for Artificial Intelligence' (2024) 11(1) *Future Healthcare Journal* 100007 1, 4.

[116] *Gill Trial* (n 68) [3755]–[3761], [3797]–[3807], [3828]–[3834] (Katzmann J). The Court determined Ethicon owed and breached a duty of care to patients by failing to adequately test device safety before release, appropriately monitor devices post-approval, or provide proper warnings about risks and probabilities.

[117] See generally El Kindi Rezig, Michael Cafarella and Vijay Gadepally, 'Technical Report on Data Integration and Preparation', *arXiv* (Preprint, 2 March 2021) <https://arxiv.org/abs/2103.01986>.

[118] See Sribala Chinta et al, 'AI-Driven Healthcare: A Review on Ensuring Fairness and Mitigating Bias' (2025) 4(5) *PLOS Digital Health* 1, 14–15.

[119] Ibid 8.

[120] Kirsten Martin, 'Ethical Implications and Accountability of Algorithms' (2018) 160(4) *Journal Of Business Ethics* 835, 845–6.

5 *Refining the Picture: Limitations of the Human-in-the-Loop*

As noted earlier, automation bias occurs when health professionals develop an over-reliance on AI clinical tools, such as CDSS, which can lead to potentially harmful outcomes when these systems provide inaccurate or incomplete advice.[121] This bias is produced by the perception that AI systems are highly reliable, which may discourage clinicians from questioning or verifying their outputs.[122] The main contributors to this reliance include clinicians' excessive trust in the system and the assumption that the tools are safe and effective simply because they are adopted and provided by the hospital.[123] Additionally, practical constraints such as limited time and high workloads may reduce clinicians' ability to critically assess AI-generated outputs, inadvertently reinforcing reliance on these tools.[124] This raises questions about the legal responsibilities of the human-in-the-loop ('HITL').

The HITL approach, where clinicians are tasked with verifying or correcting errors flagged by the AI system before finalising decisions, is intended to enhance oversight and reduce errors caused by blind reliance on automation.[125] However, questions remain about the effectiveness of this strategy. Specifically, concerns arise regarding whether institutions are adequately providing the rigorous training necessary to equip clinicians with the skills to critically engage with AI outputs, rather than passively accepting them.[126] Furthermore, there is ongoing debate about whether regulatory bodies should impose stricter oversight to ensure the safe integration of AI clinical tools into healthcare workflows, to minimise the risk that the use of these tools may undermine patient safety.[127]

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[121] Kate Goddard, Abdul Roudsari and Jeremy Wyatt, 'Automation Bias: A Systematic Review of Frequency, Effect Mediators, and Mitigators' (2011) 19(1) *Journal of American Medical Informatics Association* 121, 123.

[122] Kun-Hsing Yu and Isaac Kohane, 'Framing the Challenges of Artificial Intelligence in Medicine' (2019) 28(3) *BMJ Safety & Quality* 238, 239.

[123] Lyell et al (n 58) 8.

[124] Emely Rosbach et al, 'Automation Bias in AI-Assisted Medical Decision-Making under Time Pressure in Computational Pathology' (Conference Paper, Bildverarbeitung für die Medizin, 2 March 2025) 4.

[125] Ujué Agudo et al, 'The Impact of AI Errors in a Human-in-the-Loop Process' (2024) 9(1) *Cognitive Research: Principles and Implications* 1, 2.

[126] Lotte Schuitmaker et al, 'Physicians' Required Competencies in AI-assisted Clinical Settings: A Systematic Review' (2025) 153(1) *British Medical Bulletin* 1, 9.

[127] Haider Warraich, Troy Tazbaz and Robert Califf, 'FDA Perspective on the Regulation of Artificial Intelligence in Health Care and Biomedicine' (2025) 333(3) *JAMA Network* 241, 244–5.

Further research will be necessary to fully address the challenges of the HITL approach, particularly in light of recent global developments that have established it as a regulatory requirement.[128] However, for present purposes, the HITL approach raises the question of what constitutes a competent professional practice in relation to the deployment and use of AI clinical tools. In the absence of case law, we suggest that the proposition that reliance on AI clinical tools is widely accepted as competent professional practice would be relevant in the context of establishing the standard of care and assessing breach (whether under s 5B or 5PB of the *CLA*). Notwithstanding this, it is unlikely that complete, unquestioning reliance would be regarded as exonerating, even where the use of a specific AI clinical tool rises to the level of a widely accepted practice per s 5PB.

A separate but related issue is that arising in connection with the health professional's duty to inform patients of the risks associated with a process of diagnosis or treatment that relies on AI tools. The Black Box nature of algorithmic processes makes it difficult to anticipate risks of harm that might constitute 'material risks' for the purposes of the legal test for disclosure of information. As established in *Roger v Whitaker* and subsequently reaffirmed in *Wallace v Kam*,[129] a risk is material if a reasonable person in the patient's position is likely to attach significance to it, even if the probability of the risk of materialising is low or altogether uncertain.[130] In this sense, the intrinsic risks associated with AI, discussed above, add a further layer of complexity to the health professional's duty to disclose risks, making it more challenging to determine what must be communicated, especially in light of the uncertainty around the general risks associated with AI clinical tools.

B *Australian Consumer Law*

The Australian Consumer Law ('ACL') is a statutory regime that operates alongside the tort of negligence.[131] Its relevance in the context of AI clinical tools lies in the nature of such tools as products, the design and application of which are subject to the protections offered by this regime. The ACL provides a comprehensive framework designed to offer remedies to consumers who are harmed through the conduct of corporate bodies or commercial entities. Liability under the ACL can be established through multiple legal bases, including misleading and deceptive conduct, breach of consumer guarantees, and liability

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[128] *Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 on Artificial Intelligence (Artificial Intelligence Act)* [2024] OJ L 12.7.2024, art 14.
[129] *Rogers v Whitaker* (n 67) 490; *Wallace v Kam* (n 107) [8].
[130] *Rogers v Whitaker* (n 67) 490.
[131] *Competition and Consumer Act 2010* (Cth) sch 2 ('Australian Consumer Law').

for defective products.[132] A key feature of the ACL is its compensatory no-fault regime, which provides strict liability under pts 3–5, ensuring that injured parties can seek remedies without needing to prove fault for harm caused by an unsafe product.[133] This is defined in s 9 as a product that does not have the level of safety 'persons generally are entitled to expect'.[134] Section 138 outlines the circumstances in which this strict liability regime is enlivened. Importantly, the protections offered by this provision extend to patients injured by medical devices,[135] which would include AI-powered clinical tools.[136]

The ACL and negligence were both invoked as bases for compensation in the successful challenge by consumers injured by defective pelvic mesh implants in *Ethicon Sàrl v Gill*.[137] The case underscores the complementary roles of ACL and negligence in medical product litigation. The ACL's strict liability provisions under s 138 ensured manufacturer accountability for safety defects,[138] while the negligence claims addressed the failure to take reasonable precautions in product design and risk disclosure.[139]

The findings in the *Gill* class action are directly relevant to AI clinical tools, as both involve medical products impacting patient safety. AI-integrated medical devices such as CDSS could also be subject to ACL claims if they were to generate erroneous recommendations, cause or contribute to misdiagnosis, or be otherwise associated with patient harm. Section 138 appears applicable to an AI tool's algorithmic flaws, biases, or system failures resulting in unsafe outcomes for patients.

Furthermore, the *Gill* class action emphasised the importance of manufacturer responsibility in disclosing risks and ensuring adequate testing, a principle that extends to AI developers and software vendors operating in the clinical and

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[132] Ibid. Sections 18 and 29 specifically address misrepresentations, making it unlawful for businesses to engage in such practices. Parts 3–5 of the Australian Consumer Law impose strict liability on manufacturers and importers for goods with safety defects.
[133] See Jeannie Marie Paterson, *Corones' Australian Consumer Law* (Thomson Reuters, 4th ed, 2023) 504.
[134] For an in-depth analysis of the operation of the Australian Consumer Law with respect to therapeutic goods, and its complex interaction with the regulatory regime that governs the approval of therapeutic goods, see Rizzi, Gleeson and Paterson (n 64).
[135] Julia Symons and Marco Rizzi, 'Consumers or Patients? Medical Device Recipients under Australian Law Straddle Two Worlds' (2023) 30(3) *Journal of Law and Medicine* 572, 573.
[136] Reynolds (n 64) 502.
[137] *Ethicon Sàrl v Gill* (2021) 288 FCR 338, [4] ('*Gill Appeal*'), on appeal from *Gill Trial* (n 68) — together the cases are referred to as the '*Gill* class action'.
[138] *Gill Appeal* (n 137) [266]–[271].
[139] Ibid [715]–[723].

healthcare context.[140] The Federal Court made clear that the sufficiency of warnings does not depend on the manufacturer's subjective view of what medical professionals ought to know.[141] Instead, manufacturers must actively provide sufficient information, advice, and warnings about potential risks to ensure that clinicians and consumers can make informed decisions.[142] This reasoning is particularly relevant to AI clinical tools, where algorithmic failure modes, bias, and data limitations can significantly impact patient safety. If an AI clinical tool is deployed without sufficient validation, lacks transparency in decision-making, or fails to account for known limitations, manufacturers could face liability under the ACL for safety defects.

This would be particularly relevant where an AI model fails to generalise across diverse populations, leading to inaccurate diagnoses or treatment recommendations. As Reynolds' in-depth analysis of AI-powered medical devices notes, AI models often underperform when deployed on populations that differ from the training data, raising serious concerns about generalisability, bias, and health disparities — in other words, they can be prone to data bias, as described above.[143] AI manufacturers must manage the expectations of both patients and clinicians,[144] and provide explicit guidance on the intended use of their tools. If an AI clinical tool has been trained primarily on homogeneous patient datasets but is then deployed for broader use without appropriate disclaimers or safeguards, the risk of systemic errors increases. In the *Gill* class action, the Federal Court indicated that a medical product would not necessarily be defective if clear warnings and limitations were provided to clinicians, allowing them to make balanced, cautious, and informed judgements.[145] By analogy, AI developers must clearly communicate the limitations of their models, ensuring that users are aware of potential risks and constraints.

It is worth noting at this point that the European Union has recently adopted a revised version of its Product Liability Directive ('Directive').[146] To overcome the significant hurdles that individuals harmed by AI-powered products may encounter in demonstrating the safety defectiveness of a product, the new

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[140] See, eg, Australian Government, Department of Health, Disability and Ageing, *Demonstrating Evidence to Comply with the Essential Principles* (Guidelines, 25 August 2022) 1, 3.
[141] *Gill Appeal* (n 137) [607].
[142] Symons and Rizzi (n 135) 580.
[143] Reynolds (n 64) 516.
[144] Symons and Rizzi (n 135) 579.
[145] *Gill Appeal* (n 137) [608].
[146] *Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on Liability for Defective Products and Repealing Council Directive 85/374/EEC* [2024] OJ L 18.11.2024.

Directive establishes a series of presumptions that significantly ease the plaintiff's burden.[147] This is certainly an interesting development at the international level, and it will be interesting to follow whether the current 'Review of AI and the Australian Consumer Law', led by the federal Australian Treasury, will reach similar conclusions.[148] The process is however still very much ongoing, and no reform is expected in the immediate future.

V EXPLORING ALTERNATIVES TO ESTABLISHED LIABILITY MODELS

A *Underpinning Normative Challenges*

The discussion so far has outlined the challenges that AI clinical tools can raise for established liability frameworks in the face of patient harm associated with their use in the clinical setting. As this article aims to explore equitable ways to account and compensate for patient harm, it is important to expose the limitations of existing frameworks in order to present viable alternative mechanisms to address this goal. The (at least partial) mismatch between negligence and consumer law frameworks is no surprise. As outlined above, negligence is a fault-based liability regime and, as such, it focuses on proving that the conduct of an identifiable actor, such as a doctor or hospital, has fallen below the expected standard of care and caused an identifiable harm. Product liability on the other hand addresses the safety defect in particular and identifiable products. It responds to the separate logic of protecting consumer safety by removing the fault requirement and shifting the focus away from the conduct of the defendant, relocating that focus on the product and the legitimate safety expectations of the public.

Both the negligence and product liability frameworks can therefore struggle to address complex allocations of responsibility when harm arises from the use of AI clinical tools, as this arguably requires a twofold focus on both product and conduct, which in turn requires consideration of the contributions of different parties. In this sense, both negligence and product liability are founded on normative premises that are not necessarily suited to recognising the collective and interdependent nature of AI-driven decision-making, where liability may be diffused across multiple stakeholders, including developers, manufacturers, healthcare providers, and regulatory bodies. While complexity in allocation of

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[147] See Miriam Buiten, 'Product Liability for Defective AI' (2024) 57(1–2) *European Journal of Law and Economics* 239, 267.

[148] Australian Government Treasury, *Review of AI and the Australian Consumer Law* (Discussion Paper, 15 October 2024) 3 <https://treasury.gov.au/sites/default/files/2024-10/c2024-584560-dp.pdf>.

liability (particularly with respect to the use of technology in clinical care) is certainly not a novel situation, the types of risks and harms involved with the use of AI clinical tools as described in Part III provide us with a unique opportunity to reflect on the viability of our current models. Indeed, the mismatch between those risks and the characteristics of the legal frameworks analysed in Part IV can lead to accountability gaps, or to liability being unfairly concentrated on frontline medical professionals who may have limited control over the AI's outputs. So, as AI clinical tools become more sophisticated and embedded in decision-making, including in the WA healthcare system, the time is ripe to explore alternative approaches to redressing harm.

B *Considering Alternatives: Collective Responsibility and No-Fault Compensation, or Risk Pooling for AI Clinical Tools*

Alternative approaches to centring redress on proof of an individual actor's fault or an identifiable product defect embrace the notion that loss distribution mechanisms should reflect the distinct normative underpinning of societal responsibility for individuals' harm. The topic is vast, and a full review of these approaches is beyond the scope of this article. However, it is important to note that the idea of shifting from liability models and refocusing on alternative methods that centre on ensuring recovery for harms suffered may be well-suited to the present context, given the social utility associated with the use of AI as a way to improve accessibility to high quality healthcare treatments.[149]

Separate from, but connected to, issues of fair and adequate compensation is the equally pressing question of identifying appropriate models for the allocation of liability. Clara Cestonaro et al, for example, identified six broad approaches to liability arising in connection with the use of AI in clinical settings in their systematic review.[150] These are medical malpractice, product liability, learned intermediary rule, common enterprise liability, vicarious liability, and AI personhood.[151] The first two represent the traditional regimes that are currently available in WA and have been unpacked in the previous part. The other approaches provide useful elements worth reflecting upon, particularly the idea of common enterprise liability.

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[149] Reynolds (n 64) 526.
[150] Clara Cestonaro et al, 'Defining Medical Liability when Artificial Intelligence is Applied on Diagnostic Algorithms: A Systematic Review' (2023) 10 *Frontiers in Medicine* 1, 8.
[151] Ibid 5–7.

A central challenge in clinical AI regulation is addressing the responsibility gap, ensuring that liability for patient harm is fairly distributed. This challenge is compounded by the fact that the use of AI clinical tools involves multiple stakeholders, each with distinct roles and responsibilities. Collective responsibility refers to the shared accountability of relevant stakeholders for the outcomes of AI-driven decisions.[152] This approach recognises that AI systems are the product of collaborative efforts involving clinicians, developers, institutions, and regulators, and that each stakeholder plays a role in ensuring the safety and efficacy of AI in clinical settings. The case for collective responsibility is rooted in the recognition that harms associated with the use of AI clinical tools are often the result of systemic failures rather than individual negligence or the defectiveness of a particular product.[153]

By distributing responsibility among stakeholders, collective responsibility models can ensure that each party is held accountable for its role in the AI system's development and deployment. Within this framework, health professionals are ultimately responsible for patient care and must exercise professional judgement when using AI clinical tools. However, the model holds that their responsibility should be limited to their actual influence over the decision-making process.[154] This is complemented by developers holding responsibility for ensuring that AI algorithms are accurate, transparent, and free from biases. Developers must also provide adequate documentation and support to enable clinicians to use the tools effectively.[155] In parallel, healthcare institutions are responsible for procuring and deploying AI systems, as well as for establishing protocols for their use, ensuring that clinicians are adequately trained to interpret and act on AI-driven recommendations. Regulators play a crucial role in this model by establishing standards for AI development and deployment, as well as overseeing the implementation of safety and efficacy

[152] Isaac Taylor, 'Collective Responsibility and Artifical Intelligence' (2024) 37 *Philosophy and Technology* 1, 3.
[153] Bart Custers, Henning Lahmann and Benjamyn Scott, 'From Liability Gaps to Liability Overlaps: Shared Responsibilities and Fiduciary Duties in AI and Other Complex Technologies' (2025) 40(5) *AI and Society* 4035, 4037.
[154] Changhyun Lee, Hun-Yeong Kwon and Kyung Jin, 'Sharing Accountability of Versatile AI Systems: The Role of Developers and Practitioners' (2024) 37(1) *The International FLAIRS Conference Proceedings* 1, 2. The authors introduced the concepts of controllability and openness, where practitioners often lack the techniques to modify the algorithm model.
[155] Antian Chen, Chenyu Wang and Xinqing Zhang, 'Reflection on the Equitable Attribution of Responsibility for Artificial Intelligence-Assisted Diagnosis and Treatment Decisions' (2022) 3(2) *Intelligent Medicine* 139, 143.

protocols.[156] The clear definition of these roles is essential in distributing responsibility across the AI ecosystem.

In light of these challenges, the question of how collective responsibility should be implemented arises. Based on the literature analysed in this article, we suggest the following two primary mechanisms for implementing collective responsibility: (1) a two-pronged approach based on the establishment of a no-fault compensation fund supplemented by enterprise liability; and (2) the adoption of risk pooling frameworks within the enterprise liability model.

1 *No-Fault Compensation and Enterprise Liability*

Søren Holm et al argue that AI systems, due to their opacity and complex causal chains, render traditional fault-based liability both impractical and unjust, particularly where clinicians are held accountable for outcomes influenced by AI clinical tools they do not fully control.[157] They propose that no-fault compensation schemes, designed to circumvent the burden of proving negligence, can provide more equitable outcomes for patients while supporting transparency and error reporting within healthcare systems.[158] Nynke Vellinga advances a policy-oriented argument for an AI-specific compensation fund for high-risk systems.[159] This fund, to be financed by AI developers, distributors, and institutional users, would aim to ensure full compensation for personal injuries, including those involving mental harm, where the precise source of failure is indeterminate.[160] This is in line with the call from the World Health Organisation for the introduction of a 'Faultless Responsibility Model' under which all agents involved in the development and deployment of AI are required to promote integrity and minimise harm.[161] A key issue for any no-fault compensation regime, as identified by Genevieve Grant and Harold Luntz, is to ensure that it is tailored to effect 'a more just and comprehensive response to the burden of injury

[156] Argyri Panezi, 'Liability Rules For AI-Facilitated Wrongs: An Ecosystem Approach To Manage Risk And Uncertainty' in Pablo García Mexía and Francisco Pérez Bes (eds), *Artificial Intelligence and the Law* (La Ley, 2021) 1, 15–16.

[157] Søren Holm, Catherine Stanton and Benjamin Bartlett, 'A New Argument for No-Fault Compensation in Health Care: The Introduction of Artifcial Intelligence Systems' (2021) 29 *Health Care Analysis* 171, 173–4.

[158] Ibid.

[159] Nynke E Vellinga, 'Rethinking Compensation in Light of the Development of AI' (2024) 38(3) *International Review of Law, Computers & Technology* 391, 408.

[160] Ibid 406.

[161] World Health Organisation, *Ethics and Governance of Artificial Intelligence for Health* (Guidance, 28 June 2021) 1, 28 <https://www.who.int/publications/i/item/9789240029200>.

and disease on the basis of disability and need, rather than cause'.[162] The transformative potential of the technology in clinical care arguably calls for a model that offers secure safety nets to patients when the risks identified in Part III materialise. The complexity of AI clinical tools may otherwise put injured patients at a serious structural disadvantage if required to individually pursue liability actions (whether in negligence or product liability).[163]

In parallel to no-fault compensation, which addresses the challenge of equitably responding to harm, is the issue of actual attribution of liability. One suggested model is that of enterprise liability, in which institutional actors, including hospitals and AI developers, collectively bear legal responsibility.[164] This model acknowledges that accidental harm is often a by-product of organised activities rather than isolated individual actions. It reflects the reality that harm frequently results from systemic interactions involving technology, institutional processes, and clinical practice.[165] It is also grounded in the principle that those who benefit from an activity should also bear its burdens, thereby promoting fairness and accountability.[166] It may involve holding developers, manufacturers, or deployers of AI systems jointly liable for harm associated with the use of AI clinical tools. By attributing liability to organisations as part of the broader enterprise engaged in the design, deployment, and governance of AI clinical tools, enterprise liability can provide a structurally responsive framework to the multilayered nature of the challenges posed by AI clinical tools.

While theoretically sensible, this two-pronged approach can be politically challenging as shifting away from established liability models is not necessarily practical. As Mark Forwood highlights, Australian jurisdictions have historically shown limited appetite for broad no-fault compensation schemes, with the Whitlam Government's Woodhouse proposals and later initiatives after the 2002 insurance crisis failing to secure national adoption.[167] Similarly, a 'No Fault Compensation' paper prepared for the NSW Parliament emphasised that political

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[162] Genevieve Grant and Harold Luntz, 'The Accident Preference, "Unrigorous Thinking" and Injury Compensation Schemes' in Kylie Burns et al (eds), *Torts on Three Continents: Honouring Jane Stapleton* (Oxford University Press, 2024) 473, 473.
[163] Luciano Floridi et al, 'AI4People: An Ethical Framework for a Good AI Society: Opportunities, Risks, Principles, and Recommendations' (2018) 28 *Minds & Machines* 689, 694.
[164] Benny Chan, 'Applying a Common Enterprise Theory of Liability to Clinical AI Systems' (2021) 47(4) *American Journal of Law & Medicine* 351, 352, 375–6.
[165] Gregory Keating, *Reasonableness and Risk: Right and Responsibility in the Law of Torts* (Oxford University Press, 2024) 336, 359.
[166] Ibid 341–2.
[167] Mark R Forwood, 'Whither No-Fault Schemes in Australia: Have we Closed the Care and Compensation Gap?' (2018) 43(3) *Alternative Law Journal* 166, 166.

caution, cost concerns, and resistance from insurers and litigation lawyers have constrained reform, even as technological and systemic changes have exposed gaps in fault-based systems.[168] These findings are consistent with the ongoing resistance of both federal and state governments to deploy general no-fault compensation schemes for vaccine injuries, despite their common nature in comparable countries.[169] However, existing no-fault schemes, such as WA's Catastrophic Injuries Support scheme, are confined to clearly identified types of harm or contextual settings.[170] When emerging risks, such as catastrophic motor injuries, have revealed intrinsic weaknesses of traditional liability models, calls for no-fault approaches have re-emerged. Arguably, AI in clinical settings presents a comparable inflection point. In August 2011, the Productivity Commission ('PC') of the federal Treasury recommended the establishment of a National Injury Insurance Scheme ('NIIS').[171] The PC recommended that a NIIS be developed for catastrophic injuries caused by four types of accidents: motor vehicle accidents, workplace accidents, medical accidents, and general accidents (occurring in the home or community).[172] Subsequently, the Treasury published a 'draft without prejudice' medical treatment injury discussion paper to examine the issues around possible minimum benchmarks for compensation for medical injury within a NIIS.[173] Revisiting no-fault models, whether through a tailored extension of the WA scheme or the NIIS, or through the introduction of a bespoke one, could provide timely redress for AI-related harms.

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[168] Talina Drabsch, NSW Parliamentary Library Research Service, *No Fault Compensation* (Briefing Paper No 6/05, May 2005) 11.

[169] Duncan Fairgrieve et al, 'Comparing No-Fault Compensation Systems for Vaccine Injury' (2023) 31(1) *Tulane Journal of International and Comparative Law* 75, 78, 82–4; Australian Government, Department of the Prime Minister and Cabinet, *Commonwealth Government COVID-19 Response Inquiry Report* (Inquiry Report, October 2024) 270–1; Anastasia Tsirtsakis, 'No-Fault Indemnity Should Apply to all Vaccines', *News GP* (online, 10 August 2021) <https://www1.racgp.org.au/newsgp/professional/no-fault-indemnity-should-apply-to-all-vaccines-ra>.

[170] 'Catastrophic Injuries Support', *Insurance Commission of Western Australia* (Web Page) <https://www.icwa.wa.gov.au/motor-injury-insurance/catastrophic-injuries-support>. The Catastrophic Injuries Support ('CIS') Scheme is a no-fault scheme which provides eligible people with necessary and reasonable treatment, care, and support, in some cases for their lifetime. Anyone who experiences serious personal injuries as a result of a motor vehicle accident in WA on or after 1 July 2016, or a workplace accident on or after 1 July 2024, may be eligible to receive support from the CIS Scheme.

[171] 'National Injury Insurance Scheme', *The Treasury* (Web Page) <https://treasury.gov.au/programs-initiatives-consumers-community/niis>.

[172] Ibid.

[173] Australian Government Treasury, *Medical Treatment Injury Discussion Paper* (Draft Discussion Paper, 2019) 1, 2–4 <https://treasury.gov.au/sites/default/files/2019-03/Medical_treatment_injury_discussion_paper.pdf>.

2 *Risk Pooling*

Another proposed model to address the challenges of current liability frameworks is risk pooling, which involves the spreading of liability among stakeholders, typically through insurance mechanisms.[174] It provides a structure for compensating patients harmed through the use of AI clinical tools by distributing risk across developers, healthcare providers, insurers, and institutions. Related to an enterprise liability framework, risk pooling is based on the principle that those who benefit from a risky activity should share responsibility for any resulting harm.[175] This model invites comparison with the United Kingdom's *Automated and Electric Vehicles Act 2018* ('*AEVA 2018*'), a joint insurance scheme where compensation is awarded without fault attribution and insurers can later seek recovery if appropriate.[176] The *AEVA 2018* was enacted to establish an insurance and liability framework for Connected and Autonomous Vehicles ('CAVs'), mandating that insurers compensate third parties in accidents caused by the vehicle's autonomous operation, with a right of recovery against the manufacturer or responsible party.[177] This legislation is regarded as proactive, and therefore suitable for addressing future challenges, and as providing certainty for accident victims and stakeholders, ensuring compensation even in complex liability scenarios.[178] However, the *AEVA 2018* faces practical barriers due to some broad and imprecise definitions associated with, for example, 'automated vehicle' and 'accident', and has therefore been criticised for creating uncertainty for insurer recovery processes and software liability.[179] Such uncertainty has raised concerns in relation to regulatory disconnection and the hindering of innovation.[180] Despite the criticism, the principle of risk pooling can still provide useful guidance to the WA healthcare setting, where the current liability regimes lack clear mechanisms to allocate liability when harm arises from health practitioner reliance on AI outputs. This model also aligns with growing calls at an international level for law reform to

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[174] Smith and Fotheringham (n 5) 146.
[175] Ibid 147–8.
[176] Ibid 150.
[177] *Automated and Electric Vehicles Act 2018* (UK) ss 2(1), 5(1).
[178] Matthew Channon, 'Automated and Electric Vehicles Act 2018: An Evaluation in Light of Proactive Law and Regulatory Disconnect' (2019) 10(2) *European Journal of Law and Technology* 1, 2.
[179] Ibid 6–7.
[180] Ibid.

consider the use of risk pooling, alongside detailed professional guidance for the use of AI in healthcare spaces.[181]

VI CONCLUSION

This article has examined the current legal frameworks in WA which potentially apply in a scenario where patient harm is associated with the use of AI clinical tools in clinical practice. Rather than assessing whether the current system is fully adequate, this article has presented an overview of the key legal principles that may apply in such situations, particularly those found in negligence law and the ACL. These frameworks provide established mechanisms for addressing liability in healthcare settings, but they were developed in the context of human decision-making and traditional medical products, raising questions about their adequacy in cases involving AI-driven technologies and the specific risks these technologies present.

The discussion highlights the dependence of negligence actions on proof of fault, which can be prohibitive in cases where AI plays a role in clinical decision-making. Similarly, the ACL's product liability provisions are designed for static products rather than evolving AI systems that adapt over time. While these legal mechanisms continue to offer viable avenues for redress, we question their ability to adequately address AI-related harm in their current form.

Regulatory discussions on AI governance in Australia are ongoing, with recent proposals indicating a shift toward a risk-based approach to AI regulation. In September 2024, the federal Department of Industry, Science, and Resources proposed mandatory guardrails for high-risk AI applications,[182] including clinical AI tools, emphasising transparency, accountability, and risk management across the AI lifecycle.[183] Additionally, the federal Department of Health, Disability and Ageing has conducted a legislative review focusing on high-risk AI systems in healthcare.[184] However, at this stage, action is yet to be taken on these proposals,

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[181] Kit Fotheringham and Helen Smith, 'Accidental Injustice: Healthcare AI Legal Responsibility Must be Prospectively Planned Prior to its Adoption' (2024) 11(3) *Future Healthcare Journal* 1, 2.
[182] Australian Government, Department of Industry Science and Resources, *Safe and Responsible AI in Australia: Proposals Paper for Introducing Mandatory Guardrails for AI in High-Risk Settings* (September 2024).
[183] Ibid 30–42.
[184] Australian Government, Department of Health, Disability and Ageing, *Safe and Responsible Artificial Intelligence in Health Care: Legislation and Regulation Review* (Final Report, March 2025) 1, 3.

and in the absence of legal enforcement mechanisms, they can only serve as policy guidance.

As AI continues to integrate into clinical practice, it is important to consider whether WA's current liability framework provides sufficient clarity for both patients and health professionals when harm occurs in association with the use of AI clinical tools. This article has outlined liability mechanisms currently available in WA and canvassed potential alternatives. In particular, the combination of a no-fault compensation system with enterprise liability or a form of risk pooling could provide a more appropriate alternative to managing AI-related harm. While conceptually viable, these options will of course raise questions around political feasibility, financial implications, and specific details of regulatory reform involved, and further research is needed to fully unpack these aspects.

Finally, further research is also needed to understand how healthcare professionals navigate liability risks under the current system, especially the challenges associated with real-world implications of the HITL approach discussed in this article. Studying how health practitioners respond to AI-related legal challenges in practice will provide critical evidence to understand what reforms are necessary to ensure accountability and confidence in AI-driven healthcare.

REGULATING HIGH-RISK TECHNOLOGIES: COMPARING REGULATORY APPROACHES TO ARTIFICIAL INTELLIGENCE AND GENE TECHNOLOGY

HARIS YUSOFF*

Artificial intelligence ('AI') systems are increasingly used in high-stakes contexts such as healthcare, where their application can directly influence patient outcomes, reinforce health inequalities, and erode public trust. In recognition of these stakes, the accompanying risks, and the promised gains of AI systems, the Australian Government has issued a set of policy documents revealing its intention to enact horizontal AI legislation in pursuit of its opaque 'Safe and Responsible' AI agenda. In doing so the Government takes express inspiration from the newly enacted European Artificial Intelligence Act, favouring a similar risk-based framework, embedding product safety principles, and proposing regulatory features compromised by a pro-industry objective. These are insufficient to protect against the unpredictable nature and complex risks posed by health-related AI systems. This article seeks to inform Australia's policy choices, not only by critiquing the European framework, but by arguing that inspiration should be drawn from another legislative scheme reflecting over two decades of national experience regulating a comparably high-risk and unpredictable technology: gene technology as regulated under the Gene Technology Act 2000 (Cth). Comparing the two legislative frameworks reveals that the Gene Technology Act takes a precautionary, high-touch, and granular approach to regulating risk and achieves this by centralising risk assessment through evidence-based decision-making with significant public participation and accountability. Australia still has the opportunity to overcome deficiencies in the Artificial Intelligence Act, and it can do so by learning from how the European regime understands AI technologies, while also introducing the rigorous structural protections of the Gene Technology Act to regulate AI systems in a responsible and safe manner.

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I INTRODUCTION

This article engages with two technologies, gene technology and artificial intelligence. Gene technology is a 'modern branch of biotechnology' that allows for changes to be made in the genes of organisms.[1] Australia regulates gene technology under the *Gene Technology Act 2000* (Cth) ('*GTA*').[2] At the centre of the *GTA*'s regulatory scheme is the Office of the Gene Technology Regulator ('the Regulator'), an independent statutory body tasked with identifying and managing risks posed by gene technology.[3]

Gene technology has applications in various medical contexts, such as vaccine production, as well as agricultural contexts, such as improving crop resistance and yield.[4] The *GTA*, in turn, protects against risks posed to (1) human health, such

[1] Australian Government Department of Health, Office of the Gene Technology Regulator ('OGTR'), *What is Gene Technology?* (Factsheet, June 2018) 1.
[2] *Gene Technology Act 2000* (Cth) ('*GTA*').
[3] Australian Government Department of Health and Aged Care, *Office of the Gene Technology Regulator* (Web Page, 22 April 2024) <https://ogtr.gov.au/>.
[4] Senate Standing Committee on Community Affairs, *A Cautionary Tale; Fish Don't Lay Tomatoes*: *A Report on The Gene Technology Bill 2000* (Report, November 2000) ('*Senate Report on Gene-Tech Bill 2000*') 15–17.

as through ingestion or bodily exposure to genetically modified organisms (the regulatory subject of the *GTA*);[5] and (2) environmental risks such as to non-target flora and fauna.[6]

The second technology discussed in this article is Artificial Intelligence ('AI'). AI systems are 'machine-based' systems that infer, from input (ie, data) they receive, 'how to generate outputs such as predictions, content, recommendations, or decisions'.[7] This article will focus on health-related AI applications, which vary significantly in their adaptiveness and autonomy, spanning tools that perform disease diagnosis or clinical decision-making assistance, to those predicting hospital readmission or health insurance pricing.

While definitions of health-related AI applications are often limited to clinical decision-making tools that constitute 'Medical Devices',[8] this article will consider the full spectrum of possibilities with a view to informing new governance frameworks for AI in health more generally, not only as they relate to existing legislative frameworks.

As happened previously with gene technology, governments have faced increasing pressure to regulate AI systems by virtue of increased awareness surrounding potential risks.[9] These risks are more expansively conceived than those associated with gene technology, and in addition to primary health and safety concerns, include discrimination based on biased outputs, reinforcement of health inequalities, inaccuracies in inputs, lack of accountability, and even existential risks.[10]

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[5] Ibid 20–1; Gabrielle M O'Sullivan et al, '20 Years of Legislation: How Australia Has Responded to the Challenge of Regulating Genetically Modified Organisms in the Clinic' (2022) 9 *Frontiers in Medicine* 1, 9 ('20 Years of Legislation').

[6] *Senate Report on Gene-Tech Bill 2000* (n 4) 27–32; Michael Meissle, Steven E Naranjo and Jörg Romeis, 'Does the Growing of Bt Maize Change Abundance or Ecological Function of Non-Target Animals Compared to the Growing of Non-GM Maize? A Systematic Review' (2022) 11(1) *Environmental Evidence* 1, 2.

[7] This is a definition endorsed by the Organisation for Economic Cooperation and Development ('OECD') member countries, including Australia and the European Union. See OECD, *Explanatory Memorandum on the Updated OECD Definition of an AI System* (OECD Artificial Intelligence Papers No 8, 5 March 2024) 4.

[8] This is typical to align discussions with definitions found in medical device legislation. See, eg, *Therapeutic Goods Act 1989* (Cth) ('*TGA*').

[9] See generally Australian Human Rights Commission, *Human Rights and Technology* (Final Report, 1 March 2021) ('*AHRC Report on Human Rights and Technology*').

[10] Australian Government Department of Industry, Science and Resources, *Safe and Responsible AI in Australia Consultation: Australian Government's Interim Response* (Interim Report, 17 January 2024) 10–1 ('*Interim Discussion Paper*').

Australia, unlike other jurisdictions such as the European Union ('EU'), has not enacted AI-specific legislation to address these risks. However, inspired by other jurisdictions, in 2023–24 the Australian Government signalled an intent to begin drafting AI legislation through a discussion paper, *Safe and Responsible AI in Australia* ('*Interim Discussion Paper*'), and a *Proposals Paper for Introducing Mandatory Guardrails for AI in High-Risk Settings* ('*Proposals Paper*').[11] Alongside other policy documents, these comprise the Government's stated approach to achieving Safe and Responsible AI in Australia, which recognises AI in healthcare as a high-risk priority sector.[12] While horizontal legislation is anticipated (ie, legislation will apply to AI generally and will not be health or sector specific), this framework will be the main safeguard for health-related AI risks alongside less comprehensive privacy and medical device legislation.[13]

A distinct source of influence in the Government's proposed approach to AI regulation is the EU's newly enacted AI legislation, *Regulation 2024/1689 Laying Down Harmonised Rules on Artificial Intelligence*.[14] This Regulation is known as the *Artificial Intelligence Act* ('*AIA*'), and has inspired several of the Australian Government's proposed regulatory features, including categories that distinguish AI systems by risk level, with proportionate industry-friendly obligations overlaid across a highly decentralised model.

Australia is at a turning point in deciding the appropriate regulatory model for AI and should exercise significant caution in emulating a foreign, untested, and widely critiqued framework. Rather, this article argues that the Government should instead look domestically to find valuable and proven experience in regulating a similarly disruptive and high-risk technology — gene technology as regulated under the *GTA*. The *GTA* has a 22-year track record as an evidence-informed, technology-specific regulatory model, created in response to an emerging technology with far-reaching health consequences.

This article draws on more than two decades of direct national experience to directly illuminate a number of the policy choices that Australia faces in creating AI legislation. Lessons from the *GTA* will be drawn out by interposing the domain-specific example of European AI regulation under the *AIA*. While AI and

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[11] Ibid; Australian Government, Department of Industry, Science and Resources, *Safe and Responsible AI in Australia: Proposals Paper for Introducing Mandatory Guardrails for AI in High-Risk Settings* (September 2024) ('*Proposals Paper*').
[12] *Proposals Paper* (n 11) 4, 56.
[13] *Privacy Act 1988* (Cth); *TGA* (n 8).
[14] *Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations* [2024] OJ L 2024/1689 ('*AIA*').

gene technology differ in many respects, there are comparable regulatory features, mechanisms, and objectives in the *GTA* and *AIA* that are also reflected in the Australian Government's stated objectives for future AI regulation. Two primary questions are addressed. First, how are risks presented by AI systems and gene technologies, particularly those posed to health, identified and addressed in these two discrete legislative instruments? Second, learning from this, what comparative lessons do these instruments present for the prospective regulation of health-related AI systems in Australia?

The article is divided into three parts. Part II will address how the *AIA* and *GTA* identify and address the risks of AI and gene technology. Given the novelty of the *AIA*, the absence of recent scholarship on the *GTA*, and the complexities of these frameworks, a large proportion of this part is necessarily descriptive. Part III will compare provisions of the *GTA* and *AIA*, responding to the emerging body of critical literature surrounding the *AIA* with demonstrations of how the *GTA* has functionally addressed many of the deficiencies raised with the *AIA*. Part IV will address what comparative lessons the *GTA* and *AIA* present for the prospective regulation of health-related AI systems in Australia. This will involve contextualising the stated priorities of the Australian Government in relation to AI and identifying distinct comparative features from Part III that inform policy choices available to Australia in pursuing AI regulation.

It is typical in law and technology to reference the 'pacing problem' — the notion that regulation persistently lags behind technological advancements,[15] particularly those with fast-moving risks.[16] Scholars have challenged this notion as being inconsistent with law in practice,[17] and the *GTA* serves as a practical example of new legal regimes that have been created in a timely manner in response to technological developments. Comparative analysis of the *AIA* is particularly pertinent in this context given the power of the European bloc and the influence of EU law internationally (often referred as the 'Brussels effect').[18]

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[15] Steven Feldstein, 'Evaluating Europe's Push to Enact AI Regulations: How Will This Influence Global Norms?' (2023) 31(5) *Democratization* 1049, 1050.

[16] For AI, see *Interim Discussion Paper* (n 10) 4–6; *AHRC Report on Human Rights and Technology* (n 9). For gene technology, see *Senate Report on Gene-Tech Bill 2000* (n 4); James Collins, 'Gene Drives in Our Future: Challenges of and Opportunities for Using a Self-Sustaining Technology in Pest and Vector Management' (2018) 12(8) *BMC Proceedings* 9.

[17] See generally Joshua AT Fairfield, *Runaway Technology: Can Law Keep Up?* (Cambridge University Press, 2021).

[18] See especially Anu Bradford, *The Brussels Effect: How the European Union Rules the World* (Oxford University Press, 2020).

This article's findings demonstrate the utility of the comparative approach, both for current AI policymaking and the regulation of emerging health technologies more broadly. First, this article demonstrates that the *GTA* takes a precautionary, high-touch, and granular approach to regulating risk — necessary in a high-stakes health context — and achieves this by centralising risk assessment through evidence-based decision-making with significant public participation and accountability. By contrast, the *AIA* adopts a facilitative, pro-industry approach by only modestly regulating 'limited-risk' and 'minimal-risk' AI systems, externalising risk management of 'high-risk' AI systems to AI providers, internalising political agendas, and limiting public participation and accountability.

Further, the *GTA* demonstrates structural separation in its regulatory arrangements between political concerns, scientific expertise, and ethical and community considerations.[19] This affords flexibility to the Regulator in navigating evolving technological development, scientific understanding, and political and community expectations. This structural sophistication is not seen in the *AIA*'s approach, which has been critiqued as full of 'political compromises' and overly prescriptive in the face of complex AI-powered health tools.[20]

II UNDERSTANDING THE *GTA* AND THE *AIA*

This part addresses the question of how two legislative instruments, the *GTA* and the *AIA*, identify and address risks posed by gene technology and AI respectively.

A *Gene Technology Act*

First proposed by the Federal Government in June 2000, the *GTA* entered into force on 21 June 2001.[21] The *GTA* functions within a broader regulatory scheme, comprising the *GTA*, the *Gene Technology Regulations 2001* (Cth) ('*GT Regulations*'),[22] the intergovernmental *Gene Technology Agreement 2001*

[19] David Tribe, 'Gene Technology Regulation in Australia: A Decade of a Federal Implementation of a Statutory Legal Code in a Context of Constituent States Taking Divergent Positions' (2012) 3(1) *GM Crops & Food* 21, 21.
[20] Lillian Edwards, *Expert Opinion: Regulating AI in Europe: Four Problems and Four Solutions* (Ada Lovelace Institute, 31 March 2022) 25; Health Action International, *Interpreting the EU Artificial Intelligence Act for the Health Sector* (Report, February 2022) 14, 19.
[21] Australian Government Department of Health, OGTR, *Retrospective Report 1: Overview of the Scheme* (Report, 21 June 2021) 3–4.
[22] *Gene Technology Regulations 2001* (Cth) ('*GT Regulations*').

('*GT Agreement*'),[23] and corresponding state and territory legislation.[24] The *GTA* establishes the various bodies and stages of regulation that identify and manage risks posed by gene technologies, while the *GT Regulations* manage scope by clarifying technical definitions, setting decision-making timelines for subsidiary bodies, and serving other practical functions. The *GT Agreement* facilitates a consistent national scheme by outlining various understandings and cooperative measures between federal, state, and territory jurisdictions.

Within the *GTA*, two key terms are defined — 'gene technology' and 'genetically modified organism' ('GMO'). Gene technology is defined expansively to mean 'any technique for the modification of genes or other genetic material'.[25] GMOs include organisms modified by gene technology, as well as organisms with inherited traits because of a previous organism's genetic modification.[26] The *GT Regulations* provide clear examples of when an organism may be automatically excluded as a GMO (eg, a previously modified organism no longer demonstrating traits of modification).[27] As outlined in the explanatory statement to the *GT Regulations*, these definitions are intentionally broad to ensure they do not 'become outdated and ineffectual in response to rapidly changing technology'.[28]

1 *Regulatory Objective and Trigger*

The *GTA*'s stated objective is 'to protect the health and safety of people, and to protect the environment by identifying risks posed by or as a result of gene technology'.[29] To achieve this protective objective, the *GTA* functions under what the policy documents term a pre-market 'process trigger'.[30] This means that, rather than the *GTA* prescribing a list of final *characteristics* of a GMO that may trigger regulatory intervention (namely a 'product trigger'), it is instead the

[23] *Gene Technology Agreement 2001* ('*GT Agreement*').
[24] *Gene Technology Act 2003* (ACT); *Gene Technology Act 2003* (NSW); *Gene Technology Act 2004* (NT); *Gene Technology Act 2016* (Qld); *Gene Technology Act 2001* (SA); *Gene Technology Act 2012* (Tas); *Gene Technology Act 2001* (Vic).
[25] *GTA* (n 2) s 10.
[26] Ibid.
[27] *GT Regulations* (n 22) schs 1A–1B.
[28] Explanatory Statement, 'Gene Technology Regulations 2001 No 106)' (Cth) 3.
[29] *GTA* (n 2) s 3.
[30] Australian Government, Department of Health, Disability and Ageing, *Third Review of The National Gene Technology Scheme* (Final Report, October 2018) ('*Gene Technology Scheme Third Review Report*') 36.

process of interacting with an organism through gene technology that triggers regulation.[31]

Importantly, this process trigger is recognised — both by scholars and policymakers — as a preventative and predictable approach to a fast-moving technology presenting indeterminate risks.[32] The existence of indeterminate risk was a prevalent topic in the *GTA*'s legislative history, frequently referenced alongside the 'precautionary principle'.[33] This is an established legal principle often present in health legislation, prioritising scientific certainty and, in the absence of such, requiring significant caution in proceeding with an action.[34]

While the *GTA*'s text does not explicitly refer to the precautionary principle, its discussion in both drafting phases and the risk analysis framework accompanying the *GTA* means that the principle is implicit in the final design of the Act.[35] The precautionary approach is also functionally integrated into the *GTA*, as at *no stage* of risk analysis is the potential utility or economic benefit of a gene technology considered.[36] As discussed in Part III, this precautionary approach contrasts sharply with the *AIA*.

2 *Categories of Regulation*

The *GTA* regulates 'dealings' with GMOs, which includes, for example, making, breeding, supplying, or possessing GMOs.[37] Dealings are prohibited unless they fall within one of four streams: a licenced dealing, an exempt dealing, a notifiable low-risk dealing, or an emergency dealing. For all dealings, approval must be sought from the Regulator. This approval process involves (1) an application to the Regulator — involving a risk assessment and risk management process;

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[31] Peter Thygesen, 'Clarifying the Regulation of Genome Editing in Australia: Situation for Genetically Modified Organisms' (2019) 28(S2) *Transgenic Research* 151, 151; Joe Smith and Heidi Mitchell, 'Challenges Researchers Need to Consider When Dealing with Regulators' (2014) 9(S1) *Journal für Verbraucherschutz und Lebensmittelsicherheit* 65, 68.

[32] Thygesen (n 31) 152–3; O'Sullivan et al, '20 Years of Legislation' (n 5) 2; *Gene Technology Scheme Third Review Report* (n 30) 36–7.

[33] *Senate Report on Gene-Tech Bill 2000* (n 4) 23, 32; Sumit Salaria, 'Governing Genes for Climate Change: Analysing Values and Ideologies in Australia's Gene Technology Regulation' (Masters Thesis, Macquarie University, 2015) 94.

[34] Zada Lipman, 'Gene Technology Regulation and the Precautionary Principle: How Australia Measures Up' (2005) 8(1) *Journal of International Wildlife Law & Policy* 63, 66–8.

[35] *Senate Report on Gene-Tech Bill 2000* (n 4) 32–45; Australian Government, Department of Health, Disability and Ageing, OGTR, *Risk Analysis Framework 2013* (Policy Publication, May 2013) ('*Risk Analysis Guidance Framework*') 9.

[36] *Risk Analysis Guidance Framework* (n 35) 13–14; O'Sullivan et al, '20 Years of Legislation' (n 5) 4.

[36] *GTA* (n 2) s 10.

[37] Ibid.

(2) for successful cases, an approval with conditions (eg, licence conditions or facility accreditation requirements); and (3) ongoing regulatory compliance by the person dealing with the GMO.[38] Stage (3) will be revisited in discussions of accountability below.

(a) Licenced dealings

The most common type of approval at stage (2) is the provision of a licence, with the majority now involving human therapeutics.[39] Three specific situations under the *GTA* are envisaged as giving rise to a licence. First, an 'inadvertent dealings' licence may be available to a person who has unintentionally come into possession of a GMO, for example through unauthorised importation of a genetically modified plant.[40] This functions as a 12-month (maximum) licence permitting further dealings with, including the destruction of, a GMO.[41]

A licence is also required in two other scenarios: 'intentional release' of a GMO into the external environment,[42] or 'intentional release' within a containment facility.[43] The focus of the *GTA* is on these two streams, which typically involve higher risk applications such as in vivo human gene therapy.[44] Licences will be issued if, following risk analysis, the Regulator is satisfied that risks posed by the dealings are able to be managed in a way that protects the health and safety of people, and the environment.[45] Risk analysis is complex and central to the scheme, with licence conditions and reasons for approval made publicly accessible on the Regulator's website.[46]

(b) Exempt dealings and notifiable low-risk dealings

For both exempt and notifiable low-risk dealings, applications will be approved if particular risk management conditions are met in a certified containment facility. For notifiable low-risk dealings, the Regulator must consider the risks posed to

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[38] 'Approval Process Overview', *OGTR* (Web Page, 30 January 2024) <https://www.ogtr.gov.au/about-approval-process/process-overview>.
[39] 'Types of GMO Dealings', *OGTR* (Web Page, 29 January 2024) < https://www.ogtr.gov.au/about-approval-process/types-gmo-dealings>.
[40] 'Licence Application ID-01', *OGTR* (Web Page, 1 June 2017) <https://www.ogtr.gov.au/what-weve-approved/inadvertent-dealings-id>.
[41] *GTA* (n 2) s 60(3).
[42] Ibid pt 5 div 4.
[43] Ibid pt 5 div 3; OGTR, 'What Do We Mean by Intentional Release?' (Media Release, 22 April 2024) <https://ogtr.gov.au/news/announcement/what-do-we-mean-intentional-release>.
[44] O'Sullivan et al, '20 Years of Legislation' (n 5) 4.
[45] *GTA* (n 2) div 5.
[46] *GTA* (n 2) s 40A(1); 'What We've Approved?', *OGTR* (Web Page, 3 March 2025) <https://www.ogtr.gov.au/what-weve-approved>.

human health, safety, and the environment before the dealing is listed as low-risk in the *GT Regulations*.[47] For exempt dealings, the Regulator has less of a decision-making role for individual approvals as these typically 'correspond to basic molecular biology methods', such as those used in university research laboratories.[48] Despite this, the Regulator may at any time review — meaning revise, de-list, or add a dealing to — the current list of these dealings provided in the *GT Regulations*.[49] If either dealing is intentionally released, it no longer falls within its approval and requires a new licence.[50]

(c) Emergency dealings

In exceptional circumstances of an 'actual or imminent threat' to either human health and safety or to the environment (eg, disease breakout or pests), the *GTA* provides for an emergency dealing determination. This determination allows for the Minister responsible for gene technology[51] to expedite an approval process for a dealing to either temporarily declare something a GMO or to permit the removal of licencing conditions.[52] Emergency dealing determinations are subject to advice from the Regulator,[53] and carry specific case-by-case conditions.[54]

In summary, the *GTA* functions under a process trigger creating different regulatory streams for GMO dealings, tiered to both context of use and risk. There are two important consistencies across these different streams that will inform the comparison in Part III. First, risk is framed from a *consistent* and legislated perspective — that is, risks posed to human health and safety and the environment. Second, the Regulator maintains a key decision-making role across each of the four streams of regulated dealings. The next section provides a detailed example of this decision-making process for the *GTA's* two main sub-streams of licensed dealings: intentional environment releases and intentional contained releases.

3 *Decision-Making Process and Risk Management Structure*

Prior to approving licences for GMO releases that are either intentional releases into the external environment, or intentional releases in a containment facility,

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[47] *GT Regulations* (n 22). For notifiable low-risk dealings see s 74; for exempt dealings see div 7.
[48] Tribe (n 19) 26.
[49] *GTA* (n 2) div 7.
[50] *GT Regulations* (n 22) s 6(1)(d).
[51] This is the Minister for Health and Aged Care.
[52] *GTA* (n 2) pt 5A div 3.
[53] Ibid s 72B(2)(c).
[54] OGTR, *Guidelines for Emergency Response Under the Gene Technology Act 2000 and the Gene Technology Agreement* (Guidance Document, July 2009) 11.

the Regulator must prepare Risk Assessment and Risk Management Plans ('RARMPs').[55] Structured from guidance documents prepared by the Regulator, RARMPs are detailed documents of 40–80 pages in length that individually assess potential sources of risk, specify methods for management, and impose necessary licence conditions. For GMOs used in medical applications, RARMPs typically consider factors including pathogenicity and transmissibility.[56] During the drafting stages of RARMPs, the Regulator typically invites and considers public submissions during designated consultation periods.[57]

(a) Centralised RARMP support: technical and ethics expertise

Various expert bodies support the preparation of RARMPs. The Gene Technology Technical Advisory Committee ('Technical Committee') must be consulted for every approved dealing,[58] and in turn provides expert advice on *technical* and *scientific* aspects of gene technology.[59]

Since the *GTA* was enacted, the Technical Committee has held over 80 meetings to address licence applications, with public communiques issued after each meeting.[60] These communiques advise the Regulator on specific matters to consider in preparing RARMPs, such as the potential for accidental exposure of a GMO to humans, or to seek further information from an applicant regarding, for example, specific contents of a vaccine.[61] The Technical Committee is comprised of members with domain-specific scientific backgrounds, including immunologists, molecular biologists, crop scientists, and biosafety experts.[62] It is mandated under the *GTA* that this body contains a 'broad range of skills', including the appointment of a layperson and a member from the ethics body discussed

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[55] *GTA* (n 2) ss 47, 50.
[56] See, eg, OGTR, *Risk Assessment and Risk Management Plan (consultation version) for DIR 198: Clinical trial of a genetically modified alphavirus (Getah virus) for cancer treatment* (Risk Management Plan, 22 August 2023).
[57] This is permitted under *GTA* s 51(3). See, eg, OGTR, *Risk Assessment and Risk Management Plan for DIR 184: Clinical Trial with a Genetically Modified Human Adenovirus COVID-19 Vaccine* (Risk Management Plan, 25 June 2021); OGTR, *Risk Assessment and Risk Management Plan for DIR 185: Clinical Trial with Genetically Modified Bordetella Pertussis (BPZE1) for the Prevention of Whooping Cough* (Risk Management Plan, 8 December 2021).
[58] Note the statutory use of 'must' in *GTA* (n 2) s 50(3).
[59] Ibid s 101.
[60] 'Gene Technology Technical Advisory Committee', *OGTR* (Web Page, 3 July 2024) <https://www.ogtr.gov.au/committee/gttac>.
[61] See, eg, Gene Technology Technical Advisory Committee, '18 December 2023' (Communiqué, 18 December 2023) 2.
[62] See OGTR, *Gene Technology Technical Advisory Committee (GTTAC)* (Report, 4 July 2025).

directly below — both without the need for specific expertise in gene technology.[63]

In some but not all cases, the Regulator also consults the Gene Technology Ethics and Community Consultative Committee ('Ethics Committee').[64] Since the formation of the Ethics Committee in 2008, 18 meetings have been held. These meetings typically address general ethical issues as prompted by the Regulator, rather than specific matters within individual licence applications.[65] For example, the Ethics Committee has considered how concepts such as 'safety by design' may be incorporated into RARMPs, ethical considerations of consent and privacy when considering humans as GMOs,[66] and implications of public attitude surveys towards gene technology.[67]

As mandated under statute, the Ethics Committee is comprised of members with expertise in risk, bioethics, law, community engagement, and the environment.[68] While both committees can operate with significant flexibility, the *GT Regulations* outline their reporting and decision-making requirements, as well as disclosure of interest protocols.[69]

(b) Decentralised RARMP support: IBCs

The *GTA* also provides for the establishment of Institutional Biosafety Committees ('IBCs') which are formed upon accreditation by the Regulator.[70] These bodies facilitate decentralised risk management as they are embedded in regulated institutions,[71] similar to food safety,[72] pharmacovigilance,[73] or research ethics committees in other contexts.[74] The role of these IBCs includes evaluating low-risk dealings that do not require individual Regulator assessment, as well as

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[63] *GTA* (n 2) s 100(5)–(8).
[64] Note the statutory use of 'may' in *GTA* (n 2) s 47(4).
[65] Ibid s 107.
[66] See generally Gene Technology Ethics and Community Consultative Committee, 'Meeting of 22 November 2022' (Communiqué, 22 November 2022).
[67] 'Gene Technology Ethics and Community Consultative Committee (GTECCC)', *OGTR* (Web Page, 8 July 2021) <https://ogtr.gov.au/committee/gteccc>.
[68] *GTA* (n 2) s 108. See OGTR, *Gene Technology Ethics and Community Consultative Committee* (Report, 16 September 2025).
[69] *GT Regulations* (n 22) pts 4–5.
[70] Ibid pt 7 div 3.
[71] Tribe (n 19) 26.
[72] 'Food Safety Supervisor', *Food Standards Australia New Zealand* (Web Page, 3 February 2022) <https://www.foodstandards.gov.au/business/food-safety/fact-sheets/food-safety-supervisor>.
[73] Therapeutic Goods Administration, *Pharmacovigilance responsibilities of medicine sponsors: Australian recommendations and requirements* (Report, August 2023) 24.
[74] 'Human Research Ethics Committee', *National Health and Medical Research Council* (Web Page) <https://www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-committees>.

coordinating the preparation and implementation of RARMPs.[75] The Regulator has issued guidance documents regarding this in-house risk management, establishing requirements such as a breadth of expertise and the need for at least one external member within the IBC (ie, without formal association to the organisation in question), as well as specific requirements for the type of genetic manipulation that may be conducted.[76]

(c) Political support: Ministers Meeting and Standing Committee

To facilitate the scheme's practical operation, the *GT Agreement* provides for the creation of the Gene Technology Ministers Meeting ('Ministers Meeting'). This body is composed of one government minister from each jurisdiction (federal, state, and territory), and engages in tasks including advising on the composition of the Regulator, initiating reviews of the scheme, and issuing administrative guidelines to manage the Regulator's activities.[77] The Gene Technology Standing Committee ('Standing Committee') provides high-level support to the Ministers Meeting and is similarly composed of senior government officials.

The work of these two bodies is more political in nature than that of the Technical Committee, Ethics Committee, and IBCs, as it extends to facilitating jurisdictional coordination, drafting policy frameworks, and maintaining ministerial presence in the Regulator's actions.[78] However, the Ministers Meeting and Standing Committee are not involved directly in RARMP applications, ensuring that these bodies do not politicise the central work of the Regulator.

4 *Review, Public Participation, and Accountability*

A key feature of the scheme is that it contains robust mechanisms for review, public participation, and accountability. Legislative review begins with the Standing Committee, which is mandated under the *GT Agreement* to initiate review at least every five years, and *must* invite public submissions as well as draw on consultation with the expert Technical and Ethics Committees, the

[75] 'Organisation Accreditation Requirements', *OGTR* (Web Page, 26 March 2024) <https://www.ogtr.gov.au/about-approval-process/organisation-accreditation-requirements>.
[76] See OGTR, *Explanatory Information on the Guidelines for Accreditation of Organisations* (Guidance Document, 18 April 2013).
[77] 'Gene Technology Ministers Meeting', *National Gene Technology Scheme* (Web Page, 20 September 2024) <https://www.genetechnology.gov.au/about-the-national-scheme/how-it-works/ministers-meeting>.
[78] Ibid; Australian Government, 'Gene Technology Ministers' Meeting' (Communiqué, 20 July 2021) 2; Australian Government, 'Gene Technology Ministers' Meeting' (Communiqué, 11 December 2020) 2.

Regulator, and other industry or scientific groups as deemed relevant.[79] Depending on the type of review being conducted, periods of consultation are held and published on the Federal Government consultation hub before action plans are drafted.[80] Types of review initiated include revising guidance frameworks for risk analysis plans, technical reviews of the *GT Regulations*, and independent reviews of the *GTA*.

One of the most notable reviews was commenced in 2017 and is still in the process of implementation. The task of this substantial 'Third Review' included future-proofing the gene technology scheme against technological developments and assessing its ongoing effectiveness.[81] To manage this review, an expert panel was established, guided by the Standing Committee, which conducted several public consultations to identify key issues and inform action plans and strategies for implementation.

Across three different consultation phases, nearly 160 submissions were received, drawing input from private industry, research institutions, and consumers.[82] Upon finalising the recommendations, further consultation periods were held between 2020 and 2024 to construct a framework that would best implement the review and drafted amendments, with public support for attempts to reduce the prescriptiveness of the *GTA* and shift some technical considerations to delegated legislation.[83]

While new legislation is not anticipated until the end of 2025, a key feature of the scheme's review process is a sustained focus on public engagement. Requests for submissions are published on the Federal Government consultation hub. In addition, and of its own initiative, the Regulator regularly commissions surveys on community attitudes towards gene technology, integrating findings into

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[79] *GT Agreement* (n 23) [21(h)], [44]–[45].

[80] 'Consultation Finder: National Gene Technology Scheme', *Australian Government Department of Health and Aged Care* (Web Page, 2023) <https://consultations.health.gov.au/consultation_finder>.

[81] '2017 Review: Terms of Reference', *National Gene Technology Scheme* (Web Page, 2017) <https://www.genetechnology.gov.au/resources/publications/2017-review-terms-reference>.

[82] Australian Government, National Gene Technology Scheme, *Third Review of the Gene Technology Scheme* (Preliminary Report, March 2018) VIII.

[83] See generally Australian Government, National Gene Technology Scheme, *Modernising and future-proofing the National Gene Technology Scheme: Proposed regulatory framework to support implementation of the Third Review of the Scheme* (Consultation Regulation Impact Statement, December 2020); 'Proposed Amendments to the Gene Technology Act 2000', *OGTR* (Web Page, 18 October 2024) <https://www.genetechnology.gov.au/reviews-and-consultations/current/proposed-amendments-gene-technology-act-2000>.

various review and policy documents.[84] On a more specific level, the Regulator is *mandated* to maintain periods of open consultation with the public for individual RARMPs. [85]

There are also indirect avenues for public participation through, for example, parliamentary scrutiny in stages of legislative review. Evidence of this is seen in the 'Technical Review' of the *GT Regulations* held between 2016 and 2019. This review addressed new advances in gene technology, including self-directed nuclease techniques, and sought to amend the regulatory status of certain modification techniques no longer considered GMOs (termed 'SDN-1').[86] Following the tabling of proposed amendments in the Federal Parliament, a non-majority party (the Greens) that supported organic farmers expressed concerns that it would be increasingly difficult to guarantee GMO-free markets following deregulation of GM plants modified using SDN-1.[87] In the Greens' submission, the Regulator had insufficiently consulted with farmers on the importance of both organic farming and Australia's 'clean' market reputation, with a focus exclusively on the technical and health aspects of gene technology.[88]

While initially this call for disallowance of the amendments was rejected,[89] after public scrutiny and activism concerning the ambiguities of modern GMO classifications,[90] the legislative item proposing to deregulate certain techniques was repealed a year later.[91] Regardless of the merits, this example illustrates how

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[84] See, eg, Craig Cormick and Rob Mercer, *Community Attitudes to Gene Technology* (Report, October 2017); *OGTR Retrospective Report* (n 21).
[85] *GTA* (n 2) s 52(2)(c)(d).
[86] Australian Government, 'Explanatory Statement to Gene Technology *Amendment* (2019 Measures No 1) (Cth)', *Federal Register of Legislation* (Web Page) <https://www.legislation.gov.au/F2019L00573/latest/text /explanatory-statement>; Lauren John and Artemis Kirkinis, 'From Lab to Pasture to Plate: Amendments to the National Gene Technology Scheme', *Allens* (Blog Post, 11 August 2019) <https://www.allens.com.au/insights-news/insights/2019/08/from-lab-to-pasture-to-plate-amendments-to-the-national-gene-technology-scheme/>.
[87] Commonwealth, *Parliamentary Debates*, Senate, 13 November 2019, 3758–3766.
[88] Ibid.
[89] Ibid.
[90] 'Open Letter to Parliament: Gene Editing Deregulation Undermines Brand Australia', *OBE Organic* (Web Page, 2019) <https://www.obeorganic.com/open-letter-to-parliament-gene-editing-deregulation-undermines-brand-australia/>; 'The Gene Technology Amendment Puts Australian Families at Risk of Eating Untested, Unlabelled Genetically Modified Foods, Including Animals', *Slow Food* (Web Page, 2019) <https://www.slowfood.com/blog-and-news/the-gene-technology-amendment-puts-australian-families-at-risk-of-eating-untested-unlabeled-genetically-modified-foods-including-animals/>; 'Keep GM Animals Off Our Farms', *Friends of the Earth Australia* (Web Page, 2019) <https://www.foe.org.au/keep_gm_animals_off_our_farms>.
[91] OGTR, *Regulatory Adjustments Made in Response to 20 years of Innovation in Gene Technology* (Report, 2021) 8; OGTR, *Decision Regulation Impact Statement: Amendments to the Gene Technology Regulations 2001* (2021) 10.

the scheme has been reformed through parliamentary scrutiny and community input.[92] There are further direct mechanisms of accountability in place, such as legislative mandates for the Regulator to draft annual activity reports.[93] These reports are tabled in parliament and must include detailed information on budget activities, monitoring and enforcement updates, and operational performance matters.[94]

Further down the chain of regulation, the Regulator also monitors the activities of IBCs — the accredited organisations that conduct in-house risk assessment of GMOs. The Regulator requires annual reporting from each IBC, monitored in line with publicly accessible guidance detailing the processes of auditing, routine inspections, and spot checks.[95] Licence holders, who are often commercial sponsors in a therapeutic context,[96] therefore uphold risk management practices through local IBCs which are in turn accountable to the Regulator.

Having laid out the processes and bodies involved in regulating gene technology in Australia, the next section turns to AI in a different jurisdictional context, the EU.

B *Artificial Intelligence Act*

First proposed by the European Commission in 2021, the European *AIA* entered into force on 1 August 2024.[97] The *AIA* has a complex relationship with existing EU instruments, including data privacy regulations,[98] and the 'New Legislative Framework', an existing suite of legislation aimed to improve product safety for specific classes of goods entering the European internal market.[99] An example of these regulated goods are Medical Devices, which include AI-powered health

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[92] See generally Kerry Ross, 'Providing "Thoughtful Feedback": Public Participation in the Regulation of Australia's First Genetically Modified Food Crop' (2007) 34(3) *Science and Public Policy* 216.
[93] *GTA* (n 2) pt 9 div 5.
[94] Ibid.
[95] OGTR, *Operations of the Gene Technology Regulator Annual Report 2022–23* (13 September 2023) 13.
[96] O'Sullivan et al, '20 Years of Legislation' (n 5) 8.
[97] As a result of staggered implementation and delays, many provisions have only come into force in 2025, with others not expected until 2026 and beyond.
[98] *Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data and repealing Directive 95/46/EC (General Data Protection Regulation),* [2016] OJ L 119/1.
[99] 'New Legislative Framework', *European Commission* (Web Page) <https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en>.

tools considered 'software'.[100] The *AIA*, having the nature of a regulation, is directly applicable to EU Member States.

The *AIA* is a horizontal framework, meaning it applies broadly across different sectors rather than targeting a specific sector such as health-related AI systems. Within the complex regulatory ecosystem that governs these systems, the *AIA* will play an overlapping but central role. This centrality is similar to the expected framework in Australia. Therefore, this section will analyse the *AIA* and the broader framework only to the extent it is relevant for comparison with the *GTA* (Part III), and for the lessons it showcases for Australia (Part IV).

The *AIA* defines the subject of the Act — an 'AI system' — as a machine-based system 'designed to operate with varying levels of autonomy' that may exhibit adaptiveness and that 'infers, from the input it receives, how to generate outputs', such as predictions, content, and decisions.[101] As this definition is quite involved, recital 12 of the *AIA* refines several terms. For example, 'autonomy' indicates 'some degree of independence of actions from human involvement', and 'adaptiveness' indicates 'self-learning capabilities, allowing the system to change while in use'.[102]

Definitional questions were extensively debated in the drafting stages of the *AIA*,[103] and an important objective of this debate was to 'future-proof' the Act with a 'technology-neutral' definition.[104] The final definition attempts to strike a balance between legal certainty and flexibility regarding a fast-evolving technology.[105]

To oversee implementation of the *AIA*, the Act establishes the 'AI Office' within the European Commission. The AI Office is tasked with monitoring AI markets, providing guidelines and spaces for innovation, and, in particular, enforcing

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[100] Medical Devices in the EU are regulated under the *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC* [2017] OJ L 117/5 ('*EU Medical Devices Regulation*').
[101] *AIA* (n 14) art 3(1).
[102] Ibid recital 12.
[103] Martin Ebers et al, 'The European Commission's Proposal for an Artificial Intelligence Act: A Critical Assessment by Members of the Robotics and AI Law Society (RAILS)' (2021) 4(4) *The Impact of Artificial Intelligence on Law* 589, 591.
[104] European Commission, '*Explanatory Memorandum to COM (2021) 206 final*' (21 April 2024) 3, 12.
[105] Ibid 18; *AIA* (n 14) recital 12. See generally Dan Svantesson, 'The European Union Artificial Intelligence Act: Potential Implications for Australia' (2022) 47(1) *Alternative Law Journal* 4.

requirements on 'general purpose AI systems'.[106] It will also oversee international cooperation and stakeholder engagement by working with Member States and Commission agencies with relevant competences such as the European Centre for Algorithm Transparency.

1 *Regulatory Objective, the Risk-Based Approach, and GPAI Models*

(a) Regulatory objective

The *AIA* has two express objectives. The first is protective — to ensure 'a high level of protection of health, safety [and] fundamental rights enshrined in the Charter'.[107] The 'Charter' refers to the Charter of Fundamental Rights of the European Union, and enshrines human rights, including the rights to protection of data,[108] to non-discrimination,[109] and to freedom of expression.[110] Alongside this, the *AIA*'s second objective is to promote the development of AI technologies — to 'support innovation', 'improve the functioning of the internal market', and 'promote uptake of human-centric and trustworthy AI'.[111] In a health context, this is an attempt to mitigate potentially harmful wellbeing and health effects at both an individual and population level, while permitting AI technologies to enhance health outcomes.[112]

A distinct influence of the New Legislative Framework on the *AIA* is that the *AIA* conceives AI systems as consumer-facing products, with analogies to product safety principles in terms of mechanisms for approval and regulation.[113] If a product entering the European Internal Market is deemed a 'Medical Device' — ie any instrument or tool intended for a specific medical purpose — it must meet safety standards and is subject to regulatory oversight proportionate to risk level as laid out in sector-specific legislation.[114] Despite capturing a much broader scope of AI-powered products beyond Medical Devices, the *AIA* adopts a similar risk-based approach and envisages the overlap of some regulatory bodies.[115] The

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[106] See Decision C/2024/390, *Establishing the European Artificial Intelligence Office* (2024) ('*EU Decision Establishing the AI Office*').
[107] *AIA* (n 14) art 1.
[108] Ibid art 8.
[109] Ibid art 21.
[110] Ibid art 11.
[111] Ibid art 1.
[112] Jelena Schmidt et al, 'Mapping the Regulatory Landscape for Artificial Intelligence in Health Within the European Union (2024) 7(1) *NPJ Digital Medicine* 1.
[113] Edwards (n 20) 5–10.
[114] See, eg, *EU Medical Devices Regulation* (n 100).
[115] See Emmanouil P Vardas et al, 'Medicine, Healthcare and the AI Act: Gaps, Challenges and Future Implications' (2025) 6(4) *European Heart Journal: Digital Health* 833; Health Action International (n 20) 16–17.

implications and importance of this consumer-facing product influence will be explained below and throughout Part III.

(b) The risk-based approach

To regulate AI systems, the *AIA* adopts a risk-based approach,[116] distinguishing four categories into which any given AI system might fall: minimal risk, limited risk, unacceptable risk, and high-risk.

AI systems that fall within the 'minimal risk' category, such as email spam filters, are unregulated under the *AIA* on the basis that they are considered relatively uncontroversial.[117] In a health context, minimal risk systems might include those performing administrative tasks or automating non-patient facing processes such as billing.[118] 'Limited risk' systems, a tier above, include systems that interact with natural persons, for example wellbeing chatbots, AI systems producing medical deepfakes, or apps promoting health goals.[119] Limited risk systems are subject to disclosure obligations to ensure consumers are aware they are interacting with an AI.[120] Systems that pose 'unacceptable risk' are defined to include those that perform social scoring functions for uses such as health benefits, exploit vulnerabilities of natural persons, use biometric identification in publicly accessible spaces, or deploy 'subliminal techniques beyond a person's consciousness'.[121]

The bulk of the *AIA*'s text deals with the fourth category, 'high-risk systems'. High-risk systems either (1) are 'intended to be used as a safety component' of a product falling under sectoral product safety legislation[122] (eg, an AI system embedded in a Medical Device);[123] (2) are themselves a regulated product; or (3) fall within a list of eight application areas prescribed under the Act (eg, uses in

[116] This is explicitly stated in recital 14 of the *AIA* (n 14).
[117] European Commission, 'High Level Summary of the AI Act', *EU Artificial Intelligence Act* (Web Page, 27 February 2024) <https://artificialintelligenceact.eu/high-level-summary/>. Low-risk systems are not dealt with in the *AIA*: see 'Shaping European's Digital Future', *European Commission* (Web Page, 8 August 2024) <https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai>.
[118] Hannah van Kolfschooten and Janneke van Oirschot, 'The EU Artificial Intelligence Act (2024): Implications for Healthcare' (2024) 149 *Health Policy* 2.
[119] Ibid 2.
[120] *AIA* (n 14) art 50.
[121] Ibid art 5; Health Action International (n 20) 11.
[122] *AIA* (n 14) art 6(1) (a) and annex II.
[123] Ibid annex I pt (2) and (11).

education, employment, or emergency response services such as medical aid).[124] A more detailed analysis of high-risk systems will be provided below.

Importantly, decisions to categorise AI systems into one of the four specified risk categories are made by providers of AI (ie, organisations or individuals developing or applying AI systems),[125] rather than by an external or independent body such as the Regulator in the gene technology context. AI providers are the principal responsible subject under the *AIA*, and are typically private technology companies, although increasingly providers may include hospitals or healthcare organisations developing their own AI systems.[126] Actors further down the supply chain such as deployers and distributors of AI (eg, healthcare professionals) are given some, limited, responsibilities,[127] while importers and end-users (eg, patients) have no responsibilities.

(c) GPAI models

The *AIA* also distinguishes a particular sub-category of AI systems: *general purpose AI systems* ('GPAI'), which are defined to have capacities to 'serve a variety of purposes',[128] and are typically used as pre-trained adaptable models for further application in specialised systems.[129] In practice, this is intended to cover AI systems such as large language models ('LLM') like GPT-4, developed by established technology firms like OpenAI.[130] This includes a rapidly growing market driven by "health-focused" tech companies training LLMs with sensitive health data to make, for example, AI summarisation tools such as ambient scribes for clinical consults or automated referral generators.[131]

The *AIA* further categorises GPAIs into those that do and do not present systemic risks. GPAIs with 'systemic risks' include systems with high-impact capabilities (ie, computing power exceeding a legislated amount) or similar capabilities, 'as decided by the Commission' subject to consideration of established criteria.[132]

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[124] Ibid art 2 and annex III s (3) and (4).
[125] Ibid art 8.
[126] Kolfschooten and Oirschot (n 118) n 3.
[127] *AIA* (n 14) arts 24, 26.
[128] Ibid art 3.
[129] Future of Life Institute, *General Purpose AI and the AI Act* (Report, May 2022) 3.
[130] Ibid.
[131] See generally Stephen Gilbert et al, 'Large Language Model AI Chatbots Require Approval as Medical Devices' (2023) 29(10) *Nat Med* 2396. In Australia see, eg, 'The AI medical scribe for all clinicians', *Heidi Health* (Web Page, 2025) <https://www.heidihealth.com/au>; *Lyrebird Health* (Web Page, 2025) <https://www.lyrebirdhealth.com/au>.
[132] *AIA* (n 14) art 51(1), annex XIII.

These criteria include data set size and quality, projected impact on the internal market due to reach, and number of end-users.[133]

All providers of GPAIs are required to keep — and provide to the AI Office if requested — technical documentation to comply with the European Copyright Directive,[134] and to provide certain publicly available information via a template produced by the AI Office.[135] Additional obligations are imposed for GPAI models with systemic risks, including extra testing and mitigation measures, as well as reporting 'serious incidents' to the AI Office.[136] 'Serious incident' is defined to include death or serious harm to health, serious harm to the environment, or infringement on fundamental rights.[137]

(d) In-depth analysis of high-risk systems

High-risk systems are the main focus of the *AIA*. The central obligation on providers of these systems is to establish a 'risk management' system.[138] This includes risk assessment to identify and evaluate risks arising through both intended use and foreseeable misuse of the AI system, as well as the 'adoption of appropriate and targeted' measures to manage risk.[139]

In addition, the *AIA* imposes six other requirements. At a high level, these include requirements on data governance and training, technical documentation, record keeping, transparency, human oversight, and accuracy, robustness and cybersecurity.[140] If, further down the AI supply chain, an importer, distributor, or deployer of an AI system makes a substantial modification (ie, a change not foreseen or planned in original risk assessment),[141] then they are deemed 'providers' for the purposes of complying with high-risk obligations.[142] This ensures that any AI systems posing new or unforeseen risks re-enter regulatory cycles.

AI providers demonstrate compliance with the requirements detailed above through a 'conformity assessment' ('CA'). CAs are conducted in one of two ways:

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[133] Ibid.
[134] *Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on Copyright and Related Rights in the Digital Single Market and Amending Directives 96/9/EC and 2001/29/EC* OJ L 130.
[135] *AIA* (n 14) art 51(1)(d).
[136] Ibid art 55(1).
[137] Ibid art 3(49).
[138] Ibid art 9.
[139] Ibid art 9(2)(a)–(b).
[140] European Commission, 'High Level Summary of the AI Act' (n 117).
[141] Defined in art 3 of the *AIA* (n 14).
[142] Ibid art 25.

either by a 'Notified Body'[143] or through internal (self) assessment. A Notified Body must be established under domestic laws and is required to satisfy legislated requirements under the *AIA*.[144] Similarly, under product safety legislation, Notified Bodies must perform CAs for developers of Medical Devices.[145] Given that the majority of high-risk health-related AI systems will be classed as Medical Devices — likely as medical software[146] — the *AIA* envisages that the existing Notified Bodies for Medical Devices will perform CAs for high-risk AI systems.[147] It is still unclear how this overlap will function in practice as the *AIA* continues to take effect.[148] However, once a CA is completed, AI providers must draft a declaration of conformity which will be marked with a 'CE' mark to designate satisfaction of European product safety standards permitting free internal market movement.[149]

2 *Regulatory Features and Actors: Harmonised Standards, Post-Market Obligations and the AI Office.*

A key feature of the *AIA* is the use of harmonised standards. These are outsourced to European Standardisation Bodies,[150] and the *AIA* envisages that these standards will provide consistent and certain technical requirements for high-risk AI systems regarding underspecified legislated obligations (eg, where references are made to implement 'appropriate measures').[151] Compliance with the standards creates a presumption of conformity.[152] As for GPAI systems, the AI Office is mandated to produce a 'Code of Practice' detailing, for example, the adequate level of detail in content disclosures.[153] This Code, along with many

[143] For a list of these bodies, see 'Single Market Compliance Space: Notified bodies (NANDO)', *European Commission* (Web Page) <https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies>.
[144] *AIA* (n 14) art 31; *Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC*.
[145] *EU Medical Devices Regulation* (n 100) art 52.
[146] Ibid, ch III, r 11.
[147] See Vardas et al (n 115).
[148] Stephen Gilbert, 'The EU Passes the AI Act and its Implications for Digital Medicine are Unclear' (2024) 135(1) *NPJ Digital Medicine* 1, 1–3.
[149] *AIA* (n 14) art 48.
[150] Most relevant are CEN (European Committee for Standardisation) and CENELEC (European Committee for Electrotechnical Standardisation).
[151] 'Standard Setting', *EU Artificial Intelligence Act* (Web Page, updated June 2025) <https://artificialintelligenceact.eu/standard-setting/>.
[152] *AIA* (n 14) art 40.
[153] Ibid art 56.

standards, has been delayed until 2026,[154] but once published, adherence to it will grant a presumption of conformity to AI providers.

Though standards and codes assist in harmonising practice to some extent, the principal regulatory burden under the *AIA* rests on providers. Other actors in the AI supply chain also have some limited responsibilities. For example, distributors making AI systems available on the market are mandated to ensure providers have complied with CE certification, and to prevent distribution in the event of suspected non-compliance.[155]

Regarding post-market obligations, providers must also establish models to continuously collect, document, and analyse performance data from their AI systems.[156] This practice functions alongside 'Market Surveillance Authorities' — bodies that reside within Member States and conduct the majority of compliance investigations and enforcement actions pursuant to existing EU product regulations.[157] If during enforcement stages Member States engage in cross-jurisdictional 'joint investigations', the AI Office may provide coordinating assistance.[158] Specifically for GPAI models, the AI Office can conduct compliance evaluations as well as receive and review downstream complaints for non-compliance.[159]

One of the distinct functions of the AI Office is to promote innovation and efficient uptake of AI systems (the *AIA*'s second objective).[160] It achieves this by coordinating the implementation of 'regulatory sandboxes', which are 'controlled environments' for 'safely' testing and developing AI systems.[161] AI systems may cycle through several phases of a sandbox during development, before approaching the pre-market regulatory measures described above. The *AIA* mandates that implementing sandboxes is the responsibility of Member State authorities, which will provide one member each to compose the AI Board.[162] The

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[154] 'EU Could Water Down AI Act amid Pressure from Trump and Big Tech', *The Guardian* (online, 7 November 2025) <https://www.theguardian.com/world/2025/nov/07/european-commissio n- ai-artificial-intelligence-act-trump-administration-tech-business>.
[155] *AIA* (n 14) art 24.
[156] Ibid ch 4 art 72.
[157] Ibid art 74; *Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on Market Surveillance and Compliance of Products* OJ L 169, 25 June 2019, 1–44.
[158] *AIA* (n 14) art 74(11).
[159] *EU Decision Establishing the AI Office* (n 106) 3–5.
[160] *AIA* (n 14) art 2(2); *EU Decision Establishing the AI Office* (n 106).
[161] *AIA* (n 14) art 57.
[162] Ibid arts 57, 65.

AI Board and AI Office are mandated to encourage information sharing and best practice guidance for sandboxes.[163]

The exact composition of the AI Office is not specified in the *AIA*. However, the Commission has published an organisational structure, including five units with technical expertise in robotics, compliance, safety, innovation, and societal good, as well as two advisors, one 'Scientific' and one 'International Affairs'.[164] The *AIA* also requires the establishment of a panel composed of members with 'scientific' and 'technical' expertise on AI to be selected by the Commission.[165] The functions of this panel are to advise the AI Office on matters including systemic risks of GPAI systems, general matters of post-market enforcement, and developing 'tools and templates'.[166]

3 *Review, Public Participation, and Accountability*

Understanding the drafting history of the *AIA* can be difficult, given many of the decisions on risk, categories, and definitions were internalised in the complexities of trialogue negotiations between Member States and the Commission. Leading scholars have described many consequential decisions within the *AIA* as having, from an outward perspective, 'little or no justification'.[167] The lawmaking process can nevertheless be traced to some extent. High-risk systems, for example, were identified in part by phases of public consultation on a drafting paper.[168] This process was also informed by private expert webinars, online conferences, literature reviews by government and non-government organisations, and documents produced by Commission expert groups.[169] Sectoral considerations led to domains such as healthcare being recognised as high-stakes, and despite consultations indicating that sectoral specific legislation was preferred, a horizontal framework was ultimately decided on.[170]

Specific provisions in the *AIA* address review and amendment of the Act. Using high-risk systems as an example, if the Commission seeks to add a new group to

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[163] Ibid art 57.
[164] 'The AI Office: Structure and Functions', *European Commission* (Web Page, 2024) <https://digital-strategy.ec.europa.eu/en/policies/ai-office#ecl-inpage-the-structure-of-the-ai-office>.
[165] *AIA* (n 14) art 68.
[166] Ibid art 68.
[167] Edwards (n 20) 12.
[168] See European Commission, *White Paper on Artificial Intelligence*: *A European Approach to Excellence and Trust* (White Paper, 19 February 2020).
[169] Ljupcho Grozdanovski and Jérôme De Cooman, 'On The Obsolescence of Empirical Knowledge in Defining The Risk/Rights-based Approach to AI Regulation in The European Union' (2023) 49(2) *Rutgers Computer and Technology Law Journal* 207, 236–240.
[170] Ibid.

the AIA's established list, it must consider a range of legislated factors.[171] There is also a general power to create delegated legislation to supplement the *AIA*, provided procedural requirements are met, including consulting specific expert groups, and exposing the delegated legislation to parliamentary scrutiny.[172] Accountability in the *AIA* can also be partially traced across the lifecycle of an AI system from development to end-users. Providers of high-risk systems must address the documentation and disclosure requirements detailed above.

Upon market entry, parts of these documents are subject to public scrutiny, as the *AIA* requires providers to list their systems in a public database alongside technical data.[173] Downstream users of systems who suspect non-compliance with the *AIA* must not distribute high-risk systems to the market.[174] A significant and widely acknowledged limitation of the *AIA* relates to people impacted by AI systems (eg, patients facing discrimination from an AI-enabled decision), who are provided with no mechanisms for recourse under the Act itself.[175]

In recognising that AI systems naturally present difficulties in establishing chains of accountability,[176] the *AIA* has some focus on disclosure requirements and information sharing practices within supply chains. This includes the establishment of government regulatory sandboxes that work to streamline AI systems through testing mechanisms, maintaining close rapport with providers.[177]

Overall, the *AIA* establishes a predominantly decentralised regulatory approach, with some coordination by the AI Office and regional standards bodies. Most responsibility resides with providers to both assess and implement responses to the risks associated with AI systems, and overlap is expected with the Notified Bodies for Medical Device regulation. Further reflecting the pro-industry orientation of the Act, opportunities for public input into regulatory processes are limited.

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[171] *AIA* (n 14) art 7.
[172] Ibid art 97.
[173] Ibid art 71.
[174] Ibid art 24.
[175] Jeremias Adams-Prassl, 'Regulating Algorithms at Work: Lessons for a "European Approach to Artificial Intelligence"' (2022) 13(1) *European Labour Law Journal* 30, 49; Michael Veale and Frederik Zuiderveen Borgesius, 'Demystifying the Draft EU Artificial Intelligence Act: Analysing the Good, the Bad, and the Unclear Elements of the Proposed Approach' (2021) 22(4) *Computer Law Review International* 97, 112.
[176] Jennifer Cobbe, Michael Veale and Jatinder Singh, 'Understanding Accountability in Algorithmic Supply Chains' in *FAccT '23: Proceedings of the 2023 ACM Conference on Fairness, Accountability, and Transparency* (12 June 2023) 1186–1197 <https:doi.org/10.1145/3593013.3594073>.
[177] *AIA* (n 14) art 60 annex III, art 13.

III COMPARING THE *GTA* AND THE *AIA*

This part will compare the *GTA* and the *AIA* as two instruments regulating specific technologies that present both known and indeterminate risks in the high-stakes health sector, which manage this challenge in distinct and interesting ways. It focuses on four of the most significant points of comparison between the two Acts: (1) regulatory objectives; (2) regulatory triggers; (3) risk categorisation and decision-making; and (4) mechanisms for accountability, public participation, and review.

A *Regulatory Objectives*

The regulatory objectives of the *AIA* and *GTA* are notably different. The *GTA*'s exclusive focus is to 'protect the health and safety of people, and to protect the environment'.[178] The *AIA* partly shares this focus — to protect the health, safety, and fundamental rights of people — however, in addition, it explicitly promotes innovation, AI uptake, and improved market functioning.[179] It is therefore baked into the *AIA*'s regulatory approach that the protection of health, safety, and fundamental rights may be superseded by pro-AI market considerations. This approach seems to undermine the Act's protective objective and, indeed, the very nature of fundamental rights protections.

Express support for this pro-industry regulatory approach can be found in explanatory reports accompanying the *AIA*, stating the Act's regulatory intention to only intervene when 'strictly needed in a way that minimises the burden for economic operators'.[180] This is reflected in the *AIA*'s risk-based model, with each regulated category resulting from 'drafting compromises' that weigh the risks posed by AI systems against promised benefits, including improved health outcomes, efficiency, and market gains.[181]

This is illustrated clearly by the category of 'minimal risk' AI systems, which, by virtue of being unregulated under the *AIA*, demonstrate that the promise of economic and efficiency gains outweigh any 'minimal' level of risk presented. While some scholars have described this compromise as reasonable given risk is

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[178] *GTA* (n 2) s 3.
[179] *AIA* (n 14) art 1.
[180] European Commission, 'Communication on Fostering a European approach to artificial intelligence' (21 April 2021) [4].
[181] Johanna Chamberlain, 'The Risk-Based Approach of the European Union's Proposed Artificial Intelligence Regulation: Some Comments from a Tort Law Perspective' (2023) 14(1) *European Journal of Risk Regulation* 1, 1.

'practically never completely avoidable',[182] there have also been critiques that such a minimal degree of regulation is unacceptable in the face of unpredictable risk to health, safety, and fundamental rights.[183]

The dual objectives of the *AIA* are in stark contrast to the *GTA*'s single precautionary objective. The *GTA*'s regulatory starting position is that *all* dealings with GMOs are prohibited until permitted, regardless of their promise or predicted (even potentially negligible) levels of risk.[184] Only once dealings undergo the approval process described in Part II (eg, centralised, detailed risk assessment and licence application with ongoing obligations) can a GMO be dealt with.

At a sub-structural level, the *GTA*'s category of 'exempt dealing' can be analogised to the *AIA*'s 'minimal risk' category (eg, an AI-based system performing administrative functions in healthcare). Recalling from Part II, exempt dealings are, for example, uses of GMOs that align with methods of basic molecular biology.[185] These are listed in the *GT Regulations* as dealings that can be undertaken without a licence provided specified criteria are met, demonstrating that the gene technology scheme retains conditional oversight even of unlicensed use of gene technology. Unlike the *AIA*, the *GTA* does not presume certain uses of gene technology to be so low-risk as to not require regulation — even when that might deprive the market of a GMO of great benefit in the high-stakes context of health.

B *Regulatory Triggers*

Comparing the design of the *AIA* and the *GTA* highlights a key functional difference between the Acts, that is, the feature that triggers regulation. The *GTA* regulates dealings that may lead to GMOs, rather than GMOs themselves. This means GMOs are not only regulated as products, when there is a vaccine or modified crop ready for market, but also in early stages of research and development. Contrastingly, the *AIA* regulates AI systems as products, meaning regulation is only triggered if a developed product is proposing to enter the Internal Market. In short, the *GTA* uses a 'process trigger', while the *AIA* uses a 'product trigger'. At an international comparative level, European gene technology regulation also uses a process

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[182] Ibid 7.
[183] See Edwards (n 20).
[184] 'How We Regulate Genetically Modified Organisms (GMOs)', *OGTR* (Web Page, 4 September 2024) <https://www.ogtr.gov.au/about-ogtr/how-we-regulate-genetically-modified-organisms-gmos>.
[185] Tribe (n 19) 26.

trigger, whereas Canada is an example of a jurisdiction that employs a product trigger, regulating GMOs through assessing new traits in developed GMOs as products.[186]

The *GTA*'s third statutory review considered the merits of a process trigger against a product trigger, finding that the existing approach increases the scope of the regulatory scheme in desirable ways.[187] Regulating the full process of GMO development captures a broader range of activities, allowing 'products that do not yet have a history of safe use to be monitored'.[188] Reviews of the gene technology legislative scheme have found that technological developments have historically moved faster than regulation,[189] which, in accordance with public sentiment towards gene technologies, justifies a 'regulatory scheme with a broad scope'.[190]

While it is typically gene technology rather than AI literature that uses this product and process trigger terminology,[191] it is useful to apply here given the calls to adopt a more conservative framework that captures unforeseen risk through a large scope.[192] This terminology also assists in understanding the influence of European product safety legislation on the *AIA*. As argued by leading scholars in this area, this influence has led to the *AIA* conceiving AI systems as a tangible product,[193] creating a distinction between 'risks to rights' or pro-rights thinking — which is similar to what is observed in the *GTA* and promotes the *AIA*'s protective objective — and 'product safety' or pro-industry thinking.[194]

This explains the critiqued absence from the *AIA* of the precautionary principle,[195] which is common in health-focused regulatory models and appears in the *GTA*'s explanatory documents as necessary for protection of health risks throughout development cycles.[196] Health-related AI applications, particularly in

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[186] 'Regulating Agricultural Biotechnology', *Canadian Food Inspection Agency* (Web Page, 2023) <https://inspection.canada.ca/en/plant-varieties/plants-novel-traits/general-public/regulating-agricultural-biotechnology>.
[187] Recommendation 8 in the *Gene Technology Scheme Third Review Report* (n 30) 10, 36.
[188] Ibid 37.
[189] This was a finding in a legislative review of the gene technology scheme conducted by Allen Consulting Group: see Allen Consulting, *Review of the Gene Technology Act 2000* (Final Report, 2011) 6–7.
[190] Recommendation 8 in the *Third Review of the Gene Technology Scheme* (n 30) 10, 36.
[191] Thygesen (n 31) 65.
[192] Veale and Borgesius (n 175) 97; *Interim Discussion Paper* (n 10) 15.
[193] Veale and Borgesius (n 175) 97; Edwards (n 20) 5.
[194] Tobias Mahler, 'Between Risk Management and Proportionality: The Risk-Based Approach in the EU's Artificial Intelligence Act Proposal' [2022] *The Swedish Law and Informatics Research Institute* 247, 265.
[195] Health Action International (n 20) 14.
[196] *Senate Report on Gene-Tech Bill 2000* (n 4) 23, 32; *Risk Analysis Guidance Framework* (n 35) 9.

high-risk contexts, often follow similar product development to therapeutics that involve GMOs, including laboratory research, clinical trials, performance studies, and access to sensitive patient data. Despite this, the *AIA*'s pro-industry regulatory starting point focuses on post-market compliance as opposed to pre-market approval. While the *AIA* requires risk management systems prior to market entry as part of a system's 'lifecycle',[197] third party oversight is not present at this stage.

Similarly, in government regulatory sandboxes, to the extent that pre-market testing is required, it is generally only optional.[198] For high-risk systems, requirements for providers to self-assess a product's 'foreseeable misuse' only engage *after* a system has been classified into a risk category. This allows providers to focus on misuse that is foreseeable through intended use of the product, rather than actual use and real-world applications.[199] This second measure has been suggested as the preferred criteria of a product's risk level, particularly when assessed externally, and reveals the overly prescriptive nature of the *AIA*.[200]

The *AIA* does impose some regulatory obligations that function similarly to the *GTA*'s pre-market-facing process trigger. Most importantly, these are data training, validation, and testing requirements for providers modelling high-risk AI systems.[201] While these have been welcomed as much-needed attempts to legislate quality metrics for training data,[202] a number of critiques note the absence of clear definitions throughout the relevant article. In particular, no definition of 'bias' and no examples of positive or negative bias are provided, despite the requirement for companies to carry out their obligations in view 'of possible biases'.[203] In a health context this ambiguity lacks 'coherent

[197] Feldstein (n 15) 8.
[198] *AIA* (n 14) art 9(7).
[199] Health Action International (n 20) 14; Felix Busch et al, 'Navigating the European Union Artificial Intelligence Act for Healthcare' (2024) 7(1) *NPJ Digital Medicine* 1, 1–3.
[200] European Consumer Voice in Standardisation ('ANEC'), *ANEC comments on the European Commission proposal for an Artificial Intelligence Act* (Position Paper, 2021) 3–6; Health Action International (n 20) 14, 19.
[201] *AIA* (n 14) art 10.
[202] Ibid; Phillip Hacker, 'A Legal Framework for AI Training Data: From First Principles to the Artificial Intelligence Act' (2021) 13(2) *Law, Innovation and Technology* 257, 297.
[203] *AIA* (n 14) art 10(2)(f); Marvin van Bekkum, 'Using Sensitive Data to De-Bias AI Systems: Article 10(5) of the EU AI Act' (2025) 56 *Computer Law & Security Review* 1, 1–9. See generally Brent Mittelstadt et al, 'The Unfairness of Fair Machine Learning: Levelling Down and Strict Egalitarianism by Default' (2023) 30(1) *Michigan Technology Law Review* 1.

coordination',[204] raising complex issues of prejudice, ground truths, and discrimination.

These issues are revisited in Part IV in light of Australia's commitment to enact AI legislation mitigating discrimination and bias. The effectiveness of these provisions is further questioned by the fact that both downstream deployers and users lack mandatory access to training data, as well as the capacity to compel changes.[205] Thus, in addition to lacking definitional clarity, the provision fails to meaningfully span regulation between pre-market research and development stages and post-market deployment.

In reality, AI systems are not a product but a 'system delivered dynamically through multiple hands',[206] with complex production lines meaning risk profiles can change depending on who may be developing or applying the technology.[207] In drawing influence from product safety legislation and framing AI systems as a 'consumer-facing' product, the *AIA* has been critiqued for overlooking this dynamic nature.[208] This suggests that a broader process trigger, as exemplified in the *GTA*, without a compromised pro-industry objective may offer considerably greater protection.

C *Risk Categorisation and Decision-Making*

Both the *GTA* and the *AIA* establish different categories of regulation, which are comparable by virtue of adjusting regulatory processes and obligations to perceived levels of risk. The most notable differences are the arbitrariness of these risk categories, the decision-makers involved, and their respective roles.

Under the *GTA*, the Regulator is always involved, and their influence may change depending on the regulatory stream. For example, the Regulator's role in an emergency dealing may simply be to advise the Minister on the manageability of risk, whereas under an intentional environmental release of a GMO the Regulator's influence is mandated and fundamental to each risk assessment plan. Under the *AIA*, the AI provider is heavily involved amidst the absence of a consistent or independent decision-maker across the regulated categories.

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[204] Hacker (n 202) 298.
[205] Edwards (n 20) 10.
[206] Ibid 5.
[207] Glenn Cohen et al, 'The European Artificial Intelligence Strategy: Implications and Challenges for Digital Health' (2020) 2(7) *The Lancet Digital Health* 376, 376; Veale and Borgesius (n 175) 97; University of Melbourne, 'Safe and Responsible AI in Australia: Discussion Paper Response To Senate Inquiry' (Submission, August 2023) 16.
[208] Edwards (n 20) 5.

The *GTA* leaves work for the Regulator and a sophisticated network of expert bodies in each of its categories to ensure consistency and predictability — both intentionally designed attributes of the *GTA*.[209] By contrast, the *AIA* leaves private providers of minimal risk systems to meet limited disclosure obligations, and providers of high-risk systems to conduct risk assessments and meet their various data governance, training, and cybersecurity obligations.[210] While providers may be well placed to identify risks given they have 'detailed knowledge of the design and production process'[211] — a sentiment from product safety legislation — they are neither independent nor adapted to assess harms.

Even with the presence of Notified Bodies to conduct conformity assessments and technical documentation, there are significant concerns raised by scholars that these bodies — the same Notified Bodies regulating Medical Devices — may lack the necessary qualifications to regulate AI-specific risks.[212] Looking at indirect discrimination as an example of risk, this can be difficult to recognise without knowledge of the relevant characteristics of affected populations, which are often sensitive, protected, and potentially hidden in data sets.[213] Health-related AI tools expand the potential to exacerbate existing health and digital inequalities,[214] or to re-identify vulnerable demographics from aggregated data sets,[215] and these risks may go unnoticed without knowledge of the systematic inequalities being entrenched.

The prescriptive nature of the *AIA*'s risk-based categories has also been widely critiqued and is considered highly arbitrary,[216] particularly when framed against the *GTA*. Several examples can help illustrate this. Under the *AIA*, AI-powered diagnostic tools or clinical decision-making software are expected to be high-risk,[217] while AI-powered health apps, wellbeing chatbots, and administrative assistants are anticipated to be minimal risk. Apps calculating, for example, user fertility based on body temperature can change in risk category

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[209] *Gene Technology Scheme Third Review Report* (n 30) 3.
[210] Edwards (n 20) 6–8.
[211] *Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a Common Framework for the Marketing of Products, and Repealing Council Decision 93/465/EEC* OJ L 218/82, [22].
[212] Vardas et al (n 115) 836; Health Action International (n 20) 16–17.
[213] See generally Michael Veale and Reuben Binns, 'Fairer Machine Learning in the Real World: Mitigating Discrimination without Collecting Sensitive Data' (2017) 4(2) *Big Data & Society* 4.
[214] See generally OECD, *AI in Health: Huge Potential, Huge Risks* (Policy Brief, 2024).
[215] See generally Na Liangyuan et al, 'Feasibility of Reidentifying Individuals in Large National Physical Activity Data Sets From Which Protected Health Information Has Been Removed With Use of Machine Learning' (2018) 7(8) *JAMA Network Open* 1.
[216] Edwards (n 20) 5, 11; Health Action International (n 20) 14.
[217] Vardas et al (n 115) 16–17.

depending entirely on whether their intended purpose is conception or contraception.[218]

Similarly, 'minimal risk' administrative tools built on LLMs for basic notetaking or scribe functions have the potential to hallucinate outputs, automatically populating electronic health records with inaccurate data.[219] When relied upon by clinicians, these can emerge as unintentional clinical decision-making assistants directly affecting patient outcomes — a clear description of a high-risk tool. While LLMs are expected to be regulated by the AI Office, scholars have put forward strong cases for these to be considered Medical Devices.[220]

In other words, an LLM-powered tool that is arguably minimal risk can also be imagined as a high-risk Medical Device, or a highly capable GPAI model posing systemic risks, with each categorisation carrying various regulatory implications for different actors. A blurred line emerges between risk categories, and it is unlikely that providers, typically private companies with incentives to minimise regulatory burden,[221] are equipped to identify the full range of risks at play.

The *GTA* recognises this and positions the Regulator over licence holders, typically commercial sponsors,[222] to scrutinise unpredictable risks in a more granular, high-touch way. The *GTA* addresses issues not only through the structural design of the Regulator and granular risk categorisation, but also through IBCs. These certified bodies with detailed knowledge of the specific dealings of specific organisations are well placed to monitor and liaise with the Regulator on unpredictable risks as they emerge in both research and post-market stages.[223] While applicants, supported by IBCs, may provide information to the Regulator regarding their dealing, this simply informs the Regulator's decision-making rather than permitting self-assessment.[224] Every decision is technically informed through the rigorous scrutiny of the expert Technical Committee. To ensure scope for public consideration of ethical and societal concerns, decisions on value-laden

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[218] Health Action International (n 20) 14–15.
[219] See generally Peter Lee et al, 'Benefits, Limits, and Risks of GPT-4 as an AI Chatbot for Medicine' (2023) 388(13) *New England Journal of Medicine* 1233; Chris Stokel-Walker et al, 'What ChatGPT and Generative AI Mean for Science' (2023) *614 Nature* 214.
[220] Hugh Harvey and Mike Pogose, 'Are LLM-Based Ambient Scribes and Clinical Summarisers Medical Devices?', *Hardian Health* (Web Page, 2024) <https://www.hardianhealth.com/insights/are-llm-based-ambient-scribes-and-clinical-summarisers-medical-devices>; Gilbert (n 148) 2396.
[221] Veale and Borgesius (n 175) 97–100.
[222] O'Sullivan et al, '20 Years of Legislation' (n 5) 8.
[223] Ibid 4; Tribe (n 19) 26.
[224] See, eg, Gene Technology Technical Advisory Committee, 'GTTAC Meeting of 18 December 2023' (Communiqué, 18 December 2023) 2.

assessments are not outsourced to private standardisation bodies as in the *AIA*,[225] but draw on guidance documents following consultation with the public and the Ethics Committee. This leaves sufficient room for ethically and societally informed influence on decision-making and risk thresholds.

D *Public Participation, Accountability, and Transparency*

A critical feature drawn from Part II is the high degree of public scrutiny in the gene technology scheme. This is observed not only in stages of legislative review, where multiple phases of open consultation direct review focus, but in individual licence applications that are open for public consultation. Scholars have been critical of a distinct absence of similar measures in the *AIA*, which does not 'envisage any role for social dialogue', thereby missing an opportunity to incorporate 'on-the-ground experience' in processes such as standard setting.[226]

While there is established scope for industry lobbying and organised stakeholder participation in the *AIA*'s standard setting process,[227] scholars have called for improved 'participation rights'.[228] Given protection from high-risk systems may depend primarily on the effectiveness of standard setting, the degree to which it incorporates the high level of public debate necessary for value-laden assessments is questionable.[229]

To ensure *meaningful* public engagement in the *GTA*, review stages draw clear traceable connections between respective stages of consultation and the continually refined government approaches between preliminary papers, final reports, and action plans.[230] In contrast, the consultation period that informed the *AIA* involved more significant periods of private and political debate than public engagement.

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[225] See generally Martin Ebers, 'Standardizing AI: The Case of the European Commission's Proposal for an Artificial Intelligence Act' in Larry A DiMatteo, Cristine Poncibò and Michel Cannarsa (eds), *The Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law and Ethics* (Cambridge University Press, 2022) 321.
[226] Adams-Prassl (n 175) 49.
[227] 'Standard Setting' (n 151).
[228] Ebers (n 225) 340–7.
[229] Ibid 340.
[230] This sequence of documents is available at 'Third Review of the Gene Technology Legislation', *OGTR* (Web Page, March 2022) <https://www.genetechnology.gov.au/reviews-and-consultations/ past/2017-third-review#consultation-phases>.

To address the inherent difficulties in constructing traditional mechanisms of accountability for AI systems,[231] the *AIA* places a heavy emphasis on information sharing. Scholars have recognised that accountability in AI contexts can be maintained through sharing data sources, model accuracy, and tools to safeguard users.[232] The *AIA* promotes this through features such as a mandatory database for high-risk systems,[233] requirements to disclosure technical aspects of high-risk systems,[234] and regulatory sandboxes maintaining rapport with providers.[235]

These measures do provide a degree of accountability and transparency, which is particularly welcome in a health context given the 'ubiquitous data biases' historically ingrained across data sets,[236] as well as numerous cases of private companies mishandling health data, cyber security attacks, and disregard of patient consent.[237] Despite these measures, however, this emphasis on information sharing seemingly attempts to compensate for a stricter regulatory presence in models such as the *GTA*, permitting AI providers to meet their obligations in supposedly transparent settings without high-touch oversight of external regulatory bodies.

IV Regulatory Lessons for Australia

A *Australia's Approach*

While the Australian Government has not enacted AI-specific legislation, several key developments have brought this prospect into view. In 2019, the Department of Industry, Science and Resources ('DISR') published a voluntary set of eight 'AI Ethics Principles'.[238] These were drafted to ensure the 'responsible design,

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[231] See Cobbe (n 176).

[232] See generally Jeannie Marie Paterson, 'Misleading AI: Regulatory Strategies for Algorithmic Transparency in Technologies Augmenting Consumer Decision-Making' (2022) 34(3) *Loyola Consumer Law Review* 558.

[233] *AIA* (n 14) art 60 annex III.

[234] *AIA* (n 14) art 13.

[235] 'Regulatory Sandboxes in the AI Act', *The Future Society* (Web Page, 2022) <https://thefuturesociety.org/workstream/regulatory-sandboxes-in-the-ai-act/>.

[236] Health Action International (n 20) 16; Trishan Panch, Heather Mattie and Rifat Atun, 'Artificial Intelligence and Algorithmic Bias: Implications for Health Systems' (2019) 9(2*) Journal of Global Health* 020318:1–5.

[237] Angie Lavoipierre, 'MediSecure reveals 12.9 million Australians had personal data stolen in cyber attack earlier this year' *Australia Broadcast Corporation* (online, 18 July 2024) <https://www.abc.net.au/news/2024-07-18/medisecure-data-cyber-hack-12-million/104112736>; Cam Wilson, 'Australia's Biggest Medical Imaging Lab is Training AI on its Scan Data. Patients Have No Idea', *Crikey* (online, 19 September 2024) <https://www.crikey.com.au/2024/09/19/patient-scan-data-train-artificial-intelligence-consent/>.

[238] Australian Government, Department of Industry, Science and Resources, *Australia's Artificial Intelligence Ethics Framework: Australia's AI Ethics Principles* (2019) ('*AI Ethics Principles*').

development and implementation of AI'. Following stakeholder consultation, they were finalised to include principles focused on reliability, transparency, accountability, social wellbeing, and fairness.[239] Australia's AI Ethics Principles have informed subsequent developments, in particular the plans towards 'Safe and Responsible AI' in Australia, first announced in June 2023.[240]

At the beginning of 2024, the DISR published an *Interim Discussion Paper* on Safe and Responsible AI.[241] A key insight from this paper was that Australia's current protections are inadequate to address risks posed by AI.[242] A non-statutory expert AI group was also established, comprised of individuals with scientific, legal, and market expertise that could provide advice to the DISR on mandatory guardrails for 'AI systems in high-risk settings'.[243]

The *Proposals Paper* subsequently released in September 2024 considered options for defining high-risk AI systems, and set out 10 'mandatory guardrails' to promote principles such as accountability and transparency.[244] Alongside this, the DISR published a *Voluntary AI Safety Standard* advising developers generally,[245] and the Office of the Australian Information Commissioner issued a guidance document on generative AI and privacy obligations.[246]

Across this set of documents, there is limited attention given to AI and health, despite promises to invest in the 'priority' healthcare sector and conduct 'gap analysis' in current protective frameworks.[247] The Government most directly addresses this in a consultation paper titled *Safe and Responsible Artificial Intelligence in Health Care Legislation and Regulation Review*, released by the Department of Health and Aged Care in September 2024.[248] This paper requests

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[239] 'Consultation Hub: AI Ethics Principles', *Department of Industry, Science and Resources* (Web Page, 15 August 2019) <https://consult.industry.gov.au/australias-ai-ethics-framework/submissions/ list>.
[240] *Interim Discussion Paper* (n 10).
[241] Ibid.
[242] Ibid 5.
[243] 'AI Expert Group: Terms of Reference', *Department of Industry, Science and Resources* (Web Page, 2023) <https://www.industry.gov.au/science-technology-and-innovation/technology/artificial-intelligence/ai-expert-group-terms-reference>.
[244] Proposals Paper (n 11).
[245] See Australian Government, Department of Industry, Science and Resources, *Voluntary AI Safety Standard* (August 2024) ('*Voluntary Safety Standard*').
[246] Office of the Australian Information Commissioner, *Guidance on Privacy and Developing and Training Generative AI Models,* (Guidance Paper, October 2024).
[247] *Proposals Paper* (n 11) 4, 56.
[248] Australian Government, Department of Health and Aged Care, *Safe and Responsible Artificial Intelligence in Health Care Legislation and Regulation Review* (Final Report, March 2025) ('*AI in Health Care Consultation Paper*').

public comment on AI in healthcare, laying out the sector-specific risks but placing strong emphasis on the revolutionary promises of the burgeoning AI market, including the various use-cases to improve patient outcomes and reduce clinician burnout.

While healthcare-specific options for reform are presented, including the introduction of health care-specific laws and a regulatory body,[249] these are highly speculative and in contradiction to the intended horizontal AI framework laid out in other documents. While this set of documents can be difficult to navigate, taken as a whole they reveal several key points regarding Australia's intended approach that will structure discussions below.

First, the Government's underlying objective is what this article has characterised as 'prescriptive' and 'pro-industry' — to adopt a risk-based approach, with 'safe and responsible' AI uptake in 'high-risk settings' and 'unimpeded' uptake in low-risk settings.[250] To achieve this underlying objective, the Government aims to maximise opportunities presented by AI through investment and growing national capabilities, while enacting predictable legislation to support the AI market in offering 'safe and responsible' AI systems.[251]

Second, the *Interim Discussion Paper* and supplementing documents consistently refer to 'community first' regulation, emphasising the need for 'public involvement' placing people 'at the centre' of regulatory developments.[252] Potential models to achieve this are insufficiently raised in subsequent Government papers.

Third, and related to the above point, the need for accountability and transparency in AI regulation is repeatedly emphasised. References are made to 'designated roles' for regulatory responsibility, publicly accessible information on AI systems, and mechanisms for information sharing.[253]

B *Learning From the GTA and the AIA*

1 *Regulatory Objectives, Decision-Making, and the Risk-Based Approach*

The *Interim Discussion Paper* targets multiple purposes. The first of these is a pro-industry 'overall objective' to maximise opportunities presented by AI.[254] In

[249] Ibid 5.
[250] *Interim Discussion Paper* (n 10) 10–14.
[251] Ibid 13.
[252] Ibid 19.
[253] Ibid 20.
[254] Ibid 19, 25.

addition, the Government emphasises the need to reliably protect against risks through ex ante legislation.[255] This creates potentially conflicting purposes. In an attempt to balance these, the Government proposes a risk-based framework, suggesting more burdensome regulation in high-risk settings and minimal regulation for low-risk systems.[256]

While 'further work' is needed to define these risk-based categories,[257] consultation phases identified a number of potential harms that will inform this work. These include discrimination from algorithmic bias, accurately locating sources of error, systemic and compounding risks, and unforeseen risks driven by rapid technological change.[258] The Government has recognised healthcare as a 'high-stakes' domain, expressing concern about the representativeness of data sets and applicability to Australian populations, in particular for protected characteristics such as race, gender, and disability.[259]

In considering what constitutes a high-risk system and the necessary guardrails to manage risk, the Government has clearly stated that adverse impacts on individual health are a factor, while also stating that not all health-related AI applications are necessarily high-risk.[260] Many explicit references are made to the *AIA* as a direct influence on the Government's policy choices, with the benefits of regulatory 'interoperability' cited as justification for mirroring the approach.[261] Similar proposed features include the range of harms identified, the dual objectives, and the risk-based approach.[262] If Australia is to draw inspiration from the *AIA* in this way, a number of cautions should be mentioned.

A risk-based model can be overly prescriptive in terms of the scope of regulated categories and proportionate obligations that are codified into legislation. As covered in Part III, many scholars faced difficulties in identifying the criteria informing this codifying process under the EU model.[263] This not only means that harms may be overlooked, but also that difficulties may be encountered in justifying the addition of future AI systems to the regulatory categories.[264]

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[255] Ibid 12, 13, 19.
[256] Ibid 13.
[257] Ibid 14.
[258] Ibid 11.
[259] *Proposals Paper* (n 11) 21.
[260] *AI in Health Care Consultation Paper* (n 248) 3, 16.
[261] *Interim Discussion Paper* (n 10) 5, 24–5; *Proposals Paper* (n 11) 5.
[262] *Interim Discussion Paper* (n 10) 5, 15, 24.
[263] Mahler (n 194) 264.
[264] Edwards (n 20) 12.

This may be particularly important in AI contexts given the unpredictability of risk as acknowledged in the *Interim Discussion Paper*.[265] Potentially undetected at first, risks can present systemically to impact on, for example, the proficiency of health professionals or the stability of labour markets.[266] This is possible even in presumed 'low-risk' settings, as scholars have identified this potential for harm in, for example, the widespread use of chatbots,[267] despite them being predominantly unregulated in the *AIA* with only minimal obligations to disclose that a user is interacting with an AI system.[268] Envisioning a scenario in which a chatbot incorrectly directs users away from a public medical service, or perhaps fails to offer alternative platforms to less technology-literate customers, this appears to be a violation of the exact rights intended to be protected under high-risk categories.

Lessons can be drawn here from the *GTA*. In not grouping GMOs into a dichotomy of high- and low-risk, the *GTA* affords the Regulator the flexibility to maintain a reactive, high-touch decision-making presence under a granular model.[269] Consistent with the GTA's underlying process trigger, the *GTA* acknowledges unpredictability and attempts to capture risk across technology lifecycles, rather than fixing it at market release. This broader approach would enliven and give much-needed substance to the DISR's stated aspirations of 'reliability' and 'safety' through continuous monitoring across AI lifecycles.[270]

Another focus of the DISR's approach is mitigating the risk of bias and discrimination in AI use.[271] Recalling from Part III, the *AIA* imposes data training and testing obligations on providers of high-risk systems — provisions that have been critiqued for having insufficient clarity regarding quality criteria and definitions of bias.[272] In a health context, definitional clarity is particularly pertinent, as the term 'bias' may, for example, suggest health-data inaccuracies by

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[265] *Interim Discussion Paper* (n 10) 11.
[266] Ibid 10.
[267] 'Chatbots Are Not People: Dangerous Human-Like Anthropomorphic AI', *Public Citizen* (Web Page, September 2023) <https://www.citizen.org/article/chatbots-are-not-people-dangerous-human-like-anthropomorphic-ai-report/>; 'The Chatbot Race Must Not Be Run with Blinkers', *Australian Human Rights Commission* (Web Page, February 2023) <https://humanrights.gov.au/about/news/ opinions/chatbot-race-must-not-be-run-blinkers>.
[268] *AIA* (n 14) ch 4.
[269] Ebers et al (n 103) 264; Mahler (n 194) 247.
[270] Australian Government, Department of Industry, Science and Resources, *National Assurance Framework* (21 June 2024) 4–6 ('*National Assurance Framework*').
[271] *Interim Discussion Paper* (n 10) 11.
[272] Sandra Wachter, 'Limitations and Loopholes in the EU AI Act and AI Liability Directives: What This Means for the European Union, the United States, and Beyond' (2024) 26(3) *Yale Journal of Law and Technology* 671, 687–98.

reason of poor healthcare access, historical prejudices, or simply ground-truths (eg, certain demographics being predisposed to particular illnesses).

Similarly, notions of individual versus group fairness — 'making all groups impacted by a system worse off, rather than helping disadvantaged groups' — might be interpreted by a provider as less "discriminatory", more "fair", or less "biased".[273] Extreme implications of this interpretation might include diagnosing less patients than necessary in order to meet vague legislative criteria. While definitional certainty is desired, it may be impossible in an area where the technical and ethical boundaries of concepts such as bias and discrimination are being continuously redrawn.

Critiques of the *AIA* have illustrated how mandating training, validation, and testing to be 'free of errors' is an unrealistic and potentially impossible requirement of the *AIA*.[274] The *GTA*'s less prescriptive model should be considered here. With a singular objective to ground its approach, flexible decision-making is distributed between distinct Ethics and Technical Committees, IBCs, and the Regulator across research and development stages — comparable to pre-market data training stages. In an AI context, this model would ensure 'coherent coordination'[275] between dynamic regulatory obligations and evolving standards of bias, discrimination, and data quality metrics that contain both ethical and technical considerations.

To manage such an involved regulatory scheme, questions of scalability should be considered. The *GTA*, since 2001, has approved nine inadvertent dealings and two emergency dealings, assessed 944 applications for the two main streams of intentional GMO releases, and approved just below 15,000 notifiable low-risk dealings.[276] The significant portion of these dealings have been managed by 231 active IBCs,[277] which exist in institutions ranging from universities to private research facilities.

The *GTA*'s protective approach applied in an AI context would likely curb innovation and uptake as it complicates decision-making. If rights-based AI legislation is the goal, however, with health as a priority sector, this necessitates making a strongly pro-industry objective — and concerns of overregulation —

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[273] Ibid 689.
[274] *AIA* (n 14) art 10(3); Ebers et al (n 103) 595; Edwards (n 20) 8.
[275] This revisits terminology used to critique the AI Act in Part III: see Hacker (n 202) 298.
[276] 'What We've Approved?', *OGTR* (Web Page, 3 March 2025) <https://www.ogtr.gov.au/what-weve-approved>.
[277] As at September 2025, see 'List of Accredited Organisations', *OGTR* (Web Page, 5 September 2024) <https://www.ogtr.gov.au/what-weve-approved/accredited-organisations>.

secondary to a protective objective. In any event, the *GTA* demonstrates the possibility of accommodating innovation with timely deregulation alongside constant monitoring of evolving risk.

In 2011, reforms of the gene technology scheme led to the re-classification of genetically modified somatic cell therapies, with many clinical trials of therapeutic products no longer requiring a licence, and instead only IBC review.[278] Experts credit this as 'instrumental' in attracting clinical trials to Australia.[279] This has been contrasted with the *AIA* approach of an initial prediction with occasional amendments, and yet demonstrates the ability to balance promises of a booming market and industry pressures[280] with controlled and risk-free deregulation.

While comparative numbers for AI systems are not readily available, the DISR has estimated that around 650 AI companies are currently headquartered in Australia.[281] Given the scale and diversity of these companies, including the global reach of foreign actors, this raises questions for an AI regulatory model that reflects the *GTA*. Statutory prosecution of an IBC has never been required in the Regulator's history,[282] and between 2023 and 2024 the Regulator received and investigated 66 reports of suspected non-compliance (eg, regarding certification and licence conditions).[283] These figures are significantly below the regulatory output that might be expected of a *horizontal* AI framework. However, in line with this article's focus, scalability can be managed by taking a sector-specific approach in regard to regulatory functions that might be decentralised. There is a significant precedent for this in health-related sectors, not only under IBCs as in the *GTA* model, but also functions in food safety and pharmacovigilance. Similar to certified in-house functions that conduct and manage risk within organisations, internal AI safety bodies could assist and oversee providers and deployers of AI systems in identifying and managing health-related risks. In its early consultations, the Government listed internal review bodies as a potential

[278] O'Sullivan et al, '20 Years of Legislation' (n 5) 5–6.
[279] Ibid 7.
[280] Gabrielle O'Sullivan et al, 'Clinical Gene Technology in Australia: Building on Solid Foundations' (2022) 217(2) *The Medical Journal of Australia* 65, 67.
[281] 'Developing a National AI Capability Plan', *Department of Industry, Science and Resources* (Web Page, 2024) <https://www.industry.gov.au/news/developing-national-ai-capability-plan>.
[282] 'Overview of GMO Monitoring and Compliance', *OGTR* (Web Page, February 2022) <https://www.ogtr.gov.au/ongoing-regulatory-compliance/overview-gmo-monitoring-and-compliance>.
[283] OGTR, *Operations of the Gene Technology Regulator Annual Report 2023-2024'* (September 2024) 61.

oversight mechanism,[284] and although this has diminished in priority with the release of the *Proposals Paper*, it could involve, for example, decentralised bodies embedded in hospitals to directly interact with deployers like practitioners or public health authorities.

The *GTA* provides a worked-through approach where internal and external risk review bodies draw on both ethical and technical expertise in reporting to a regulatory body. This can be efficiently complemented by harmonised standards as contemplated by the *Interim Discussion Paper*, while also addressing scholarly cautions about the appropriateness of standards in light of value-laden and unpredictable risk assessments.

2 *Community First Regulation*

An anticipated feature of the Australian AI framework is 'community first' regulation. This concept is not defined in key documents but, as stated by the DISR, involves placing communities at the centre of the regulatory framework, building public trust, and maintaining close consultation with industry and the community.[285] Early intent to achieve this is signalled by the influence of public participation in refining the current approach. The DISR and the Department of Health and Aged Care have conducted various phases of consultation, seeking advice on gaps in current legal frameworks, and have recommended mechanisms to address these gaps.[286]

Beyond standard practices of consultation within the lawmaking process, a true community first approach requires that the public has a meaningful role within the AI regulatory framework. This is a key feature of the *GTA*, and one that has attracted widespread approval.[287] In AI contexts, public input is particularly important given AI systems move through lifecycles, with risks that change and present differently to different individuals.[288] The gene technology scheme demonstrates the particular importance of this in a high-stakes health context, providing multiple avenues for public engagement which are taken seriously in

[284] *National Assurance Framework* (n 270) 8.
[285] *Interim Discussion Paper* (n 10) 18–19.
[286] Ibid 13–15. See *AI in Health Care Consultation Paper* (n 248).
[287] Kerry (n 92) 216. See generally Richard Hindmarsh and Rosemary Du Plessis, 'GMO Regulation and Civic Participation at the "Edge of the World": The Case of Australia and New Zealand' (2008) 27(3) *New Genetics and Society* 181.
[288] *AI Ethics Principles* (n 238) 5; Michael Guihot, Anne Matthew and Nicolas Pierre Suzor, 'Nudging Robots: Innovative Solutions to Regulate Artificial Intelligence' (2017) 20(2) *Vanderbilt Journal of Entertainment & Technology Law* 385, 414.

relation to individual risk assessment plans (RARMPs), whereas the *AIA* leaves little room for this.[289]

In the DISR's *Voluntary Safety Standard*, stakeholder engagement is listed as a proposed guardrail for AI developers, with a focus on values such as diversity, inclusion, and fairness.[290] In the *Proposals Paper*, which focuses on high-risk settings specifically, stakeholder engagement does not feature as a proposed guardrail and no emphasis is placed on active consultation processes during risk assessment phases, similar to the *AIA*. The *National Assurance Framework* for AI use in government briefly, but marginally, acknowledges the need for this engagement, recognising that stakeholder views may assist when conducting impact assessments.[291] The *National Assurance Framework* also makes mention of 'co-designed' regulation,[292] but subsequent papers do not propose models for this.

This appears to be a shift away from the 'community first' terminology used to lead the national approach. If Australia is to approach AI regulation with a consistent community first attitude, it must present continuous avenues for civic input — particularly given the low levels of public trust in AI and the sensitive nature of health data.[293]

The *GTA* separates political, scientific, and ethical decision-making into different statutory bodies, and incorporates community engagement primarily as an ethical consideration feeding into its risk assessment plans. This model would function well in an AI context, given that even the most technical decisions are necessarily value-laden in the presence of fundamental rights implications.[294] As there is a strong call for human rights-based AI regulation in Australia,[295] it follows that these values should be continuously upheld and grounded in a statutory body. This would give effect to many of the Government's AI Ethics Principles, including promoting human-centred values and AI systems that benefit individuals and society.[296]

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[289] Ebers (n 103) 595.
[290] *Voluntary Safety Standard* (n 245) 42.
[291] *National Assurance Framework* (n 270) 13.
[292] Ibid 26.
[293] Department of the Cabinet and Prime Minister, *How might artificial intelligence affect the trustworthiness of public service delivery?* (Briefing Report, 2023) 15–17.
[294] Veale and Borgesius (n 175) 105.
[295] See generally *AHRC Report on Human Rights and Technology* (n 9).
[296] *AI Ethics Principles* (n 238).

Finally, the gene technology scheme presents other replicable mechanisms for a community first approach, including the statutory nature of the Ethics Committee, the regular outsourcing of public opinion surveys, and established stages of consultation that work to openly refine policy developments and guide RARMPs.

3 *Accountability and Transparency*

Accountable and transparent regulation are intended to be central to the Government's safe and responsible AI plan. However, the vague proposal for risk categories in the *Proposals Paper* brings into question the transparency of the Australian approach, especially when positioned in contrast to the clarity of the *GTA*.

Under the *GTA*, the Regulator is a centralised source of accountability and transparency. For example, the Regulator's website breaks down complicated features of the *GTA* for the general public, listing dealings in accessible formats, and detailing communiques of all bodies informing risk decision-making. Further, the Regulator provides recourse avenues for people impacted by GMOs, and publishes RARMPs to permit public scrutiny. This ensures that rationales for decision-making are clear and accessible, both at a high level and in more detailed stages of application approval. The Australian Government proposed similar avenues as guardrails for AI in both high-risk and general contexts as well as an established Ethics Principle,[297] a welcome deviation from the *AIA* where this is insufficiently addressed.

Currently Australia supports a National AI Centre and a Responsible AI Network, ostensibly to enable sharing of best practice guides, tools, and learning modules under a collaboration of 'knowledge partners'.[298] However, the orientation of both activities is to the *business* community — not to the general public, and similarly not for the purposes of transparency and accountability. Neither body assists, for example, in supporting accountability principles such as ensuring the contestability of decisions. Presumably this is a crucial element of what constitutes 'responsible' and accountable AI — terms that are central to the national approach yet lack substantive definition in policy documents. While establishing accountability in AI contexts can present unique difficulties, this is

[297] *Proposals Paper* (n 11) 35; *Voluntary Safety Standard* (n 245) 34.

[298] 'Responsible AI Network (RAIN)', *Department of Industry, Science and Resources* (Web Page, 2023) <https://www.industry.gov.au/science-technology-and-innovation/technology/national-artificial-intelligence-centre/responsible-ai-network>.

particularly important in health contexts as products with obscured development cycles have the potential to directly influence patient outcomes.

In constructing accountability chains, scholars have recommended approaches to AI accountability that balance external oversight with internal mechanisms.[299] The Australian approach should therefore learn from both the *AIA* and *GTA*. The principal weaknesses of the *AIA* are its dependency on private providers to meet obligations, and its insufficient avenues for recourse. However, it does have the support of surveillance bodies and downstream obligations on AI deployers to report on non-compliance. Feeding substantially modified AI systems back through the regulatory cycle also recommences regulatory obligations in a way that would benefit Australia's framework.

The *GTA* again offers a more comprehensive approach with IBCs uniquely adapted to identifying health-related risks built across technological lifecycles. If a post-development product trigger is favoured in an AI context, similar bodies specialising in AI and healthcare should be established across, for example, healthcare centres or hospitals where private AI-powered tools are flourishing. Regulatory feedback loops in the *AIA* can also be learnt from and adapted to reflect the *GTA*'s high-touch approach by constructing oversight mechanisms for changes in intended and actual use of health-related AI systems to align with scholarly cautions. As demonstrated above, the *GTA*'s consistent regulatory presence could be worked into an AI context through facilitating engagement with expert internal and external bodies, accompanied by transparency and accountability obligations to address the unpredictable and high-risk nature of AI systems.

V Conclusion

As described by the Australian Human Rights Commission, Australia's current AI protection framework is 'patchwork at best'.[300] In the absence of AI-specific legislation, Australia is exposed to both the known and unknown risks of AI systems, which are exacerbated in high-stakes health contexts. Under increasing public pressure, the Australian Government has begun drafting a regulatory approach. In doing so, lessons can be sourced from both the bold first-mover

[299] See generally Robert Gorwa and Michael Veale, 'Moderating Model Marketplaces: Platform Governance Puzzles for AI Intermediaries' (2024) 16(2) *Law, Innovation and Technology* 341.
[300] 'Australia Needs AI Regulation', *Australian Human Rights Commission* (Web Page, 15 August 2023) <https://humanrights.gov.au/about/news/australia-needs-ai-regulation>.

approach of the EU's *AIA*, and Australia's sustained regulatory experience protecting from health risks under the *GTA*.

Comparisons between these regulatory models and the ways in which they approach the far-reaching consequences of two distinct emerging technologies reveal a number of fundamental lessons. At the centre are contrasting approaches to innovation, risk assessment, and fundamental rights that situate a critical decision for Australia. By signalling a clear intent to maximise the economic opportunities presented by AI, rather than adopt a public safety and pro-rights approach, the Australian Government appears to be making a calculus that weighs innovation first and foremost.

Given the unpredictability and high-risk nature of health-related AI systems, this pursuit of innovation without the sophisticated regulatory protections of the gene technology scheme would position Australia without the benefits of technically and ethically informed decision-making by independent experts, meaningful community engagement, or mechanisms for accountability. By adopting a protective objective with a trigger that prioritises pre-market regulation, Australia can regulate AI systems in a manner consistent with precautionary approaches to technologies that are yet without a history of safe use.

This grounding starting point, paired with granular risk categorisation and flexible decision-making powers, provides the foundation for a framework that regulates AI systems not as consumer-facing, tangible products, but as dynamic and unpredictable systems. This would permit risk assessment and regulatory obligations to be framed against the real-world application of AI systems, rather than their intended or predicted use. As illustrated by the *GTA*, these processes should be diversely informed by expert statutory committees, industry-embedded bodies, and the general public. Australia still has the opportunity to overcome the deficiencies identified by scholars expert in the European approach, and in doing so should draw from the rigorous structural protections of the *GTA* in order to regulate AI systems in a responsible and safe manner.

AUSTRALIAN ABORTION LAW IN THE 21ST CENTURY: A JURISDICTIONAL ANALYSIS OF FLAWED LEGISLATION

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During the first quarter of the 21st century, all Australian jurisdictions enacted legislation regulating the provision of abortion services. The purpose of this article is to canvass and assess that legislation from the perspective of whether it serves to recognise a woman's right to abortion. The article contends that practical recognition of this right occurs when the law regulates abortion care in the same manner as other standard health care. The article consequently provides a comparative analysis of the legislation in each jurisdiction in terms of whether medically unjustified conditions are placed upon the lawful provision of abortion care.

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I INTRODUCTION

During the first quarter of the 21st century, all Australian jurisdictions enacted legislation dealing specifically with abortion.[1] The first jurisdiction to do so was the Australian Capital Territory ('the ACT') in 2002,[2] and the final jurisdiction to do so was Western Australia ('WA') in 2023.[3] The aim of this article is to assess such legislation from the perspective of whether it recognises a woman's right to abortion.[4] This article does not make the argument as to why women should have a right to abortion, but rather assumes that women should have this right as an essential step towards achieving the feminist goal of reproductive freedom,[5] which is 'inescapably, the core issue of women's equality and liberty'.[6] Although the concept of reproductive freedom is complex and often controversial, for the purposes of this article the following working definition will suffice: reproductive freedom constitutes 'the condition under which women are able to make truly voluntary choices about their reproductive lives'.[7]

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[1] See *Crimes (Abolition of Offence of Abortion) Act 2002* (ACT); *Medical Practitioners (Maternal Health) Amendment Act 2002* (ACT); *Abortion Law Reform Act 2008* (Vic); Reproductive Health (Access to Terminations) Act 2013 (Tas); *Termination of Pregnancy Law Reform Act 2017* (NT); *Termination of Pregnancy Law Reform Legislation Amendment Act 2021* (NT); *Termination of Pregnancy Act 2018* (Qld); *Abortion Law Reform Act 2019* (NSW); *Termination of Pregnancy Act 2021* (SA); *Abortion Legislation Reform Act 2023* (WA). It should be noted that a number of jurisdictions had also enacted abortion specific legislation prior to the 21st century but all such pre-21st century legislation has now been superseded: see, eg, *Acts Amendment (Abortion) Act 1998* (WA); *Health Regulation (Maternal Health Information) Act 1998* (ACT).

[2] See *Crimes (Abolition of Offence of Abortion) Act 2002* (ACT); *Medical Practitioners (Maternal Health) Amendment Act 2002* (ACT).

[3] See *Abortion Legislation Reform Act 2023* (WA). Although Queensland passed legislation in 2024 that amended the *Termination of Pregnancy Act 2018* (Qld), the primary legislation (ie *Termination of Pregnancy Act 2018* (Qld)) was enacted prior to the WA legislation: see *Health and Other Legislation Amendment Act 2024* (Qld). Similarly, NSW recently enacted the *Abortion Law Reform Amendment (Health Care Access) Act 2025* (NSW), but the primary legislation was enacted earlier: see *Abortion Law Reform Act 2019* (NSW).

[4] This article will refer to 'woman' and 'women' in the interests of clarity and consistency with terminology found in the relevant legislation. However, the author acknowledges that there will be individuals that will seek access to abortion services who do not identify as women. This issue of gender identification is a complex issue beyond the scope of this article.

[5] As Moen explains, '[a] basic assumption of feminist theory is that women have the right to reproductive freedom and control over their bodies, and that this freedom-right-control is essential if they are to have full and equal opportunity in society': Elizabeth Moen, 'Women's Rights and Reproductive Freedom' (1981) 3(2) *Human Rights Quarterly* 53, 53.

[6] Sylvia A Law, 'Rethinking Sex and the Constitution' (1984) 132(5) *University of Pennsylvania Law Review* 955, 1028. See also Ruth Colker, 'Equality Theory and Reproductive Freedom' (1994) 3(1) *Texas Journal of Women and the Law* 99.

[7] Susan Sherwin, *No Longer Patient: Feminist Ethics and Health Care* (Temple University Press, 1992) 115. Sherwin goes on to provide a more detailed definition as follows: 'Reproductive freedom for women requires that they have control over their sexuality, protection against coerced sterilization … and access to the social and economic support necessary to care for any

This is not to say that recognising a right to abortion would thereby result in reproductive freedom (and women's substantive equality) because another crucial aspect of reproductive freedom (among many others) is the right to decide whether to become pregnant, which remains elusive in contemporary society. Nonetheless, establishing a right to abortion facilitates the conditions necessary for reproductive freedom, and if women can decide whether they wish to remain pregnant, then reproductive freedom is thereby enhanced.[8]

In terms of what constitutes legislative recognition of a woman's right to abortion, this article draws on the methodology of prior work,[9] but simplifies the legislative assessment into one question: is abortion treated by the law in the same manner as other standard health care? This question stems from the premise that the practical legal expression of a woman's right to abortion is for the law to treat abortion care purely as health care, which means that abortion must be regulated in the same manner as any standard medical procedure or health service.[10] Thus, for there to exist a woman's right to abortion, no conditions or regulations should be placed upon the lawful provision of abortion care that are not clinically justified or medically substantiated.[11] Consequently, as one might surmise from the title of this article, no jurisdiction in Australia has fully recognised a woman's right to abortion as no jurisdiction has yet achieved the goal of treating abortion care in the same manner as other standard health care. Nonetheless, the analysis embarked upon below remains useful in order to highlight how far each

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children each may choose to bear. It requires that women be free to define their roles in society according to their concerns and needs as women': at 133–4.

[8] See, eg, Rosalind Petchesky, *Abortion and Woman's Choice: The State, Sexuality, and Reproductive Freedom* (Longman, 1984); Lisa Smyth, 'Feminism and Abortion Politics: Choice, Rights, and Reproductive Freedom' (2002) 25(3) *Women's Studies International Forum* 335; Liz Beddoe, 'Reproductive Justice, Abortion Rights and Social Work' (2022) 10(1) *Critical and Radical Social Work* 7; Ann Furedi, *The Moral Case for Abortion: A Defence of Reproductive Choice* (Palgrave Macmillan, 2nd ed, 2021).

[9] See Mark Rankin, 'The Disappearing Crime of Abortion and the Recognition of a Woman's Right to Abortion: Discerning a Trend in Australian Abortion Law?' (2011) 13(2) *Flinders Law Journal* 1, 5–7.

[10] See ibid 31, 35, 37, 45, 48; South Australian Law Reform Institute ('SALRI'), *Abortion: A Review of South Australian Law and Practice* (Report 13, October 2019) 17, 24, 48, 52; Ronli Sifris and Suzanne Belton, 'Australia: Abortion and Human Rights' (2017) 19(1) *Health and Human Rights Journal* 209, 209; Christine Forster and Vedna Jivan, 'Abortion Law in New South Wales: Shifting from Criminalisation to the Recognition of the Reproductive Rights of Women and Girls' (2017) 24(4) *Journal of Law and Medicine* 850, 850.

[11] This is not to say that abortion should be unregulated, as this would have adverse health consequences for women, but simply that it should be no more regulated than is medically necessary. That is, abortion should be regulated by the general health framework. For a discussion of how this would function in practice: see Judith Dwyer et al, 'Is There Still a Need for Abortion-Specific Laws? The Capacity of the Health Framework to Regulate Abortion Care' (2021) 46(2) *Alternative Law Journal* 141.

jurisdiction is from treating abortion care purely as health care. Prior to commencing this assessment of each jurisdiction, there are certain legislative creations that are common to all jurisdictions, and these will be canvassed at the outset.

II COMMONALITIES AND ISSUES

First and foremost, it is now the case that all Australian jurisdictions have legislated to decriminalise abortion (to varying degrees, and with contrasting levels of success), and no jurisdiction retains an offence for a 'woman who consents to, assists in, or performs a termination on herself'.[12] From a women's rights perspective, this is an irrefutably constructive development 'as one cannot have a right to a crime'.[13] Decriminalisation also reduces the social stigma often associated with abortion, and enhances access to abortion services.[14]

Nonetheless, as mentioned above, all jurisdictions continue to treat abortion care differently to other health care. The most obvious illustration of this differential treatment, or 'abortion exceptionalism',[15] is the existence of abortion specific legislation.[16] The other clear instance of such exceptionalism is that, despite

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[12] *Termination of Pregnancy Act 2018* (Qld) s 10. For similar provisions in other jurisdictions see *Crimes (Abolition of Offence of Abortion) Act 2002* (ACT) s 3; *Reproductive Health (Access to Terminations) Act 2013* (Tas) s 8; *Abortion Law Reform Act 2008* (Vic) s 11 and *Crimes Act 1958* (Vic) s 65(2); *Criminal Code Act 1983* (NT) s 208A(4); *Abortion Law Reform Act 2019* (NSW) s 12; *Termination of Pregnancy Act 2021* (SA) s 16; *Abortion Legislation Reform Act 2023* (WA) s 4 and *Public Health Act 2016* (WA) s 202MO.

[13] Mark J Rankin, 'Recent Developments in Australian Abortion Law: Tasmania and the Australian Capital Territory' (2003) 29(2) *Monash University Law Review* 316, 317. Although the criticism should be noted that this might result in a 'shift from criminalisation to medicalisation' without any necessary recognition of women's reproductive rights: see Forster and Jivan (n 10) 856.

[14] See, eg, Ronli Sifris, 'Abortion in Australia: Law, Policy, and the Advancement of Reproductive Rights' in Mary Ziegler (ed), *Research Handbook on International Abortion Law* (Elgar Publishing, 2023) 124, 127–8 ('Abortion in Australia'). However, it should also be noted that decriminalisation does not, in itself, solve problems of access: see Tania Penovic and Ronli Sifris, 'Facilitating Safe Access to Health Care through Legislative Reform: The Australian Experience' (2024) 31 *Journal of Law and Medicine* 185, 187.

[15] Millar describes 'abortion exceptionalism' as 'the singling out of abortion from other areas of medicine on the grounds that it is special, different, or more complex or risky than is empirically justified', and further observes that '[a]bortion exceptionalism signals the various discourses and practices that differentiate abortion from routine medical care': Erica Millar, 'Abortion Stigma, Abortion Exceptionalism, and Medical Curricula' (2023) 32(3) *Health Sociology Review* 261, 261, 263. For further discussion of this term see Johanna Commins and Erica Millar, 'Exceptionalising Abortion Law: Decriminalised Jurisprudence in Australia' (2024) 33(3) *Griffith Law Review* 253, 264–6.

[16] That is, few other areas of health care are so specifically targeted by the law. It might be argued that such abortion specific legislation was necessary in order to decriminalise the practice, as all jurisdictions had created the offence of abortion in the early 20th century, but this just moves the exceptionalism proposition to the legislation that defined abortion as a crime in the first place.

ostensibly abolishing the offence of abortion, all jurisdictions nonetheless maintain a residual crime of abortion.[17]

A *The Residual Offence of Abortion*

The crime relevant to abortion that exists in all jurisdictions is that of an unqualified person performing, or assisting in the performance of, an abortion, including the provision or administration of abortifacients.[18] In all jurisdictions this constitutes a serious offence punishable by lengthy imprisonment.[19]

In all jurisdictions other than the ACT, South Australia ('SA'), and WA the applicable offences remain in the criminal law.[20] In the ACT, the *Crimes (Abolition of Offence of Abortion) Act 2002* (ACT) ensured that all criminal law provisions on abortion were abolished,[21] yet created two new offences within the *Health Act 1993* (ACT): (1) performing a surgical abortion (as distinct from a medical abortion)[22] in a non-approved facility;[23] and (2) the performance of an abortion

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For an example of such legislation see the historical versions of *Crimes Act 1900* (NSW) ss 82–4; *Criminal Code Act 1899* (Qld) ss 224–6; *Criminal Code Act 1924* (Tas) ss 134–5.

[17] See Barbara Baird and Erica Millar, 'When history Won't Go Away: Abortion Decriminalisation, Residual Criminalisation and Continued Exceptionalism' (2024) 21(3) *History Australia* 416, 433; Commins and Millar (n 15) 266. Some jurisdictions also retain the offence of child destruction, which carries implications for gestational limits for lawful abortion: see Mark J Rankin, 'The Offence of Child Destruction: Issues for Medical Abortion' (2013) 35(1) *Sydney Law Review* 1 ('The Offence of Child Destruction'). This issue will be discussed further below.

[18] See *Public Health Act 2016* (WA) s 202MN(1); *Criminal Code Act 1924* (Tas) s 178D(1); *Criminal Code Act 1983* (NT) ss 208A(1)–(2); *Criminal Code Act 1899* (Qld) ss 319A(1)–(2); *Crimes Act 1900* (NSW) ss 82(1)–(2); *Crimes Act 1958* (Vic) s 65(1); *Health Act 1993* (ACT) ss 81–82; *Termination of Pregnancy Act 2021* (SA) ss 14(1)–(2). The definitions of 'qualified' and 'unqualified' in this regard differ between jurisdictions, but for the purposes of this article a broad definition/distinction will suffice as follows: a 'qualified' person is a registered health practitioner, and in many jurisdictions a registered medical practitioner. The ACT legislation provides a succinct definition of abortifacient as follows: 'abortifacient means a medicine, drug or other substance that causes a pregnancy to end prematurely': *Health Act 1993* (ACT) s 80(1).

[19] Most jurisdictions prescribe a penalty of seven years imprisonment: see *Public Health Act 2016* (WA) s 202MN(1); *Criminal Code Act 1983* (NT) ss 208A(1)–(2); *Criminal Code Act 1899* (Qld) ss 319A(1)–(2); *Crimes Act 1900* (NSW) ss 82(1)–(2); *Termination of Pregnancy Act 2021* (SA) s 14(1). In the ACT a lesser penalty of five years is imposed, and in Victoria a greater penalty of 10 years is specified: see *Health Act 1993* (ACT) ss 81–2; *Crimes Act 1958* (Vic) s 65(1).

[20] See *Criminal Code Act 1924* (Tas) s 178D; *Criminal Code Act 1983* (NT) s 208A; *Criminal Code Act 1899* (Qld) s 319A; *Crimes Act 1900* (NSW) s 82; *Crimes Act 1958* (Vic) s 65(1).

[21] That is, *Crimes Act 1900* (ACT) ss 44–6 were repealed and any common law offence of abortion was abolished: see *Crimes (Abolition of Offence of Abortion) Act 2002* (ACT) s 3.

[22] This distinction was the result of amendments enacted by the *Health (Improving Abortion Access) Amendment Act 2018* (ACT), which will be discussed further below. The definition of 'medical abortion' is as follows: 'medical abortion means the prescription, supply or administration of an abortifacient': *Health Act 1993* (ACT) s 80(2).

[23] See *Health Act 1993* (ACT) s 83.

by an unqualified person.[24] In SA, the *Termination of Pregnancy Act 2021* (SA) removed abortion from the ambit of criminal law legislation but created the new offence of '[t]ermination of pregnancy by unqualified person' within that abortion specific legislation.[25] Similarly, in WA the *Abortion Legislation Reform Act 2023* (WA) repealed the relevant criminal code provisions on abortion,[26] but also created the offence of '[a]n unqualified person who performs an abortion' within the *Public Health Act 2016* (WA).[27]

It is beyond the scope of this article to provide a detailed analysis of these residual offences.[28] It will suffice for present purposes to point out that the existence of such abortion specific offences necessarily results in a finding that abortion care is not being treated in the same manner as other standard health care, as no other standard health care is similarly explicitly criminalised.[29] This is not to say that an unqualified person performing other medical procedures would not be subject to being charged for an offence under general health law or criminal law; the point is simply that in other forms of health care the legislature has not specifically criminalised such behaviours. That is, if an unqualified person performs surgery on another, or administers a drug outside the appropriate regulatory framework, this will constitute an offence, either under the general criminal law, or pursuant to applicable health law, but particular actions are not specified. For example, it would be a crime for an unqualified person to remove another person's appendix, but such behaviour is not expressly criminalised in the sense of it being an explicit offence for an unqualified person to remove another person's appendix; rather, it

[24] See ibid ss 81–2.
[25] *Termination of Pregnancy Act 2021* (SA) s 14.
[26] See *Abortion Legislation Reform Act 2023* (WA) s 4, which deleted *Criminal Code Act Compilation Act 1913* (WA) s 199.
[27] *Public Health Act 2016* (WA) s 202MN(1).
[28] However, it is of interest to note that there exists scant, if any, evidence that such offences address any real societal need, in that there is no material evidence that abortions performed by unqualified persons are occurring within Australia: see Baird and Millar (n 17) 420–5, 430. Baird and Millar suggest that such offences are more about 'medical control' over women's bodies for reproduction: at 418, 425; and serve to 'position abortion seekers as vulnerable and in need of protection': at 428.
[29] Voluntary assisted dying legislation in most jurisdictions also provides for specific offences with respect to that practice: see, eg, *Voluntary Assisted Dying Act 2021* (Qld) pt 9; but voluntary assisted dying is not 'standard' health care as the practice involves the intentional killing of a person. It might be argued that abortion should be similarly differentiated as the practice involves the intentional killing of the foetus, but this argument is inherently flawed as the foetus is not a person but (arguably) part of the pregnant woman's body: see below n 153.

is an offence for an unqualified person to perform surgery,[30] and the removal of an appendix constitutes an instance of surgery.

In other words, the reason such conduct is not expressly targeted by the legislature is that the need is already met by general health law and criminal law. Put simply, it is an offence in every jurisdiction for a person to provide a regulated health service without being a recognised health practitioner.[31] The same may be said of the performance of an abortion by an unqualified person: it is *prima facie* unlawful under such generally applicable health law or criminal law provisions because that would constitute the provision of a regulated health service by a person unqualified to do so. Thus, to expressly create an offence for an unqualified person to terminate a pregnancy is to distinguish abortion care from all other forms of health care for no credible medical or legal purpose. As Baird and Millar assert: '[t]he residual offences exemplify how the decriminalising Acts continue to exceptionalise abortion as a medical procedure'.[32] Furthermore, the maintenance of such offences means that each jurisdiction has, at best, only achieved partial decriminalisation of abortion.[33]

B *Conscientious Objection*

In a comparable manner, all jurisdictions expressly provide for conscientious objection with regard to abortion care, despite the fact that relevant professional standards, codes of conduct, and guidelines already provide for conscientious objection (and permit a refusal to participate on that basis) with respect to any medical procedure or health service.[34] In some jurisdictions the abortion specific conscientious objection provisions arguably reflect such standards, codes of

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[30] That is, as one cannot consent to serious bodily harm in such circumstances (see, eg, *R v Holmes* (1993) 2 Tas R 232), surgery performed by an unqualified person will constitute a serious offence in every jurisdiction. Indeed, in some jurisdictions it might constitute an aggravated offence to, eg, wounding, inflicting bodily harm, or assault occasioning actual bodily harm: see, eg, *Crimes Act 1900* (ACT) s 48A(2).

[31] See, eg, *Health Act 1993* (ACT) s 127.

[32] Baird and Millar (n 17) 417. See also Commins and Millar (n 15) 266.

[33] See Suzanne Belton, Felicity Gerry and Virginia Stulz, 'A Reproductive Rights Framework Supporting Law Reform on Termination of Pregnancy in the Northern Territory of Australia' (2018) 6(2) *Griffith Journal of Law & Human Dignity* 25, 26; Commins and Millar (n 15) 263.

[34] See, eg, Australian Health Practitioner Regulation Agency & National Boards, *Code of Conduct* (June 2022) cl 1.3(f); Australian Medical Association, *AMA Position Statement: Conscientious Objection* (March 2019); Nursing and Midwifery Board of Australia, Australian Health Practitioner Regulation Agency, *Code of conduct for nurses* (March 2018, as updated June 2022) cl 4.4(b); Pharmaceutical Society of Australia, *Code of Ethics for Pharmacists* (2017) 12; Medical Board, Australian Health Practitioner Regulation Agency, *Good medical practice: a code of conduct for doctors in Australia* (October 2020) cl 3.4.6.

conduct, or guidelines, thereby making them superfluous.[35] In other jurisdictions the provisions are possibly inconsistent with those standards, codes of conduct, or guidelines, thereby creating unnecessary legal complexity and perhaps confusion amongst health practitioners as to which process should be followed.

In Victoria, Queensland and the Northern Territory ('the NT'), the abortion-specific conscientious objection provisions stipulate that if a health practitioner has a conscientious objection to abortion, that practitioner must make that objection known to the patient, and then refer or transfer the care of the patient to another practitioner or health service provider that the objecting practitioner knows, or reasonably believes, has no such objection.[36]

In the ACT, Tasmania, SA, WA, and New South Wales ('NSW'), no such direct referral is mandated. In the ACT 'an authorised person' with a conscientious objection (on religious or other grounds) may refuse to provide any abortion services.[37] However, any such conscientious objection must be 'immediately' conveyed to the person requesting abortion services.[38] The person requesting abortion services must also either be provided with information on how to locate or contact another health practitioner who the conscientious objector

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[35] One might argue that the relevant health practitioner codes of conduct and ethical standards are not law, so legislation is required to give legal substance to such standards. However, whenever those standards are repeated in legislation, a failure to meet them (eg a failure to refer a patient) does not carry a legislatively imposed penalty. In such instances the health practitioner is simply liable to disciplinary action for that failure: see, eg, *Termination of Pregnancy Act 2018* (Qld) s 9. This is essentially the same disciplinary action that might result from a failure to meet the non-legislative health practitioner standards. Furthermore, to argue that relevant health practitioner standards, codes of conduct, or guidelines carry no legal substance or consequence is to ignore the fact that a failure to meet them might well be the basis for a civil action against such a health practitioner for professional negligence.

[36] See *Abortion Law Reform Act 2008* (Vic) s 8(1); *Termination of Pregnancy Act 2018* (Qld) ss 8(2)–(3); *Termination of Pregnancy Law Reform Act 2017* (NT) ss 11(2), 12(2). In Queensland the objecting practitioner need only 'believe' in this regard: see *Termination of Pregnancy Act 2018* (Qld) s 8(3). In the Northern Territory and Victoria the objector must 'know' that the other practitioner has no such objection: see *Termination of Pregnancy Law Reform Act 2017* (NT) ss 11–12; *Abortion Law Reform Act 2008* (Vic) s 8(1)(b). Of course, enforcing the obligation to refer is problematic and practitioners may not do so or deliberately seek to delay that referral, which serves to 'obstruct access': Ronli Sifris, 'Conscientious Objection in Australia: A Comparison between Abortion and Voluntary Assisted Dying' (2022) 29(4) *Journal of Law and Medicine* 1079, 1086 ('Conscientious Objection in Australia').

[37] *Health Act 1993* (ACT) s 84A(1). Unless an emergency situation exists: s 84A(2). This exception to the right to conscientiously object in emergency situations applies in all jurisdictions: see *Termination of Pregnancy Law Reform Act 2017* (NT) s 13; *Abortion Law Reform Act 2008* (Vic) ss 8(3)–(4); *Termination of Pregnancy Act 2021* (SA) s 11(5); *Reproductive Health (Access to Terminations) Act 2013* (Tas) ss 6(3)–(4); *Abortion Law Reform Act 2019* (NSW) s 9(5); *Termination of Pregnancy Act 2018* (Qld) s 8(4); *Public Health Act 2016* (WA) s 202MI(4).

[38] *Health Act 1993* (ACT) s 84A(4)(a).

'reasonably believes' has no objection to providing the abortion services requested,[39] or transferred into another health practitioner's care that the conscientious objector reasonably believes has no such objection to providing the abortion services requested.[40]

Similarly, in SA and NSW, direct referral is mentioned as an option, but is not a requirement. That is, in SA and NSW the medical practitioner with the conscientious objection may either transfer the care of the patient directly, or simply provide information to the patient 'on how to locate or contact a medical practitioner who, in the first practitioner's reasonable belief, does not have a conscientious objection to the performance of the termination'.[41] In both jurisdictions this obligation to provide information is also met if the medical practitioner provides information approved by the Minister (in SA) or the Secretary of the Ministry of Health (in NSW) for that purpose.[42]

In WA, a registered health practitioner that 'has a conscientious objection to abortion' must disclose that conscientious objection 'immediately',[43] but may then refuse to provide any assistance to the patient, including mere advice.[44] However, if the conscientious objector is a medical practitioner,[45] then, similar to the situation in SA and NSW, that medical practitioner must 'without delay transfer the patient's care' to another registered health practitioner or health facility that 'in the refusing practitioner's reasonable belief', can provide the requested service,[46] or 'immediately give the patient information, approved by the Chief Health Officer … about how to locate or contact' a registered health practitioner or facility of this 'kind'.[47] In Tasmania, conscientious objectors merely have an obligation to 'provide the woman with a list of prescribed health services

[39] Ibid s 84A(4)(b)(i)(A). Or provide information on how to contact or locate a medical facility 'where they reasonably believe a health practitioner working at the facility can provide the abortion service and would not refuse to do so because of a conscientious objection': s 84A(4)(b)(i)(B).
[40] Ibid s 84A(4)(b)(ii).
[41] *Abortion Law Reform Act 2019* (NSW) s 9(3)(a); *Termination of Pregnancy Act 2021* (SA) s 11(3)(a).
[42] See *Termination of Pregnancy Act 2021* (SA) s 11(4); *Abortion Law Reform Act 2019* (NSW) s 9(4).
[43] *Public Health Act 2016* (WA) s 202MH(2).
[44] Ibid s 202MH(1). A relevant health profession student may also refuse to assist on this basis: s 202MJ.
[45] It should be noted that, with medical practitioners, the refusal to participate may stem from 'a conscientious objection to abortion or for some other reason': ibid s 202MI(1)(b).
[46] Ibid s 202MI(2)(a).
[47] Ibid s 202MI(2)(b).

from which the woman may seek advice, information or counselling on the full range of pregnancy options'.[48]

This provision of lists or contact information in the above jurisdictions has been labelled 'passive referral' as distinct from the 'active referral' of actual transfer of care.[49] The problem with merely providing such lists or information, rather than actually referring or transferring the care of a patient, is that this may cause further delay as the woman concerned is then compelled to seek out such health practitioners or services at her own convenience, and often in stressful, time-critical, and complex circumstances. It is arguable that this fails to meet a health practitioner's professional ethical obligations to provide appropriate health care to their patient as it may fall short of the standards that would otherwise be applicable if conscientious objection with respect to abortion was not specifically legislated for.[50] That is, the relevant professional standards, codes of conduct, or guidelines arguably imply an obligation to directly refer the patient to another health practitioner or service provider in order to access the health care requested.[51] This referral obligation is implied on the basis of the express obligations of the conscientious objector to 'minimise disruption to patient care',[52] to 'ensure the patient has alternative care options',[53] and to act in a manner that 'appropriately facilitates continuity of care for the patient'.[54]

It is beyond the scope of this article to provide further analysis on abortion specific conscientious objection.[55] It is also unnecessary in terms of the focus of

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[48] *Reproductive Health (Access to Terminations) Act 2013* (Tas) s 7(2).

[49] See Casey M Haining et al, 'Abortion Law in Australia: Conscientious Objection and Implications for Access' (2022) 48(2) *Monash University Law Review* 238, 258–9.

[50] See, eg, Public Health Association of Australia, *Abortion: Policy Position Statement* (September 2023) 4.

[51] See, eg, NSW Parliamentary Research Service, *Issues Backgrounder: Abortion and the Reproductive Health Care Reform Bill 2019* (Report No 3, August 2019) 10. The failure to directly refer is also condescending to the woman concerned: see Kate Gleeson, 'The Other Abortion Myth: The Failure of the Common Law' (2009) 6 *Journal of Bioethical Inquiry* 69, 81–2. See also Forster and Jivan who argue that an obligation to refer is necessary to protect the reproductive rights of women: Forster and Jivan (n 10) 859–61.

[52] Australian Medical Association (n 34) cls 1.5, 2.2. The AMA further stipulate that the conscientious objector must also 'take whatever steps are necessary to ensure the patient's access to care is not impeded': at cl 2.3.

[53] Australian Health Practitioner Regulation Agency & National Boards (n 34) cl 1.3(f).

[54] Pharmaceutical Society of Australia (n 34) 12. Cf Anna Walsh and Tiana Legge, 'Abortion Decriminalisation in New South Wales: An Analysis of the Abortion Law Reform Act 2019 (NSW)' (2019) 27(2) *Journal of Law and Medicine* 325. Walsh and Legge make the point that an obligation not to impede patient access to the service requested does not necessarily result in a further obligation to refer the patient: at 334–5.

[55] For a comprehensive discussion of all such legislative provisions, with an emphasis on the obligations of conscientious objectors, especially with regard to duties of referral, see Haining et al

this article, as the fact that all jurisdictions have specifically legislated for conscientious objection in the provision of abortion care, even though this issue is already catered for within relevant professional standards, codes of conduct, or guidelines that apply to all health care provision, thereby distinguishes abortion care from most other forms of health care.[56]

The other legislative instance of abortion specific provisions common to all jurisdictions is that of safe access zone legislation.[57] However, analysis of this issue is not required for the purposes of this article, as safe access zone legislation constitutes an example of clinically (and pragmatically) justified differential treatment, in that such legislation is necessary to secure access to a place of employment or the health service sought.[58] As mentioned earlier, this article focuses on highlighting legislative provisions that are clinically or medically unjustified, such as the maintenance of the residual offence of abortion and the specific provision for conscientious objection with respect to abortion care discussed above. These examples of abortion exceptionalism indicate that, in every jurisdiction, further law reform is required in order to realise the goal of treating abortion care in the same manner as other forms of health care. Notwithstanding this determination, this article will now examine the other aspects of the Australian legislative reforms that have occurred in the 21st century.

(n 49) 246–62. Haining et al conclude that allowing health practitioners to conscientiously object serves to impede access to abortion and causes delay in receiving that care: at 264–6. See also Anne O'Rourke, Lachlan de Crespigny and Amanda Pyman, 'Abortion and Conscientious Objection: The New Battleground' (2012) 38(3) *Monash University Law Review* 87; Ronli Sifris, 'Tasmania's Reproductive Health (Access to Terminations) Act 2013: An Analysis of Conscientious Objection to Abortion and the "Obligation to Refer"' (2015) 22 *Journal of Law and Medicine* 900; Sifris, 'Conscientious Objection in Australia' (n 36) 1081–2.

[56] Conscientious objection is also specifically mentioned in relevant euthanasia legislation: see, eg, *Voluntary Assisted Dying Act 2022* (NSW) s 21(2)(a); *Voluntary Assisted Dying Act 2021* (SA) s 10; *Voluntary Assisted Dying Act 2019* (WA) s 9; *Voluntary Assisted Dying Act 2017* (Vic) s 7. However, as contended above, euthanasia is not 'standard' health care.

[57] See *Health Act 1993* (ACT) ss 85–7; *Public Health Act 2010* (NSW) pt 6A; *Termination of Pregnancy Law Reform Act 2017* (NT) pt 3; *Termination of Pregnancy Act 2018* (Qld) pt 4; *Health Care Act 2008* (SA) pt 5A; *Reproductive Health (Access to Terminations) Act 2013* (Tas) ss 9–12; *Public Health and Wellbeing Act 2008* (Vic) pt 9A; *Public Health Act 2016* (WA) ss 202N–Q. For discussion of safe access zone legislation, see Ronli Sifris and Tania Penovic, 'Anti-Abortion Protest and the Effectiveness of Victoria's Safe Access Zones: An Analysis' (2018) 44(2) *Monash University Law Review* 317; Mark J Rankin, 'Safe Access Zone Legislation in Australia: Determining an Appropriate Legislative Template for South Australia and Western Australia' (2020) 39(2) *University of Tasmania Law Review* 61.

[58] To emphasise this point, it should be noted that in NSW safe access zones are not limited to premises that only provide abortions, but are established around 'any premises at which medical services relating to aspects of human reproduction or maternal health are provided': *Public Health Act 2010* (NSW) s 98A.

III AUSTRALIAN ABORTION LEGISLATION

The purpose of this examination is to determine how far each jurisdiction is from treating abortion care as health care, and thereby recognising a woman's right to abortion. In this sense the practical focus is upon whether medically unnecessary or unjustified processes must be satisfied in order to perform a lawful abortion. For example, in most jurisdictions there is a requirement for two medical practitioners to agree on the appropriateness of the abortion after a certain gestation. In some jurisdictions there are further conditions — that only specialists may lawfully perform abortions, or that the provision of mandatory information concerning accessing counselling must occur prior to an abortion being lawfully performed — or an insistence that abortions may only be lawfully performed in prescribed facilities, or the imposition of an arbitrary gestational limit on the practice of lawful abortion. Although many of these processes may be medically justified or clinically necessary in specific circumstances, according to an individual patient's needs and interests,[59] to mandate such conditions in advance in every case is not medically justified or clinically necessary.[60] Thus, the legislative imposition of such conditions results in the conclusion that abortion care is not being regulated in the same manner as standard health care.

The first four jurisdictions to enact abortion specific legislation this century — the ACT, Victoria, Tasmania, and the NT — will be discussed separately, as each of those jurisdictions takes a markedly different approach. The remaining jurisdictions will be discussed as a thematic bundle, as all such legislation draws on the Victorian legislative model to varying degrees.

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[59] For example, in a particularly complex case, consulting with another health practitioner may well be medically appropriate, but to impose such consultation in advance in every case is not.

[60] It should be noted at the outset that such imposed conditions on a lawful abortion do not apply in emergency situations. In Queensland, NSW, and WA an 'emergency' situation exists when the relevant medical practitioner considers the abortion necessary in order to either save the woman's life or the life of another foetus: see *Termination of Pregnancy Act 2018* (Qld) s 6(3); *Abortion Law Reform Act 2019* (NSW) s 6(5); *Public Health Act 2016* (WA) s 202ME(5). In the NT an 'emergency' exists when 'the medical practitioner considers the termination is necessary to preserve the life of the woman': *Termination of Pregnancy Law Reform Act 2017* (NT) s 10. In SA 'emergency' is left undefined: see *Termination of Pregnancy Act 2021* (SA) s 6(3). The emergency exemption is not specifically mentioned in the ACT, Victorian or Tasmanian legislation, other than with respect to conscientious objection: see *Health Act 1993* (ACT) s 84A(2); *Abortion Law Reform Act 2008* (Vic) ss 8(3)–(4); *Reproductive Health (Access to Terminations) Act 2013* (Tas) ss 6(3)–(4). However, one may assume it applies in any case as a result of reasonable and appropriate clinical practice.

A *The Australian Capital Territory*

The ACT has gone through perhaps more legislative changes with respect to abortion law than any other jurisdiction, as there has been legislation dealing with aspects of abortion law and practice in 1998,[61] 2002,[62] 2015,[63] and 2018.[64] The most significant legislation was passed in 2002 with the *Crimes (Abolition of Offence of Abortion) Act 2002* (ACT), the *Health Regulation (Maternal Health Information) Repeal Act 2002* (ACT), and the *Medical Practitioners (Maternal Health) Amendment Act 2002* (ACT). In combination this legislation achieved the objective of removing abortion entirely from the criminal law,[65] and regulating the practice solely through health law.[66]

The 2002 legislation was amended by the *Health (Improving Abortion Access) Amendment Act 2018* (ACT). This legislation substituted new sections for much of Part 6 of the *Health Act 1993* (ACT), which deals with abortion and safe access zones. The changes made to the provisions on safe access zones were too minor to warrant mention, but the 2018 legislation did clarify an issue with respect to the practice of abortion by explicitly defining (and thereby distinguishing) medical and surgical abortion.[67] This had important implications in terms of the offence of performing an abortion in a non-approved facility, as the legislation now makes it clear that only surgical abortions must be performed in such facilities.[68]

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[61] See *Health Regulation (Maternal Health Information) Act 1998* (ACT).
[62] See *Crimes (Abolition of Offence of Abortion) Act 2002* (ACT); *Health Regulation (Maternal Health Information) Repeal Act 2002* (ACT); *Medical Practitioners (Maternal Health) Amendment Act 2002* (ACT).
[63] See *Health (Patient Privacy) Amendment Act 2015* (ACT).
[64] See *Health (Improving Abortion Access) Amendment Act 2018* (ACT).
[65] That is, by repealing *Crimes Act 1900* (ACT) ss 44–6 and abolishing any common law offence of abortion: see *Crimes (Abolition of Offence of Abortion) Act 2002* (ACT) s 3. However, as noted above, the ACT still retains offences with regard to abortion: see *Health Act 1993* (ACT) ss 81–3.
[66] This was achieved by inserting pt 4B into the *Medical Practitioners Act 1930* (ACT): see *Medical Practitioners (Maternal Health) Amendment Act 2002* (ACT). The 2002 amendments to the *Medical Practitioners Act 1930* (ACT) were moved without amendment into the *Health Professionals Act 2004* (ACT), and then into the *Health Act 1993* (ACT) pt 6, in which the regulation of abortion currently resides.
[67] See *Health Act 1993* (ACT) s 80. Surgical abortion is now defined as 'a surgical procedure or any other procedure or act (other than the administration or supply of an abortifacient) that causes a pregnancy to end prematurely': at s 80(1). Medical abortion is defined as 'the prescription, supply or administration of an abortifacient': at s 80(2).
[68] See ibid s 83. This is a significant practical development because it means that a woman may now go to her general practitioner (in person or via telemedicine), receive a prescription for an abortifacient, and administer it herself in the comfort of her own home. To further this objective, the 2018 legislation made it clear that a pharmacist (or a person assisting a pharmacist) commits no offence by supplying an abortifacient 'in accordance with a prescription': at s 81(2).

Thus, in the ACT, a lawful surgical abortion is one performed in an approved medical facility (or an approved part of a medical facility) by a registered medical practitioner upon the pregnant woman's request,[69] (and any person may assist a medical practitioner in carrying out a surgical abortion),[70] and a registered pharmacist (or a person assisting a pharmacist) may supply abortifacients for the purposes of a medical abortion in accordance with a prescription.[71] In other words, other than the approved medical facility requirement,[72] and the conscientious objection and residual offence issues canvassed earlier in the article, abortion is arguably treated like any other medical procedure in the ACT. Furthermore, the approved medical facility requirement is not as onerous as it would first appear for two reasons: (1) as mentioned above, the approved medical facility requirement only applies to surgical abortion and does not apply to medical abortion;[73] and (2) the process for making an application to be so approved is relatively straightforward because, upon receiving an application, the Minister 'must approve the application if reasonably satisfied the medical facility is suitable'.[74]

Furthermore, unlike all the other jurisdictions discussed below, the ACT stands alone in not mandating an arbitrary gestational limit upon which further (more restrictive) regulation is required. Perhaps most significantly, unlike any other jurisdiction, in the ACT, regardless of gestation, there is no requirement to provide two medical practitioners' opinions, nor to specifically justify the abortion by reference to legislatively mandated criteria.[75] However, the ACT retains the offence of child destruction, which arguably creates an implicit upper gestational limit for lawful abortions.[76] As noted earlier, there may well be a clinically

[69] Ibid ss 80–4.
[70] Ibid s 82(2).
[71] Ibid s 81(2).
[72] Which is self-evidently not treating abortion like any other medical procedure, and which places a medically unnecessary burden on women seeking abortion. SALRI made the point that demanding a prescribed facility was 'at odds with current clinical practice and undermines equitable and effective access': SALRI (n 10) 192.
[73] See *Health Act 1993* (ACT) ss 80, 83.
[74] Ibid s 84(2).
[75] That is, in every other jurisdiction, at some point, it is mandated that the medical practitioner(s) must be satisfied of certain criteria. For example, even in the otherwise relatively progressive jurisdictions of Victoria and Queensland, at a certain gestation the legislation mandates that the medical practitioner(s) must be satisfied that the abortion is appropriate (or should be performed) 'in all the circumstances': see *Abortion Law Reform Act 2008* (Vic) s 5(1); *Termination of Pregnancy Act 2018* (Qld) s 6(1). One might argue that such a consideration is quite broad, and not overly prescriptive, but SALRI has made the point that any such specified criteria for defining lawful abortion should be avoided: see SALRI (n 10) 19, 27, 207–10.
[76] See *Crimes Act 1900* (ACT) s 42. Where that upper limit lies is open to interpretation: see Rankin, 'The Offence of Child Destruction' (n 17).

necessary upper limit for a particular abortion based upon specific medical concerns for that patient, but there should be no arbitrary legal limit set for lawful abortion.[77] This is not only clinically unnecessary, but potentially detrimental to the pregnant woman's health.[78]

B *Victoria*

There is no upper gestational limit for lawful abortion in Victoria.[79] This was one of many achievements of the *Abortion Law Reform Act 2008* (Vic).[80] This legislation was, like the ACT legislation before it, innovative and broadly supportive of a woman's right to abortion, as evidenced by the fact that abortion is arguably treated like any other health care service, provided the woman concerned is not more than 24 weeks pregnant. That is, up until 24 weeks gestation, Victoria has established a situation of abortion on demand: a woman may request an abortion, and a medical practitioner may perform that abortion.[81] In common with other medical procedures, neither counselling nor specialist opinions are required, nor is a specific approved facility mandatory. Furthermore, registered pharmacists or registered nurses may supply or administer drugs to cause an abortion, provided the woman concerned is not more than 24 weeks pregnant.[82] This recognition of other registered health practitioners reflects modern clinical practice and is conducive to patient-managed health care. Some jurisdictions limit the provision of abortion services, including medical abortion, to medical practitioners (as will be discussed below). This not only impedes access and is not evidence-based, but is also inconsistent with the regulation of

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[77] See, eg, SALRI, recommending that there be no upper limit to lawful abortion because '[a]bortions occurring later in gestation are especially likely to involve complex medical circumstances, including serious or fatal fetal abnormalities where the diagnosis is delayed, the prognosis is uncertain, or the fetus is one of a multiple pregnancy; or complex personal circumstances, including late recognition of pregnancy, delayed access to services, social and geographic isolation, domestic or family violence, socio-economic disadvantage, or mental health issues': SALRI (n 10) 215. See also Belton, Gerry and Stulz (n 33) 41.

[78] See Jeanne M Snelling, 'Beyond Criminalisation: Abortion Law Reform in Aotearoa New Zealand' (2022) 30(2) *Medical Law Review* 216, 234–5.

[79] That is, there is no express upper limit mentioned in the *Abortion Law Reform Act 2008* (Vic), and that legislation repealed *Crimes Act 1958* (Vic) s 10, thereby abolishing the offence of child destruction.

[80] For a discussion of the manner in which the 2008 Victorian reform passed through Parliament see Jenny Morgan, 'Abortion Law Reform: The Importance of Democratic Change' (2012) 35(1) *UNSW Law Journal* 142, 157–72.

[81] See *Abortion Law Reform Act 2008* (Vic) s 4.

[82] Ibid s 6. Such health practitioners must be authorised to do so pursuant to the *Drugs, Poisons and Controlled Substances Act 1981* (Vic).

other health care which allows for the participation of non-medical practitioner health professionals when the clinical need requires it.[83]

After 24 weeks gestation, a medical practitioner may only perform an abortion if that medical practitioner 'reasonably believes that the abortion is appropriate in all the circumstances',[84] and 'has consulted at least one other registered medical practitioner who also reasonably believes that the abortion is appropriate in all the circumstances'.[85] In making this assessment a registered medical practitioner must consider '(a) all relevant medical circumstances; and (b) the woman's current and future physical, psychological and social circumstances'.[86] The regulation of abortion after 24 weeks gestation is thus more restrictive,[87] and the decision is no longer solely the pregnant woman's to make,[88] but rather the relevant two medical practitioners. However, the matters which the medical practitioners must consider are broad, and are clearly matters that should be considered by medical practitioners in any case, as part of appropriate clinical practice. Nonetheless, the demand for a compulsory second practitioner opinion is not medically necessary. A medical practitioner might seek a second opinion if the individual patient's circumstances warranted it, but there is no clinically based need to make it mandatory. On this basis (and despite the positive attributes of the legislation with respect to pre-24 weeks gestation abortions discussed above), one may conclude that abortion care is not regulated in the same manner as other comparable health care in Victoria because, with other health care, it is the patient that makes the decision, and not the medical profession. This criticism — that at a certain gestation the decision-making power is taken out of the pregnant woman's hands and granted to the medical

[83] See, eg, Dwyer et al (n 11) 143.
[84] *Abortion Law Reform Act 2008* (Vic) s 5(1)(a).
[85] Ibid s 5(1)(b).
[86] Ibid s 5(2).
[87] Post-24 weeks gestation the woman concerned can also no longer access abortifacients as easily, as although a registered pharmacist or registered nurse may still supply or administer such medication, that pharmacist or nurse must be employed or engaged by a hospital: ibid ss 7(1), (3)–(4); and can only do so upon the written direction of a medical practitioner that has satisfied the above conditions with respect to performing an abortion post-24 weeks gestation (including obtaining the requisite second opinion): at ss 7(1)–(4). However, it should be noted that the definition of 'hospital' for these purposes is quite broad and incudes 'a public hospital, private hospital or day procedure centre within the meaning of the *Health Services Act 1988*': at s 7(5).
[88] As Morgan notes, the Victorian legislation 'configures women as responsible decision-makers, at least until the foetus is at 24 weeks' gestation. After that time, their responsibility is constrained by the requirements to consult with two doctors': Morgan (n 80) 172. See also Forster and Jivan, who conclude that prior to 24 weeks there exists 'an unfettered right to choose abortion … but after 24 weeks that right is removed and authority shifts from the woman herself to members of the medical profession who become gatekeepers of her right': Forster and Jivan (n 10) 854.

profession — is common to all jurisdictions other than the ACT, as all other jurisdictions (with the exception of Tasmania and the NT) broadly follow the Victorian legislative template in this and other respects.

C *Tasmania*

Tasmania has engaged in a number of legislative reforms of abortion law,[89] culminating in the *Reproductive Health (Access to Terminations) Act 2013* (Tas).[90] As a result of this legislation, the termination of a pregnancy is lawful provided that the woman concerned is not more than 16 weeks pregnant,[91] and provided the termination is performed by a medical practitioner with the woman's consent.[92] There is no requirement for counselling or the involvement of more than one medical practitioner, nor is it necessary that the abortion be performed in an approved facility. However, as only medical practitioners may provide abortions, abortion care is thereby treated differently to other forms of health care that allow for the involvement of a diverse range of health care professionals based on clinical need and patient interest.

Terminations post-16 weeks' gestation may only be performed by a medical practitioner (with the woman's consent) if that medical practitioner:

> (a) reasonably believes that the continuation of the pregnancy would involve greater risk of injury to the physical or mental health of the pregnant woman than if the pregnancy were terminated; and
>
> (b) has consulted with another medical practitioner who reasonably believes that the continuation of the pregnancy would involve greater risk of injury to the physical or mental health of the pregnant woman than if the pregnancy were terminated.[93]

In making the above assessments, the medical practitioners 'must have regard to the woman's physical, psychological, economic and social circumstances'.[94] The second medical practitioner consulted need not have personally examined the

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[89] For a discussion of such past reforms see Rankin, 'Recent Developments in Australian Abortion Law' (n 13) 317–26.
[90] That is, this legislation certainly bettered the legislation that preceded it: see *Criminal Code Act 1924* (Tas) ss 134–5, 164 as repealed by *Reproductive Health (Access to Terminations) Act 2013* (Tas) s 14.
[91] *Reproductive Health (Access to Terminations) Act 2013* (Tas) s 4.
[92] Ibid. Terminating a pregnancy includes either using an instrument or drug to 'discontinue' the pregnancy: at s 3.
[93] Ibid s 5(1).
[94] Ibid s 5(2).

woman concerned, but at least one of the two medical practitioners must specialise in 'obstetrics or gynaecology',[95] the sourcing of which may cause delay.

Clearly, abortions post-16 weeks gestation are thereby regulated unlike any other health care. Not only is the clinically unnecessary approval of two medical practitioners required (with the further medically unwarranted demand that one be a specialist) but, unlike those imposed in Victoria post-24 weeks gestation, the mandated assessments are markedly different to those which apply in all other standard health care. Although an assessment of the health risks associated with any requested medical procedure is always part of best clinical practice (and necessary in order for the patient to make an informed decision) and that assessment may involve considering whether a requested medical procedure constitutes a greater health risk than not performing that procedure, to prohibit the requested medical procedure solely on the basis that it constitutes a greater health risk to the patient than not performing the procedure is the height of paternalism, and defines women as less than full moral persons able to make informed, rational decisions on their own behalf, and in their own interests. If such reasoning were applied to all other medical procedures, many elective surgeries (such as cosmetic surgery) would potentially be deemed unlawful.

Fortunately for women seeking abortions post-16 weeks gestation, the required assessment is also arguably redundant as childbirth is always a greater somatic risk to a woman than the termination of a pregnancy by a qualified health practitioner.[96] Therefore, the conditions for lawful abortion post-16 weeks will arguably be met in every instance. Put simply, serious somatic complications from abortion are rare, and even minor complications are uncommon.[97] It has also

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[95] Ibid s 5(3).

[96] See, eg, Sheldon, 'The Decriminalisation of Abortion: An Argument for Modernisation' (2016) 36(2) *Oxford Journal of Legal Studies* 334, 343–4 ('The Decriminalisation of Abortion'). This is especially the case in the early stages of pregnancy when early medication abortion remains available: see Anne O'Rourke, Suzanne Belton and Ea Mulligan, 'Medical Abortion in Australia: What are the Clinical and Legal Risks? Is Medical Abortion Over-regulated?' (2016) 24(1) *Journal of Law and Medicine* 221, who make the point that there are 'negligible medical risks associated' with the use of abortifacients such as mifepristone, and that such medication has less adverse health consequences than paracetamol: at 221, 227. See also Nathalie Kapp et al, 'Medical Abortion in the Late First Trimester: A Systematic Review' (2019) 99(2) *Contraception* 77, 84. Even late term abortions remain comparatively safer procedures than childbirth, as evidenced by the fact that the maternal mortality rate for lawful abortion, throughout Australia, has been less than 1 per 100,000 for some time now: see, eg, Caroline de Costa, 'Induced Abortion and Maternal Death' (2013) 15(1) *O&G Magazine* 37, 37. Yet the maternal mortality rate for childbirth continues to be approximately 6–8 per 100,000: see, eg, Preventive Health SA, *Maternal and Perinatal Mortality in South Australia 2021* (Report, December 2024) 12.

[97] See, eg, South Australian Abortion Reporting Committee, Preventive Health SA, *Annual Report for the Year 2023* (April 2024) 14–15.

been proven for some time now that abortion does not, generally, have any deleterious psychological effects.[98] Thus, it is hard to imagine a case in which an abortion could be described as posing a greater risk to the health of a pregnant woman than childbirth itself, especially given that the woman's 'physical, psychological, economic and social circumstances' must be part of that assessment.[99] On another positive note from an access perspective, there is no longer an express nor implicit upper limit to lawful abortion.[100] Thus, although there are increased restrictions on lawful abortion post-16 weeks gestation, an abortion may be performed at any time under those conditions.

Nonetheless, it remains the case that the law stipulates conditions on post-16 weeks gestation abortions that are not medically necessary. Aspects of clinical practice may well differ with respect to different gestation abortions, but legality should not.[101] Applicable health law, professional ethics and standards, and clinical guidelines will determine best health practice in the patient's best interests in any given situation.[102] To mandate different treatment based on gestation is to treat abortion unlike any other health care.

D *The Northern Territory*

The NT has been comparatively active on abortion law reform from the late 20th century,[103] with the most recent reform occurring in 2021.[104] In the NT an abortion may lawfully be performed by a medical practitioner,[105] through

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[98] See, eg, Sarah Romans-Clarkson, 'Psychological Sequelae of Induced Abortion' (1989) 23(4) *Australian and New Zealand Journal of Psychiatry* 555.

[99] *Reproductive Health (Access to Terminations) Act 2013* (Tas) s 5(2).

[100] That is, no upper limit is expressed in the relevant abortion specific legislation, and that legislation also repealed the offence of child destruction: see *Criminal Code Act 1924* (Tas) s 165 as repealed by *Reproductive Health (Access to Terminations) Act 2013* (Tas) s 14 which, if maintained, places an implicit upper limit on lawful abortion: see Rankin, 'The Offence of Child Destruction' (n 17).

[101] SALRI reported no clinical necessity for upper gestational limits to lawful abortion and concluded that any such limits would be 'inappropriate': SALRI (n 10) at 28, 242.

[102] For example, gestational limits may operate as a matter of clinical practice in specific cases: see, eg, Queensland Law Reform Commission ('QLRC'), *Review of termination of pregnancy laws* (Report No 76, June 2018) 58.

[103] The Northern Territory first engaged with abortion law reform in 1974 (ie the enactment of *Criminal Code Act 1983* (NT) s 174 based on the 1969 South Australian legislation), then in 2006 (ie the redrafting of *Criminal Code Act 1983* (NT) s 174 and the relocating of those provisions into the *Medical Services Act 1982* (NT) s 11), and then in 2017: see *Termination of Pregnancy Law Reform Act 2017* (NT). Initially this 2017 legislation allowed relatively easy access to abortion only until 14 weeks gestation, but recent amendments have extended that time period to 24 weeks gestation: see *Termination of Pregnancy Law Reform Legislation Amendment Act 2021* (NT) s 5, which amended *Termination of Pregnancy Law Reform Act 2017* (NT) s 7.

[104] See *Termination of Pregnancy Law Reform Legislation Amendment Act 2021* (NT).

[105] See *Termination of Pregnancy Law Reform Act 2017* (NT) s 6(1).

'surgical procedure' or the administration of a 'termination drug',[106] on a woman of any age,[107] and at any premises, provided the woman is not more than 24 weeks pregnant,[108] but only if the medical practitioner 'considers the termination is appropriate in all the circumstances'.[109] In making this determination the medical practitioner must have regard to:

> (a) all relevant medical circumstances; and
>
> (b) the woman's current and future physical, psychological and social circumstances; and
>
> (c) professional standards and guidelines.[110]

As explained with respect to the Victorian legislation, mandating that the relevant medical practitioner only perform an abortion when 'appropriate in all the circumstances', and compelling consideration of the above factors, is arguably superfluous as it does not add value to what a medical practitioner is obliged to do with respect to any medical procedure. That is, to act in accordance with applicable health law, professional standards and guidelines, and make an informed clinical decision on the available medical evidence and in the patient's best interests. In addition, it might be argued that specifically mandating these requirements only serves to delay the process of accessing an abortion because a medical practitioner may thereby seek to make especially sure that all such legislative requirements are met, rather than simply performing the safe and common medical procedure that is being requested.[111]

More problematic from a women's rights perspective is that the provision effectively serves to remove the abortion decision from the woman concerned. That is, the legislation makes it clear that the medical practitioner decides whether the abortion is 'appropriate in all the circumstances',[112] which serves to erode the pregnant woman's 'agency and autonomy'.[113] In all other jurisdictions, the abortion decision is initially the pregnant woman's to make, but then

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[106] Ibid.
[107] See ibid s 4. Prior to the 2017 legislation, further conditions applied if the woman was under 16 years of age: see the repealed *Medical Services Act 1982* (NT) s 11(5).
[108] See *Termination of Pregnancy Law Reform Act 2017* (NT) s 7.
[109] Ibid.
[110] Ibid. Such standards and guidelines may be set by the Chief Health Officer: see *Termination of Pregnancy Law Reform Regulations 2017* (NT) rr 5–7.
[111] The relative safety of abortion has been highlighted earlier: see above nn 96–8. The fact that it is a common procedure is based on data that suggests that approximately one third of Australian women will have an abortion: see, eg, Belton, Gerry and Stulz (n 33) 28; SALRI (n 10) 113.
[112] *Termination of Pregnancy Law Reform Act 2017* (NT) s 7.
[113] Ronli Sifris, Tania Penovic and Caroline Henckels, 'Advancing Reproductive Rights through Legal Reform' (2020) 43(3) *UNSW Law Journal* 1078, 1081.

becomes, at a certain gestation, a decision for the medical profession.[114] In the NT, it is never the woman's decision, and there exists no abortion on demand at any stage, as the medical profession is granted legal gatekeeping power in this regard for the duration of any pregnancy.[115] No other health service or medical procedure is so categorically taken out of the adult patient's hands.

After 24 weeks gestation the medical practitioner that performs the termination of pregnancy must have 'consulted with at least one other medical practitioner who has assessed the woman',[116] and each medical practitioner must consider the termination 'appropriate in all the circumstances'[117] upon an assessment of the identical issues (as quoted above) with respect to a termination of not more than 24 weeks gestation.[118] Both of the requisite two medical practitioners must have personally examined the woman concerned in arriving at this assessment, which does not reflect current clinical practice,[119] and is likely to cause delay in accessing the service, especially in remote areas.[120]

Finally, although no upper limit is mentioned in the *Termination of Pregnancy Law Reform Act 2017* (NT), the NT maintains the offence of child destruction, which may serve to place an implicit upper limit on lawful abortions.[121] This is problematic for a number of reasons,[122] not the least of which is that upper legal

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[114] That is, in Victoria, Tasmania, Queensland, NSW, SA, and WA, although the abortion decision is taken out of the woman's hands at certain gestations, at which point the abortion will only be lawful if the requisite medical practitioners conclude that it is appropriate to perform the abortion, up until those gestational limits are reached the abortion decision is solely the woman's to make. The exception to this is the ACT, in which the abortion decision remains the woman's to make regardless of gestation.

[115] There is no medical basis for this: see, eg, Forster and Jivan, who contend that '[t]here is no compelling reason to prefer medical practitioners over pregnant women and girls as the decision-makers in abortion. Even when termination requires medical advice, there is no compelling reason why practitioners should not, as in any other medical decision, provide the appropriate advice to assist the woman or girl to make the best decision for herself': Forster and Jivan (n 10) 863.

[116] *Termination of Pregnancy Law Reform Act 2017* (NT) s 9(a).

[117] Ibid s 9(b).

[118] See ibid.

[119] This requirement of two opinions has been described as outdated, unnecessary, and possessing no cogent basis: see SALRI (n 10) 348. The further requirement of that second opinion being necessarily based upon an in-person examination of the patient reinforces this description in the age of telehealth.

[120] This issue with remote patients is alleviated somewhat if the patient is not more than 14 weeks pregnant, in which case a medical practitioner may 'direct an authorised ATSI health practitioner, authorised midwife, authorised nurse or authorised pharmacist to assist in the performance of a termination': *Termination of Pregnancy Law Reform Act 2017* (NT) s 8(1).

[121] See *Criminal Code Act 1983* (NT) s 170.

[122] For example, by maintaining the offence of child destruction, the NT has arguably enacted conflicting legislation as a foetus at 24 weeks gestation is likely to be a 'child capable of being born

limits tend to have negative health consequences for women.[123] As mentioned previously, there is no medical basis for mandating such limits in every case, so maintaining gestational limits constitutes a further example of the legal exceptionality of abortion.[124]

E *The Victorian Model: Queensland, New South Wales, South Australia, and Western Australia*

In Queensland, NSW, SA, and WA, the Victorian legislation was utilised as the basic template for abortion law reform.[125] In chronological order, the relevant legislation in the jurisdictions that followed aspects of the Victorian model are as follows: *Termination of Pregnancy Act 2018* (Qld), *Abortion Law Reform Act 2019* (NSW), *Termination of Pregnancy Act 2021* (SA), and *Abortion Legislation Reform Act 2023* (WA). In all of these jurisdictions, a termination of pregnancy achieved prior to a certain gestation is lawful in a broad set of circumstances.

1 *Lawful Abortion Prior to Specific Gestation*

In Queensland, provided the termination is performed at no more than 22 weeks gestation by a medical practitioner,[126] or a registered health practitioner if the termination is achieved by use of abortifacients,[127] there now effectively exists a situation of abortion on demand.[128] This is also the case at no more than 22 weeks gestation in NSW, provided the termination is performed by 'a prescribed health

alive', and thus arguably protected by those child destruction provisions. For discussion of such issues see Rankin, 'The Offence of Child Destruction' (n 17).

[123] See, eg, World Health Organization, *Safe abortion: technical and policy guidance for health systems* (Department of Reproductive Health and Research, 2nd ed, 2012) 93–4. The Public Health Association of Australia contends that 'gestational limits are inappropriate mechanisms for regulating the provision of abortion': Public Health Association of Australia (n 50) 2.

[124] See Erica Millar, 'Maintaining Exceptionality: Interrogating Gestational Limits for Abortion' (2022) 31(3) *Social & Legal Studies* 439.

[125] One might argue that the NT legislation also utilised the Victorian model, but the fact that the abortion decision in the NT is never the woman's to make (as outlined above) constitutes a fundamental deviation from the Victorian legislation.

[126] See *Termination of Pregnancy Act 2018* (Qld) s 5.

[127] See ibid s 6A. Registered health practitioners include midwives, nurses, and any other 'practitioner prescribed by regulation': at s 6A(1).

[128] Other registered health practitioners 'in the practice of the practitioner's prescribed health profession' may assist 'in the performance of the termination', whether it be a surgical or medical termination of pregnancy: ibid s 7(2). Health profession students may also assist under supervision: at s 7(3). It is also implicit that any failure by a qualified person to comply with the conditions stipulated under the *Termination of Pregnancy Act 2018* (Qld) will not be penalised criminally, but rather the qualified person will be left to such professional disciplinary proceedings and consequences as might eventuate with non-compliance with the statutory standards of any other medical procedure: at s 9.

practitioner',[129] who has 'obtained informed consent' for the termination.[130] This is defined as consent given 'freely and voluntarily' and in accordance with applicable guidelines.[131] One might argue that the provision is thereby redundant as informed consent so defined is already 'an integral aspect of health law and practice'.[132]

In SA, provided the pregnant woman 'is not more than 22 weeks and 6 days pregnant', an abortion may be lawfully performed 'by a medical practitioner acting in the ordinary course of the practitioner's profession'.[133] The legislation also makes it clear that 'any other registered health practitioner acting in the ordinary course of the practitioner's profession' may terminate a pregnancy by administering abortifacients, provided the registered health practitioner is authorised to prescribe such medication.[134] In common with Queensland and NSW, no reasons need to be provided by the pregnant woman in requesting an abortion, and the decision is hers to make, as the medical practitioner or health

[129] *Abortion Law Reform Act 2019* (NSW) s 5(1). The original 2019 legislation only allowed for medical practitioners to perform abortions, but this was amended by the *Abortion Law Reform Amendment (Health Care Access) Act 2025* (NSW) to allow for prescribed health practitioners, which includes 'an endorsed midwife' or a nurse practitioner: *Abortion Law Reform Act 2019* (NSW) s 5(4). In common with the Queensland legislation, in terms of assistance, registered health practitioners, in the practice of their health profession, may assist the medical practitioner, including a 'nurse, midwife, pharmacist or Aboriginal and Torres Strait Islander health practitioner, or another registered health practitioner prescribed by the regulations': at s 8(1).

[130] *Abortion Law Reform Act 2019* (NSW) s 5(2). Unless an emergency situation exists, and it is not practicable to do so: at s 5(3).

[131] Ibid sch 1.

[132] SALRI (n 10) 22. However, it should be noted that such applicable guidelines, in relation to the performance of an abortion, may be decided upon by the Secretary of the Ministry of Health, and may place further burdens on informed consent with respect to abortion care than are prescribed in other forms of health care: see *Abortion Law Reform Act 2019* (NSW) s 14.

[133] *Termination of Pregnancy Act 2021* (SA) s 5(1)(a). It is submitted that 'acting in the ordinary course of the practitioner's profession' is a meaningless condition because it is fulfilled the moment the practitioner performs the termination, which includes '(a) administering or prescribing a drug or other substance; or (b) using a medical instrument or other thing': at s 3.

[134] Ibid s 5(1)(b). A 'registered health practitioner' is defined as any person (other than a student) registered under the *Health Practitioner Regulation National Law*: at s 3. It is also the case that, whether the abortion is performed by a medical practitioner or other registered health practitioner, another registered health practitioner (including a medical practitioner) 'acting in the ordinary course of the practitioner's profession' may assist in that termination of pregnancy: at s 10. As mentioned above with respect to the Victorian legislation, authorising non-medical practitioner health professionals to perform medical abortions is laudable as it enhances access to abortion services and reflects best clinical practice.

practitioner does not need to be satisfied that legislatively mandated criteria are met.[135]

In WA, provided the person concerned is not more than 23 weeks pregnant,[136] a medical practitioner 'is authorised to perform an abortion',[137] and a 'prescribing practitioner' may prescribe, supply, or administer abortion drugs for that purpose.[138] A 'registered health practitioner in a relevant health profession (other than pharmacy)' may supply or administer an abortion drug 'on the direction of a directing practitioner'.[139] Further, a pharmacist is authorised to supply an abortion drug on the basis of a relevant direction or prescription.[140] Other registered health practitioners, and relevant health profession students, may assist in the performance of an abortion at any gestation, provided that abortion is authorised under the legislation.[141] One may readily note that the conditions described in the above jurisdictions broadly reflect the Victorian model.

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[135] This is not quite correct, as certain information on counselling must be provided: *Termination of Pregnancy Act 2021* (SA) s 8; and an abortion must not be performed 'for the purposes of sex selection': at s 12(1). These issues will be discussed further below.

[136] *Public Health Act 2016* (WA) s 202MC. It should be noted that the legislation refers to 'person' rather than 'woman'. It should also be noted that if the person is under 18 years of age and the registered health practitioner considers that the patient 'does not have the capacity to consent, on their own behalf, to the abortion being performed on them because the patient has not achieved a sufficient understanding and intelligence to enable them to understand fully what is proposed', or 'it is not possible to ascertain whether the patient has the capacity to consent', then a parent or guardian may participate in the decision making process, including providing the relevant consent or refusal, but only if the patient agrees to that participation: at s 202MM.

[137] Ibid s 202MC. The performance of an abortion constitutes doing 'any act with the intention of causing the termination of the pregnancy': at s 202MB(1). It includes prescribing, supplying or administering 'an abortion drug': at ss 202MB(2)(a)–(c). It also includes 'carrying out a surgical or other procedure': at s 202MB(2)(d). However, merely 'assisting a person to do an act done with the intention of causing the termination of a pregnancy' does not constitute the performance of an abortion: at s 202MB(3).

[138] Ibid s 202MD. The definition of 'prescribing practitioner' refers to registered health practitioners that are authorised to prescribe an abortion drug under the *Medicines and Poisons Act 2014* (WA) and the relevant regulations: *Public Health Act 2016* (WA) s 202MD(1).

[139] *Public Health Act 2016* (WA) s 202MF(3). As mentioned above, permitting non-medical practitioner health professionals to perform medical abortions has a positive impact on access to abortion services, is best clinical practice, and is consistent with a patient centred approach.

[140] Ibid s 202MF(2). After 23 weeks gestation, any such prescription must be issued by a medical practitioner, while prior to 23 weeks the prescription may be issued by a prescribing health practitioner: at s 202MF(1).

[141] Ibid s 202MG. If the registered health practitioner or relevant health profession student 'knows' that the abortion is being performed 'other than as authorised' under the legislation, then such assistance is not permitted: at ss 202MG(2), (5). The definition of 'health profession' has a wide meaning pursuant to *Health Practitioner Regulation National Law (WA) Act 2010* (WA) s 5, including medical practitioners, nurses, midwives and pharmacists: see *Public Health Act 2016* (WA) ss 4, 202MA.

However, in NSW and SA, more is required in order to perform a lawful abortion. In NSW, prior to performing an abortion, the relevant registered health practitioner must also 'assess whether or not it would be beneficial to discuss with the person accessing counselling about the proposed termination',[142] and 'if, in the registered health practitioner's assessment, it would be beneficial and the person is interested in accessing counselling, provide all necessary information to the person about access to counselling'.[143] Although at first glance this echoes some features of the now repealed WA legislation of 1998,[144] unlike that WA legislation, the NSW provision does not require mandatory counselling. Instead, there is merely a requirement that an assessment be made as to whether the person concerned would benefit from access to counselling.[145] Furthermore, in practice it may have little effect, as a medical practitioner might satisfy the provision by simply asking whether the woman concerned wants information with respect to access to counselling. In SA, prior to performing an abortion (whether performed by a medical practitioner or other registered health practitioner) 'all necessary information … about access to counselling, including publicly-funded counselling' must be provided to the person seeking an abortion.[146] To mandate the provision of such information is condescending to the woman concerned, as it presumes that she has not already considered all such matters prior to deciding to terminate her pregnancy.[147] Nonetheless, in common with NSW, the SA legislation does not mandate counselling, only the provision of information about accessing counselling, so it remains the woman's prerogative whether to seek counselling, or indeed to even read the information provided.

2 *Lawful Abortion After Specific Gestation*

As highlighted previously, there are no medical or clinical reasons to mandate further conditions on lawful abortion after a specified gestation period. Thus, the imposition of such requirements must have another purpose. Most legislation is silent as to what this objective might be, but in Queensland the basis of such provisions is arguably a contested view of the status of the foetus. The *Termination of Pregnancy Act 2018* (Qld) is, with some minor changes, the

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[142] *Abortion Law Reform Act 2019* (NSW) s 7(1)(a).
[143] Ibid s 7(1)(b).
[144] See the historical versions of *Health (Miscellaneous Provisions) Act 1911* (WA) ss 334(3)(a), (5).
[145] That is, the provision of relevant access to counselling information is only mandated consequent to that assessment: see *Abortion Law Reform Act 2019* (NSW) s 7(1)(b). For a discussion of the NSW counselling provisions see Walsh and Legge (n 54) 328–31.
[146] *Termination of Pregnancy Act 2021* (SA) s 8(1). Such information need not be provided in cases of emergency: at s 8(2). This ignores the SALRI recommendation not to mandate such information provision: see SALRI (n 10) 280.
[147] See, eg, SALRI (n 10) 278–80.

enactment of the Draft Termination of Pregnancy Bill 2018 put forward by the Queensland Law Reform Commission ('QLRC') in its 2018 report.[148] The Queensland Parliament thus took what the QLRC described as the 'combined' approach.[149] This incorporates a gradualist position on the status of the foetus,[150] with restrictions on accessing abortion services increasing as the gestational age of the foetus increases because, as the QLRC explained, 'the interests of the fetus have increasing weight'[151] and 'as the fetus develops, its interests are entitled to greater recognition and protection'.[152] It is arguable that all jurisdictions other than the ACT have implicitly adopted a similar perspective on the foetus in restricting access to abortion care after a certain gestation, but Queensland stands alone in making that link more explicit by accepting the QLRC position in that regard. However, the QLRC view ignores two crucial points. First, it is arguably a doubtful, and certainly a contestable, moral/philosophical position to take as to whether the foetus has interests that warrant legal protection.[153] Second, any such legal protection afforded the foetus necessarily erodes any legal protection or rights afforded to the pregnant woman.[154] The Queensland approach thus infringes upon the rights of an actual person, on the basis of an implicit determination upon an issue that is philosophically intractable, and for

[148] See QLRC (n 102) app F.
[149] Ibid 59.
[150] See ibid 274.
[151] Ibid 6.
[152] Ibid 94.
[153] That is, whether the foetus is a moral person is open to debate. However, there is no doubt that the foetus is not a legal person. This has been the common law position for centuries, either implicitly, by virtue of the fact that the foetus cannot be the victim of homicide: see, eg, Edward Coke, *The Third Part of the Institutes of the Laws of England: Concerning High Treason, and Other Pleas of the Crown, and Criminal Causes* (W Clarke & Sons, 1791) 47–50; *R v Poulton* (1832) 5 C & P 329, 330; *R v Hutty* [1953] VLR 338, 339; *Barrett v Coroner's Court of South Australia* (2010) 108 SASR 568, 573–5; or expressly. Perhaps the most pertinent statement is made by Justice Lindenmayer, in concluding that the foetus 'has no legal personality and cannot have a right of its own until it is born and has a separate existence from its mother': *In the Marriage of F* (1989) 13 Fam LR 189, 194. Indeed, Justice Lindenmayer went so far as to label the foetus a 'non-person': at 197. See also *Attorney General (Qld) (ex rel Kerr) v T* (1983) 46 ALR 275, 277 (Gibbs CJ); *Paton v British Pregnancy Advisory Service Trustees* [1979] 1 QB 276, 279 (Baker P). Similar determinations are evident in legislation: see, eg, *Criminal Code Act 1924* (Tas) s 153(4). This lack of foetal personhood has been described as a 'fundamental premise of both civil and criminal law': SALRI (n 10) 12. It should also be noted that the *Human Rights Act 2019* (Qld) does not apply to a termination of pregnancy or 'an unborn child': at s 106. Indeed, it has recently been decided with respect to the *Human Rights Act 2019* (Qld) that 'only individuals have human rights, and an unborn child is not yet an individual': *Darling Downs Hospital and Health Service v J* [2024] QSC 330, [39]. However, it should also be noted that one may owe certain ethical obligations to an organism that is neither a moral nor legal person.
[154] See, eg, Judith Jarvis Thomson, 'A Defense of Abortion' (1971) 1(1) *Philosophy and Public Affairs* 47, 53–4; Smyth (n 8) 337; Furedi (n 8) 201–2.

which there is no societal consensus, which is a completely inappropriate determination for the law to make. As there exists a lack of philosophical and societal unanimity of opinion on the status of the foetus, the law must take 'a minimalist, morally neutral position'.[155] To do otherwise arguably 'undermines the legitimacy' of our legal system.[156] Contrary to this reasoning, all jurisdictions other than the ACT prescribe further restrictions on lawful abortion once a certain gestation has been reached. As detailed above, Victoria imposes such restrictions post-24 weeks gestation.[157] The relevant legislation in Queensland, NSW, SA, and WA reflects this approach.

In Queensland, after 22 weeks gestation only medical practitioners may lawfully terminate a pregnancy, and the medical profession (not the woman concerned) is granted the decision-making power, as a medical practitioner may only perform a termination of pregnancy if:

> (a) the medical practitioner considers that, in all the circumstances, the termination should be performed; and
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> (b) the medical practitioner has consulted with another medical practitioner who also considers that, in all the circumstances, the termination should be performed.[158]

As mentioned previously, the requirement of a second opinion is medically unjustified, and not legislatively mandated in any other standard medical procedure.[159] As to the matters that must be considered in forming this assessment, the relevant medical practitioners must consider:

> (a) all relevant medical circumstances; and
>
> (b) the woman's current and future physical, psychological and social circumstances; and

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[155] Andrew McGee, Melanie Jansen and Sally Sheldon, 'Abortion Law Reform: Why Ethical Intractability and Maternal Morbidity are Grounds for Decriminalisation' (2018) 58(5) *Australian and New Zealand Journal of Obstetrics and Gynaecology* 594, 595.
[156] Ibid 596.
[157] See *Abortion Law Reform Act 2008* (Vic) s 5.
[158] *Termination of Pregnancy Act 2018* (Qld) s 6(1).
[159] Which is not to say that it might be best clinical practice to seek a second opinion in certain circumstances; the point is simply that it is not medically warranted to prescribe such a second opinion in all cases. Sheldon argues that the requirement of two medical practitioner opinions serves a bureaucratic rather than medical purpose: see Sheldon, 'The Decriminalisation of Abortion' (n 96) 345; and that this requirement of two opinions 'is at the heart of the medical control' of abortion: Sally Sheldon, 'British Abortion Law: Speaking from the Past to Govern the Future' (2016) 79(2) *Modern Law Review* 283, 314.

(c) the professional standards and guidelines that apply to the medical practitioner in relation to the performance of the termination.[160]

Thus, the legal situation in Queensland post-22 weeks gestation is almost identical to that prescribed in Victoria post-24 weeks gestation.[161] The only difference is that in Queensland the two medical practitioners must also consider 'professional standards and guidelines'[162] in arriving at a determination that the abortion should be performed 'in all the circumstances'.[163] As was the case with this aspect of the Victorian legislation, the criticism of superfluous requirements may be directed against the above provisions,[164] as a medical practitioner must contemplate all these matters in any case.[165]

The law in WA is similar to Queensland, in that, after 23 weeks gestation, a medical practitioner is only authorised to perform an abortion if he or she 'reasonably believes that performing the abortion is appropriate in all the circumstances',[166] and 'has consulted with at least 1 other medical practitioner who … also reasonably believes that performing the abortion is appropriate in all the circumstances'.[167] In forming this belief, both medical practitioners must have regard to almost identical concerns as exist in the Queensland and Victorian Acts.[168] However, the obligation to consult with another medical practitioner post-23 weeks gestation is somewhat more flexible than in those other jurisdictions, in the sense that the other medical practitioner need not necessarily be practising in WA,[169] and if that other medical practitioner does not believe that the abortion is appropriate in all the circumstances, the primary medical

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[160] *Termination of Pregnancy Act 2018* (Qld) s 6(2).
[161] Indeed, the matters listed under *Termination of Pregnancy Act 2018* (Qld) ss 6(2)(a)–(b) are taken directly from those listed under *Abortion Law Reform Act 2008* (Vic) s 5(2).
[162] *Termination of Pregnancy Act 2018* (Qld) s 6(2).
[163] Ibid s 6(1).
[164] SALRI also make the point that such criteria are inherently 'problematic', and even the broad criterion of 'in all the circumstances' is 'so vague as to be meaningless': SALRI (n 10) 209.
[165] That is, in any medical procedure the relevant health practitioner must consider all the medically relevant factors, including the patient's current and future circumstances, and applicable professional standards and guidelines.
[166] *Public Health Act 2016* (WA) s 202ME(1)(a).
[167] Ibid s 202ME(1)(b).
[168] Ibid s 202ME(2): '(a) all relevant medical circumstances; and (b) the person's current and future physical, psychological and social circumstances; and (c) the professional standards and guidelines commonly accepted by members of the medical profession that apply to the medical practitioner in relation to the performance of the abortion.' This is not an exhaustive list, as medical practitioners may also have regard to other matters when determining whether the abortion is 'appropriate': at s 202ME(3).
[169] See ibid s 202ME(4)(a).

practitioner may approach another medical practitioner for the purposes of securing the desired second opinion.[170]

In NSW, after 22 weeks gestation, the legal situation becomes more restrictive than it is in Victoria, Queensland or WA because only a 'specialist medical practitioner' may perform the termination,[171] and only if he or she and another specialist medical practitioner that they have consulted, 'considers that, in all the circumstances, there are sufficient grounds for the termination to be performed'.[172] In making this required assessment, both specialist medical practitioners must consider largely identical criteria to those that exist in Queensland.[173] As indicated earlier, there is no clinical necessity for two medical practitioner opinions in every case. Accordingly, there is certainly no clinical need for two specialist opinions, or for a specialist to perform the procedure. That is, although an abortion post-22 weeks gestation is a more serious procedure than early abortion, and in some circumstances might require second opinions or specialists, this should be decided on a case-by-case clinical basis according to good health practice and the patient's best interests, not arbitrarily by the law.[174] To dictate the necessity of such specialists in advance 'undermines patient autonomy',[175] and indicates that abortion is clearly not being treated like any other medical procedure.

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[170] See ibid s 202ME(4)(b). One may assume that the primary medical practitioner may approach any number of other medical practitioners until the opinion sought is provided. Of course, it is arguably the case that in other jurisdictions a similar practice of seeking second opinions may lawfully be initiated, but WA stands alone in specifically allowing for that practice in the relevant legislation.

[171] *Abortion Law Reform Act 2019* (NSW) s 6(1). Informed consent must also be obtained: at s 6(1)(c). 'Specialist medical practitioner' is defined as '(a) a medical practitioner who, under the Health Practitioner Regulation National Law, holds specialist registration in obstetrics and gynaecology, or (b) a medical practitioner who has other expertise that is relevant to the performance of the termination, including, for example, a general practitioner who has additional experience or qualifications in obstetrics': at sch 1.

[172] Ibid ss 6(1)(a)–(b).

[173] That is, '(a) all relevant medical circumstances, and (b) the person's current and future physical, psychological and social circumstances, and (c) the professional standards and guidelines that apply to the specialist medical practitioner in relation to the performance of the termination': ibid s 6(3). The legislation allows for the Secretary of the Ministry of Health to 'issue guidelines about the performance of terminations' and 'a registered health practitioner performing a termination, or assisting in the performance of a termination, must perform the termination in accordance with the guidelines': ibid ss 14(1), (3). Such guidelines might well restrict the practice of abortion further.

[174] SALRI recommended that neither specialists nor two medical opinions should be mandated: see SALRI (n 10) 19, 26, 28, 242, 348.

[175] Ibid 19.

In addition, the NSW legislation mandates that, in cases of an abortion at post-22 weeks gestation, the 'specialist medical practitioner must provide all necessary information to the person about access to counselling, including publicly-funded counselling'.[176] Although some women might desire such information, to mandate its provision demeans a woman's decision-making ability as it presupposes that she has not already considered all such matters and seriously contemplated the termination she is requesting.[177] Nonetheless, the provision does not mandate counselling itself, which would constitute a serious insult to the pregnant woman's agency and autonomy, but rather only compels the provision of information relevant to accessing counselling. Thus, the decision to engage with counselling remains solely the woman's to make. NSW also departs from the Victorian template by demanding that post-22 weeks gestation terminations must be performed in a hospital or 'approved health facility',[178] which might well be clinically appropriate in some instances, but should not be dictated in advance.[179]

In SA, after 22 weeks and 6 days gestation, the law is similar to that in NSW, but more restrictive. Post-22 weeks and 6 days gestation, an abortion is only available in SA if performed by a 'medical practitioner acting in the ordinary course of the practitioner's profession',[180] and where both that medical practitioner and a second medical practitioner who has been consulted consider that, 'in all the circumstances':

> (i) the termination is necessary to save the life of the pregnant person or save another foetus; or
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> (ii) the continuance of the pregnancy would involve significant risk of injury to the physical or mental health of the pregnant person; or
>
> (iii) there is a case, or significant risk, of serious foetal anomalies associated with the pregnancy.[181]

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[176] *Abortion Law Reform Act 2019* (NSW) s 7(2).
[177] See SALRI (n 10) 278-80.
[178] *Abortion Law Reform Act 2019* (NSW) s 6(1)(d). Such approval is made via the Secretary of the Ministry of Health: at s 13. There is no requirement that 'any ancillary services necessary to support the performance of a termination be carried out only at the hospital or approved health facility at which the termination is, or is to be, performed': at s 6(2); and 'ancillary services' includes tests, other medical procedures, treatments and services, and the 'administration, prescription or supply of medication': at s 6(6).
[179] See, eg, Sheldon, who makes the point that this approved facility criterion is 'unsupported by any current medical evidence base': Sheldon, 'The Decriminalisation of Abortion' (n 96) 345.
[180] *Termination of Pregnancy Act 2021* (SA) s 5(2)(a).
[181] Ibid ss 6(1)(a)–(b).

These conditions echo the repealed criminal law provisions on abortion.[182] However, it should be noted that the above conditions are less severe than those of the repealed criminal law. First, the second medical practitioner referred to above only needs to be 'consulted', whereas the repealed law required both medical practitioners to have 'personally examined the woman' in arriving at their requisite opinions.[183] Second, the repealed law required the continuance of the pregnancy to constitute a 'greater risk' to the pregnant woman's health,[184] whilst the new law only requires that there be a 'significant risk' in that regard.[185] As mentioned previously, abortion is generally always safer than childbirth,[186] so the above conditions would probably be met in almost every case. This is especially likely in SA (as compared with Tasmania) as it is only necessary to show 'significant risk', rather than 'greater risk'. In addition, unlike the Tasmanian legislation, the SA legislation does not expressly mandate a comparative assessment of risk as between abortion and childbirth, so the definition of 'significant risk' is left largely untethered, subjective, and consequently vague. Indeed, it might be reasonably argued that the continuance of a pregnancy would necessarily involve significant risk to the pregnant woman's mental health if that pregnancy were unwanted. In other words, the provisions are arguably pointless. Nonetheless, the burden of meeting these additional legal criteria after a certain gestation is not medically justified, and dilutes patient autonomy because the abortion decision is thereby no longer the woman's to make and the medical profession become the legal gatekeepers to abortion care.[187]

In addition, an abortion post-22 weeks and 6 days gestation must be 'performed at a prescribed hospital' in SA,[188] information about accessing counselling must be provided,[189] and the above medical practitioners must also hold the abortion

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[182] See the repealed *Criminal Law Consolidation Act 1935* (SA) s 82A(1)(a).
[183] Ibid s 82A(1)(a). Such opinions also needed to be certified: at s 82A(4)(a).
[184] See ibid s 82A(1)(a)(i). This remans the requisite assessment in Tasmania: see *Reproductive Health (Access to Terminations) Act 2013* (Tas) s 5(1).
[185] See *Termination of Pregnancy Act 2021* (SA) ss 6(1)(a)(ii), (b)(ii). There are also slight differences in terms of the foetal abnormality ground: see the repealed *Criminal Law Consolidation Act 1935* (SA) s 82A(1)(a)(ii); *Termination of Pregnancy Act 2021* (SA) ss 6(1)(a)(iii), (b)(iii); but such differences are not important as the foetal abnormality ground would be subsumed within the maternal health risk grounds for a lawful abortion.
[186] See above nn 96–8.
[187] This is also arguably contrary to the principle of self-determination, as the medical profession should not be gatekeepers to the rights of women: see Forster and Jivan (n 10) 862–3.
[188] *Termination of Pregnancy Act 2021* (SA) s 6(1)(c). A 'prescribed hospital' is that prescribed by the regulations: at s 3; *Termination of Pregnancy Regulations 2022* (SA) reg 4 and sch 1. This provision goes against the SALRI recommendation that no such approved or prescribed facility condition be included in the legislation: see SALRI (n 10) 20, 27, 192.
[189] See *Termination of Pregnancy Act 2021* (SA) s 8(1).

to be 'medically appropriate' considering '(a) all relevant medical circumstances; and (b) the professional standards and guidelines that apply to the medical practitioner in relation to the performance of the termination'.[190] As mentioned above with respect to the equivalent Victorian, Queensland, WA, and NSW provisions,[191] mandating the consideration of the above factors is arguably superfluous as applicable health law and standards would require medical practitioners to consider these issues in any case as part of appropriate clinical practice. However, the SA legislation goes beyond the above mentioned jurisdictions and imposes further compulsory assessments that medical practitioners must 'have regard to' when performing abortions post-22 weeks and 6 days gestation.[192] These matters that the medical practitioners must consider are excessive, cumbersome, and from a woman's reproductive rights perspective, insulting, including (but not limited to): whether the survival of other foetuses would be impacted in cases involving a multiple pregnancy;[193] whether foetal abnormality might have been diagnosed prior to 22 weeks and 6 days gestation;[194] whether the foetus had been exposed to 'infective agents' that may have damaged the foetus;[195] whether specialist services might have been accessed prior to 22 weeks and 6 days gestation;[196] and whether the pregnant woman has a 'medical condition … incompatible with an ongoing pregnancy'.[197] Some of the matters listed above (and others not mentioned above, but listed in the legislation) may be medically relevant in some situations, and in those situations would have to be considered by a health practitioner acting in accordance with generally applicable health law and standards. However, to mandate the consideration of all these issues is clinically unjustified and a clear statement by the SA Parliament that abortion post-22 weeks and 6 days gestation is unlike any other health care practice. Furthermore, the convoluted and numerous matters that must be considered by medical practitioners might serve to discourage medical practitioners from providing abortion services after 22 weeks and 6 days gestation.[198]

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[190] Ibid s 6(2).
[191] See, eg, *Abortion Law Reform Act 2008* (Vic) s 5(2).
[192] *Termination of Pregnancy Act 2021* (SA) s 9.
[193] See ibid s 9(a).
[194] See ibid s 9(b).
[195] Ibid.
[196] See ibid s 9(c).
[197] Ibid s 9(g).
[198] It might be argued that this was the purpose of mandating such assessments, but there is no direct evidence of this in the relevant parliamentary debates.

3 *Further Issues in New South Wales and South Australia*

The restrictive nature of abortion law in both NSW and SA is exacerbated by the problematic issues of 'born' foetuses and sex selection. In both of these jurisdictions, provision is made for when an attempted termination results 'in a person being born'.[199] In such a case, the legislation states that a health practitioner may exercise their duty to provide that person 'with medical care and treatment',[200] and that 'the duty owed by a registered health practitioner to provide medical care and treatment to a person born as a result of a termination is no different than the duty owed to provide medical care and treatment to a person born other than as a result of a termination'.[201] This is a confounding requirement.[202] Assuming that being 'born' in this context follows the common law definition of being fully extruded from the mother and exhibiting 'any sign of life, no matter how faint or fleeting',[203] it is self-evidently the case that a health practitioner does not owe the same duties to a foetus so 'born' (ie, one that may 'live' for only a moment) compared to a viable newborn. This provision is extremely insulting to the woman having the abortion, as it defines her as a mere vessel for the foetus that is so 'born'.

The other challenging subject that the legislation in NSW and SA deals with is sex selection.[204] The *Abortion Law Reform Act 2019* (NSW) makes the statement that 'Parliament opposes the performance of terminations for the purpose of sex selection.'[205] Recent guidelines provided by the Minister pursuant to s 14 of the *Abortion Law Reform Act 2019* (NSW) have expressly stated that if the request for an abortion is motivated 'for the sole purpose of sex selection', then 'the practitioner must not perform the termination, unless not performing the termination will cause significant risk to the woman's health or safety'.[206]

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[199] *Abortion Law Reform Act 2019* (NSW) s 11(1); *Termination of Pregnancy Act 2021* (SA) s 7(1).
[200] *Abortion Law Reform Act 2019* (NSW) s 11(2); *Termination of Pregnancy Act 2021* (SA) s 7(2).
[201] *Abortion Law Reform Act 2019* (NSW) s 11(3); *Termination of Pregnancy Act 2021* (SA) s 7(3).
[202] It should be noted that the NSW provisions were one of many late amendments to the Bill made by the National Party's Niall Blair. For a list of all such amendments see 'In Review: Abortion Law Reform Act 2019', *The House in Review* (Web Page, 2 October 2019) <https://thehouseinreview.com/2019/10/02/in-review-abortion-law-reform-act-2019/>.
These provisions were followed verbatim by the SA Parliament. A Bill reflecting a similar position was recently proposed at the federal level by the National Party's Senator Matthew Canavan: see Human Rights (Children Born Alive Protection) Bill 2022 (Cth).
[203] Rankin, 'The Offence of Child Destruction' (n 17) 19. See also *R v Iby* (2005) 63 NSWLR 278; *Barrett v Coroner's Court of South Australia* (2010) 108 SASR 568.
[204] See *Abortion Law Reform Act 2019* (NSW) s 16; *Termination of Pregnancy Act 2021* (SA) s 12.
[205] *Abortion Law Reform Act 2019* (NSW) s 16(1).
[206] NSW Health, Policy Directive: Framework for Termination of Pregnancy in New South Wales (17 June 2025) 7.

Similarly, in SA 'a registered health practitioner must not perform a termination of a pregnancy for the purposes of sex-selection',[207] unless 'the registered health practitioner is satisfied that there is a substantial risk that the person born after the pregnancy (but for the termination) would suffer a sex-linked medical condition that would result in serious disability to that person'.[208]

Given that the legislation in each jurisdiction does not expressly impose upon the pregnant woman concerned any obligation to justify her request for a termination, it seems unlikely that the pregnant woman would volunteer such a motivation for the termination of her pregnancy, so one would expect few refusals to perform terminations on this basis.[209] In addition, as there is no reliable evidence that the performance of abortions for the purpose of sex selection is occurring to any significant extent in NSW or SA,[210] there seems little point in the provision.[211] The condition serves only to unduly complicate what is already a complex area of law. Furthermore, the reason why a woman wants to terminate her pregnancy should be irrelevant from a legal standpoint; such reasons may be relevant from a clinical perspective but should have no bearing on the legality of the procedure.

This is not to say that sex selection in abortion is not philosophically nor morally problematic. Indeed, as it seems clear from an analysis of societies in which sex selection is comparatively common that female foetuses will be terminated more frequently than male foetuses,[212] it presents a feminist dilemma. As indicated briefly earlier, an unfettered right to abortion is necessary to protect women's

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[207] *Termination of Pregnancy Act 2021* (SA) s 12(1).
[208] Ibid s 12(2).
[209] The recent report from the Secretary of the Ministry of Health on the extent to which terminations are being performed for the purpose of sex selection (prepared pursuant to an obligation to so report under *Abortion Law Reform Act 2019* (NSW) s 16) indicates that less than 0.02 per cent of abortions in the reporting period were performed for the sole purpose of sex selection: see Secretary of the Ministry of Health, *Review of termination of pregnancy for the purpose of sex selection in NSW* (December 2020) 7, 14.
[210] See, eg, Ministry of Health (n 209) 7, 14.
[211] Another argument made by SALRI to not adopt this aspect of the NSW legislation is that any such prohibition on abortions for the purpose of sex selection would be largely unenforceable: see SALRI (n 10) 330–1.
[212] See, eg, Naryung Kim, 'Breaking Free from Patriarchy: A Comparative Study of Sex Selection Abortions in Korea and the United States' (1999) 17(3) *UCLA Pacific Basin Law Journal* 301, 317–20; April L Cherry, 'A Feminist Understanding of Sex-Selective Abortion: Solely a Matter of Choice?' (1995) 10(2) *Wisconsin Women's Law Journal* 161, 168–75; Colleen Davis and Heather Douglas, 'Selective Reduction of Fetuses in Multiple Pregnancies and the Law in Australia' (2014) 22(1) *Journal of Law and Medicine* 155, 171–2.

rights to equality,[213] bodily integrity,[214] self-determination,[215] and autonomy (among other rights),[216] yet a preference for males in sex selection abortions necessarily defines females as inferior, which negatively affects women as a class. This tension has been framed by Cherry as an example of the conflict between liberal feminism (with its focus on individual rights) and radical feminism (with its focus on substantive and collective outcomes).[217] Whilst acknowledging this complex philosophical friction, it is nonetheless this author's opinion that in the interests of reproductive freedom the abortion right must be absolute. Thus, if a woman wants to terminate her pregnancy for the purposes of sex selection, then that is her right.[218] Steps might well be taken to reduce the incidence of abortions undertaken for this reason, but those steps cannot include making that decision or termination unlawful if a woman's right to abortion is to be fully respected.[219] In any case, the above discussion amply highlights the now convoluted nature of providing lawful abortion services in NSW, and especially SA, and the clear legislative intention in both jurisdictions to regulate abortion care differently to other forms of health care by imposing conditions on the lawful practice of abortion that have no medical or clinical justification.[220]

On a more positive note, there appears to be no upper gestational limit for lawful abortions in NSW or SA.[221] This is also the case in Queensland. While retaining the offence of child destruction,[222] amendments made by the *Termination of*

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[213] See, eg, Catharine A MacKinnon, 'Reflections on Sex Equality Under Law' (1991) 100(5) *Yale Law Journal* 1281, 1308–11.

[214] See, eg, Christyne L Neff, 'Woman, Womb, and Bodily Integrity' (1991) 3(2) *Yale Journal of Law and Feminism* 327; Furedi (n 8) 124–9, 184–6; Petchesky (n 8) 378; Smyth (n 8) 343.

[215] See, eg, Petchesky (n 8) 387; Kathryn Kolbert, 'A Reproductive Rights Agenda for the 1990's' (1989) 1(1) *Yale Journal of Law and Feminism* 3; Furedi (n 8) 181–200.

[216] Furedi argues that all such rights are inextricably linked: Furedi (n 8) 126; and to deny women these rights is to deny women their humanity: at 200. All such rights may also be viewed as essential components of the overarching principle of reproductive freedom.

[217] See Cherry (n 212) 165–6, 208–16.

[218] See, eg, Walsh and Legge (n 54) 328; SALRI (n 10) 330.

[219] Obviously, this is a far broader and more complex issue than such a determination indicates. However, it is beyond the scope of this article to enter into a detailed analysis of the issue, so the above simplification must suffice.

[220] For example, the requirement in SA for two medical practitioners to make the requisite labyrinthine assessment: see *Termination of Pregnancy Act 2021* (SA) ss 6, 9; or the insistence that abortions may only be lawfully performed in prescribed hospitals: at s 6(1)(c).

[221] That is, no reference is made to an upper gestational limit in the *Abortion Law Reform Act 2019* (NSW), and NSW does not have a child destruction provision that might otherwise place an implicit limit on lawful abortions. Also see *Termination of Pregnancy Act 2021* (SA) sch 1 pt 2, repealing *Criminal Law Consolidation Act 1935* (SA) ss 82A(7)–(8), which previously placed upper gestational limits on lawful abortion.

[222] See *Criminal Code Act 1899* (Qld) s 313(1). The offence is actually labelled 'killing unborn child' but is the equivalent of the offence of child destruction in other jurisdictions.

Pregnancy Act 2018 (Qld) to the *Criminal Code Act 1899* (Qld) mean that, provided a person performs, or assists in performing, a termination of pregnancy in accordance with the *Termination of Pregnancy Act 2018* (Qld), they commit no criminal offence under the child destruction provision.[223] However, WA retains the offence of child destruction in its older form, which may place an implicit upper gestational limit on lawful abortions.[224]

IV CONCLUSION

No Australian jurisdiction fully recognises a woman's right to abortion as no jurisdiction regulates abortion care in the same manner as other standard health care.[225] As indicated at the outset of this article, the fact that all jurisdictions maintain a residual offence of abortion and specifically cater for conscientious objection to abortion necessarily results in this finding, and this initial conclusion has been reinforced throughout the course of this article by reference to the various conditions placed upon the lawful provision of abortion services that have no coherent medical basis.[226]

The predominant issue remains that, with the exception of the ACT, all jurisdictions mandate that women receive medical approval for the abortion beyond what is necessary from a clinical perspective. This is exacerbated when the approval of two medical practitioners is required.[227] Such conditions serve only to erode women's autonomy,[228] and restrict and delay access to abortion

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[223] See ibid s 313(1A) as inserted by *Termination of Pregnancy Act 2018* (Qld) s 24. However, this arguably means that any failure to meet the requirements of a lawful abortion pursuant to the *Termination of Pregnancy Act 2018* (Qld) enlivens the child destruction provisions, even for a qualified person performing or assisting in that abortion. As explained previously, in the interests of achieving legal clarity and certainty, the child destruction offence is best abolished, rather than attempting such piecemeal exceptions: see Rankin, 'The Offence of Child Destruction' (n 17).

[224] See *Criminal Code Act Compilation Act 1913* (WA) s 290.

[225] Forster and Jivan contend that the failure to treat abortion in the same way as any other health service results in the further determination that 'no jurisdiction in Australia is fully in accord with international obligations' to recognise women's reproductive rights: Forster and Jivan (n 10) 855, 862. See also Belton, Gerry, and Stulz (n 33) 25, 42–4. Sifris and Belton argue that 'treating abortion differently to other forms of healthcare is inherently discriminatory … [because] … abortion is an aspect of health care required only by women … [thus] … differential treatment that the law accords to abortion as against other forms of medical treatment … constitutes a form of discrimination against women': Sifris and Belton (n 10) 212.

[226] Millar describes this as 'abortion exceptionalism': Millar (n 15) 262–3. Millar contends that it probably stems from 'framing abortion as primarily a moral rather than medical issue': at 271.

[227] Forster and Jivan make the point that such laws grant the medical profession 'paternalistic gatekeeping responsibilities' at odds with women's basic human rights: see Forster and Jivan (n 10) 862. See also SALRI (n 10) 46.

[228] SALRI emphasised that there should be no 'specified criteria for access to lawful abortion': see SALRI (n 10) 27, 207–210; thus removing the medical profession as legal gatekeepers to the

services.[229] As Sifris asserts, this requirement that the medical profession validate a woman's reasons for an abortion 'infantilizes women and undermines basic principles of agency, autonomy, and self-determination'.[230]

With the exception of the NT (in which medical approval is required for all abortions regardless of gestation),[231] this clinically unwarranted medical profession approval only becomes necessary once a certain gestation is reached.[232] In Tasmania, NSW, and SA the medically unjustified criteria necessary for that approval can be quite extensive and do not reflect best clinical practice.[233] In Victoria, Queensland, and WA the relevant legislation requires a medical profession assessment that is consistent with good clinical practice (thereby making such requirements arguably superfluous), and no further conditions (such as specialists or prescribed facilities) are imposed. However, mandating the approval of two medical practitioners in every case has no clinical justification.[234] The only jurisdiction in which medical profession approval is not mandated is the ACT, in which no conditions (other than requiring surgical abortions to be performed in a prescribed facility)[235] are attached to a woman's request for an abortion. The ACT thus almost regulates abortion in the same manner as other

practice: at 240; and thereby ensuring that women's autonomy and decision-making power were respected: at 209.

[229] See Sheldon, 'The Decriminalisation of Abortion' (n 96) 365.

[230] Sifris, 'Abortion in Australia' (n 14) 138.

[231] Up until 24 weeks gestation only one medical practitioner need approve the abortion, but after that period the approval of two medical practitioners is required: see *Termination of Pregnancy Law Reform Act 2017* (NT) ss 7, 9.

[232] In Victoria it is 24 weeks; in Tasmania it is 16 weeks; in Queensland and NSW it is 22 weeks; in SA it is 22 weeks and 6 days; and in WA it is 23 weeks. It might thus be argued that such increased conditions do not apply to the vast majority of abortions, which are performed in the first trimester; for example, in SA approximately 90% of terminations are performed in the first trimester: South Australian Abortion Reporting Committee (n 97) 9. However, from a woman's right to abortion perspective, the only question is whether the imposition of these conditions is medically justified; if not so justified, any pragmatic argument concerning the number of abortions to which the unjustified conditions are applicable is not significant.

[233] As indicated in this article, these jurisdictions differ in terms of the criteria necessary for the requisite approval, but a sample list taken from all three jurisdictions would include such requirements as: specialist approval; the provision of counselling information; the performance of the abortion in prescribed facilities; and the satisfaction of the 'greater' or 'significant' health risk assessment. Sheldon contends that all such criteria constitute 'clinically unwarranted impediments to the provision of high quality abortion services': Sheldon, 'The Decriminalisation of Abortion' (n 96) 347.

[234] See, eg, SALRI (n 10) 26, 348.

[235] See *Health Act 1993* (ACT) s 83.

standard health care,[236] and thereby comes closest to recognising a woman's right to abortion.

However, despite being the preferred legislation from a women's rights perspective, this article does not suggest that the ACT legislation be the template for other jurisdictions to adopt because the ACT legislation still creates issues for lawful abortion that have no medical justification: namely, maintaining a residual offence of abortion;[237] allowing for conscientious objection to abortion with no obligation to refer the patient to another health practitioner that has no such objection;[238] retaining the offence of child destruction which places an implicit (and arbitrary) upper gestational limit on lawful abortion;[239] and mandating that every surgical abortion be performed in a prescribed facility.[240] In order for abortion care to be regulated in the same manner as other standard health care, all such medically unjustified conditions on the practice of lawful abortion need to be removed.[241]

There is nothing clinically peculiar about the provision of abortion care that requires special laws.[242] In 21st century Australia, abortion is a common and safe medical procedure when performed in accordance with generally applicable health law and standards by qualified health professionals.[243] The further, exceptional, and medically unjustified, overregulation of abortion that the legislation canvassed in this article creates, differentiates abortion from other forms of health care, and, as a consequence, serves to deny Australian women a right to abortion.[244]

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[236] See Sifris and Belton (n 10) 211; Forster and Jivan (n 10) 854–5; Victorian Law Reform Commission, *Law of Abortion* (Final Report 15, March 2008) 7. The ACT model, but with no mandated approved facility, and with no gestational limit, was also the model preferred by SALRI: see SALRI (n 10) 18, 239.

[237] See *Health Act 1993* (ACT) ss 81–2.

[238] See ibid s 84A.

[239] See *Crimes Act 1900* (ACT) s 42.

[240] See *Health Act 1993* (ACT) s 83.

[241] The Public Health Association of Australia has recently stated that '[a]bortion is a safe, common procedure that should be regulated in the same way as other medical procedures … without additional conditions': Public Health Association of Australia (n 50) 1; and that the practice should be 'regulated under existing health care legislation': at 4.

[242] See Commins and Millar (n 15) 263.

[243] See, eg, SALRI (n 10) 113; Belton, Gerry and Stulz (n 33) 28.

[244] Furthermore, the imposition of such conditions on the practice of lawful abortion care implies that Australian legislatures do not consider women rational beings capable of making their own health decisions. In other words, such laws implicitly proclaim, to varying degrees, that women are not full moral or legal persons.

Thus, in terms of what legislation is required to effectively recognise a woman's right to abortion, it is quite minimalist: remove all offences specific to abortion from the law,[245] and repeal all the abortion legislation discussed in this article.[246] Once this is achieved, general health law and relevant health practitioner regulatory standards and codes of conduct will regulate the provision of abortion care, consistent with proper clinical practice, and in the patient's best interests,[247] as is the case for all other standard health care.[248] In such a legal environment, a woman may approach her health practitioner at any stage of her pregnancy,[249] request an abortion, and have that request granted.[250] In other words, women would thereby have a right to abortion.

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[245] Such offences might be found in either criminal law or health law, and might be expressly applicable to abortion, such as the residual offence of abortion discussed earlier in this article, or might be potentially applicable to abortion, such as the offences of child destruction or concealment of birth. For examples of the offence of child destruction, see *Crimes Act 1900* (ACT) s 42; *Criminal Code Act Compilation Act 1913* (WA) s 290; *Criminal Code Act 1983* (NT) s 170. For examples of the offence of concealment of birth, see *Criminal Law Consolidation Act 1935* (SA) s 83; *Crimes Act 1900* (ACT) s 47; *Criminal Code Act 1899* (Qld) s 314; *Criminal Code Act Compilation Act 1913* (WA) s 291.

[246] Other than those provisions establishing safe access zones, which are required for clinical or pragmatic reasons of access to employment and health care: see Rankin, 'Safe Access Zone Legislation in Australia' (n 57) 63; Commins and Millar (n 15) 269.

[247] At this point abortion becomes solely a health issue, as was recommended by SALRI: see SALRI (n 10) 27, 52.

[248] There is no question that the general health framework is quite capable of regulating abortion, as it does with respect to all other health services: see, eg, Dwyer et al (n 11). As Sheldon explains, 'abortion services might simply be regulated by the same mass of general criminal, civil, administrative and disciplinary regulations that govern all medical practice': Sheldon, 'British Abortion Law' (n 159) 316. The amount of legislation applicable to health care is too voluminous to recite in full here, but, taking SA as the example, at least the following Acts would apply to the regulation of abortion: *Health Practitioner Regulation National Law (South Australia) Act 2010* (SA); *Civil Liability Act 1936* (SA); *Health and Community Services Complaints Act 2004* (SA); *Health Care Act 2008* (SA); *Consent to Medical Treatment and Palliative Care Act 1995* (SA); *Therapeutic Goods Act 1989* (Cth). Similar amounts of legislation would apply in all other jurisdictions.

[249] That is, there is no clinical necessity to confine all aspects of the practice solely to medical practitioners: see SALRI (n 10) 26, 175; and there is no medical basis for upper gestational limits on lawful abortions: at 20–1, 27–8, 242.

[250] Either by that health practitioner, or if that health practitioner has a conscientious objection to abortion, by another health practitioner to which the patient's care was transferred by the objecting health practitioner, pursuant to generally applicable conscientious objection guidelines. Depending on the gestation and complexity of the procedure the abortion might have to be performed in a particular facility, or by particular specialists, and more than one medical practitioner might need to be involved, but that would be decided on a case-by-case basis determined solely on a clinical need assessment.

A TERMINAL TUSSLE: ASSISTED DYING ON THE PRECIPICE OF LEGALISATION FOR ENGLAND AND WALES BUT WILL THIS BRING SAFEGUARDING OVERREACH?

MEREDITH BLAKE*

The issue of assisted dying in the United Kingdom ('UK') has been a consistent feature of legal and political discourse for several decades. A series of court decisions in which it was decided that neither UK common law nor the Human Rights Act 1998 (UK) supported a change to the ban on assisted suicide in the criminal law stymied the introduction of voluntary assisted dying laws. While 2009 saw the UK Director of Public Prosecutions introduce a set of guidelines designed to inform the prosecution of assisted suicide, the argument for legal change to the substantive law has persisted. This has taken the form of private members' bills which have to date failed or lapsed at various stages of parliamentary consideration. In 2025, however, the Terminally Ill Adults (End of Life) Bill 2024 has passed both stages of the Commons and is on the precipice of being debated in the House of Lords. This short commentary assesses the key provisions of this proposed legislation, comparing it to the Western Australian Voluntary Assisted Dying legislation. It identifies key provisions in both pieces of legislation and questions whether the safeguards underlying the Bill[1] *will ultimately provide an obstacle for those seeking access to the statutory scheme.*

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[1] Labour MP Kim Leadbeater, who introduced the Bill into the House of Commons on 11 November 2024, has stated that '[t]his bill already contains the strongest safeguards anywhere in the world, but I promised to give close attention to the advice we have received on how the bill could be made even stronger, and that is what I have done': Harry Farley, 'Replacing judge with experts', *BBC News* (online, 11 February 2025) <https://www.bbc.com/news/articles/c2egl17pvldo>.

I INTRODUCTION

On 20 June 2025 the United Kingdom ('UK') House of Commons passed the Terminally Ill Adults (End of Life) Bill ('TIAB') by a margin of 23 votes (314–291).[2] The securing of the approval of the House of Lords remains the only hurdle to this assisted dying ('AD') legislation becoming law in England and Wales. The passage of the TIAB marks a turning point in the long history of the UK wrestling with the issue of AD.[3] Although a form of AD is found in many Western democracies,[4] there has been a stubborn resistance to legalising this in the UK despite the many efforts of advocates and politicians. This article will firstly plot out a short history of these efforts, focusing on the judicial aspect given the insights which these give to the relevant legal frameworks. It will then assess key aspects of the TIAB, comparing these to provisions in the *Voluntary Assisted Dying Act 2019* (WA) ('*WAVADA*'). The reason for the choice of this comparator lies in the *WAVADA* being

[2] 'UK parliament votes for assisted dying, paving way for historic law change', *ABC News* (online, 21 June 2025) <https://www.abc.net.au/news/2025-06-21/uk-parliament-votes-for-assisted-dying/ 105445246>.

[3] The term 'assisted dying' ('AD') will be used in this commentary to refer to all situations in which a person is voluntarily helped to die by administration of a lethal substance, whether self or other administered. The term euthanasia is deliberately avoided given its lack of consistent understanding and its emotional connotations, evident in the decision in *Airedale NHS Trust v Bland* [1993] AC 789 (HL) ('*Bland*') in which the English courts drew a sharp, if spurious distinction, between withdrawing life-sustaining treatment and the ending of life by a lethal injection: see Hoffmann LJ at 831.

[4] *Medical Assistance in Dying Act*, RSC 2016 c 7; *Death with Dignity Act,* ORS 2023, 800–995; *Death with Dignity Act of 2016*, DC Law 21-182; *Termination of Life on Request and Assisted Suicide (Reviews Procedures Act)* (the Netherlands); *End of Life Choice Act 2019* (NZ). AD legislation has now been passed in all Australian states and the Australian Capital Territory ('ACT'): *Voluntary Assisted Dying Act 2017* (Vic); *Voluntary Assisted Dying Act 2019* (WA); *Voluntary Assisted Dying Act* 2021 (Qld); *Voluntary Assisted Dying Act 2022* (NSW); *Voluntary Assisted Dying Act 2021* (SA); *End-of-Life Choices (Voluntary Assisted Dying) Act 2021* (Tas); *Voluntary Assisted Dying Act 2024* (ACT).

the second-longest regime in Australia, its proportionately high rates of uptake,[5] and the fact that access provisions have been considered by the State Administrative Tribunal ('SAT') on several occasions, providing the opportunity for the interpretation of its provisions.[6] It has been described in the Voluntary Assisted Dying Board Western Australia's 2023–2024 Annual Report as 'an established and enduring end of life choice'.[7] The comparison identifies key differences in the regulatory schemes, raising, it is argued, potential issues for accessing AD in England and Wales, should the TIAB be ultimately implemented in its current form.

II UK HISTORICAL BACKDROP

There has long been popular support for AD in the UK.[8] The National Centre for Social Research notes that a 2024 British Social Attitudes survey indicated that 79% of people expressed support for a doctor being able to end the life of a person with an incurable and painful terminal illness if the person requests it, similar to the result in 2016, when 78% expressed their support.[9] Leading up to the second reading of the TIAB, a number of opinion polls and surveys on public attitudes were published indicating that a majority of the population supported a change to the law to allow someone to help a person who is terminally ill to end their life if they have voluntarily requested it.[10]

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[5] Although note that AD was briefly legal in the Northern Territory — the *Rights of the Terminally Ill Act 1995* (NT) — before it was effectively annulled by the federal government in 1997. The Voluntary Assisted Dying Board Western Australia ('WA')'s Annual Report for 2023–2024 notes that deaths under the legislation account for 1.6% of the total deaths in WA: WA State Government, Department of Health, *Voluntary Assisted Dying Board Annual Report* (2023–24). While under the *Voluntary Assisted Dying Act 2021* (Qld) the 2023–2024 Annual Report reported that deaths under that scheme accounted for approximately 2% of deaths, it is suggested that this may be associated with the broader residential requirements under the legislation which contains a Queensland residency exemption.

[6] See the discussion in Aidan Ricciardo, 'Voluntary Assisted Dying and State Residence Requirements: A Western Australian Perspective' (2024) 51(2) *UWA Law Review* 146.

[7] WA State Government, Department of Health (n 5) Foreword.

[8] Note that this commentary does not purport to discuss developments on AD in Scotland and Northern Ireland which both have devolved Parliaments responsible for making laws on certain matters, notably health.

[9] 'Public support for assisted dying remains high and stable', *National Centre for Social Research* (Media Release, 18 March 2025) <https://natcen.ac.uk/news/public-support-assisted-dying-remains-high-and-stable#:~:text=Gillian%20Prior%2C%20Deputy%20Chief%20Executive, doctor%20%20for%20someone%20with%20an>. See also 'Two thirds of UK public continue to think assisted dying should be legal, provided certain conditions are met', *Ipsos* (Web Page, 14 October 2024) <https://www.ipsos.com/en-uk/two-thirds-uk-public-continue-think-assisted-dying-should-be-legal-provided-certain-conditions-are?_ >.

[10] See Sally Lipscombe et al, 'The Terminally Ill Adults (End of Life) Bill 2024-25' (Research Briefing, House of Commons Library, House of Commons, 22 November 2024) 32–3.

Despite evidence of this support, the numerous challenges to the existing illegality of AD have been unsuccessful to this point. The illegality is founded in the UK homicide laws, specifically murder and assisting suicide. In *Airedale NHS Trust v Bland* ('*Bland*'),[11] several members of the then House of Lords relied on the moral and legal difference between withdrawing or not administering life-sustaining or saving treatment and positively administering a lethal substance to hasten death. While these judges noted the artificiality of the deontological theory-based act/omission distinction,[12] they nonetheless identified the need for the law to draw a clear line as to legal and illegal conduct in this context.[13]

It is difficult to quantify the effect of *Bland* on the AD debate in England and Wales. Lord Goff's specific comment referencing 'the Rubicon which runs between on the one hand the care of the living patient and on the other hand euthanasia — actively causing his death to avoid or end his suffering'[14] has been often cited in the jurisprudence,[15] and is therefore perhaps an example of its effect. It can confidently be stated, however, that post *Bland*, the UK courts have consistently resisted endeavours to legalise AD through the judicial route.

The legal challenges have mostly centred on the *Suicide Act 1961* (UK) ('*Suicide Act*') which makes it an offence for a person to intentionally encourage or assist the suicide (or attempted suicide) of another.[16] The applicants in the three most significant cases considered by the UK courts asserted that this prohibition contravened the *Human Rights Act 1998* (UK) ('*HRA*') which incorporates the European Convention on Human Rights ('ECHR'), to which the UK is a signatory.[17] In the first of these cases, Dianne Pretty, a woman living with motor neurone disease, argued that the *Suicide Act* could potentially apply to someone who

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[11] *Bland* (n 3).
[12] Discussed in a wide range of articles: see, eg, Andrew McGee, 'Finding a Way Through the Ethical and Legal Maze: Withdrawal of Medical Treatment and Euthanasia' (2005) 13(3) *Medical Law Review* 357; John Keown, 'Medical Murder by Omission? The Law and Ethics of Withholding and Withdrawing Treatment and Tube Feeding' (2003) 3(5) *Clin Med (London)* 460.
[13] See *Bland* (n 3) 865, 885 and 887 (Lords Goff, Browne-Wilkinson and Mustill).
[14] *Bland* (n 3) cited in, eg, JM Finnis, 'Bland: Crossing the Rubicon?' (1993) 109 *Law Quarterly Review* 329, 329.
[15] Colleen Davis, 'Merciful Acts and Cruel Omissions' (2013) 1(2) *Griffith Journal of Law and Human Dignity* 166, 166–89; John Keown, 'Restoring Moral and Intellectual Shape to the Law after Bland' in *The Law and Ethics of Medicine: Essays on the Inviolability of Human Life* (online ed, Oxford Academic, 20 September 2012) ch 12 <https://doi.org/10.1093/acprof:oso/9780199589555.003.0012>; *Nicklinson & Ministry of Justice v DPP* [2012] EWHC 2381, [60] (Toulson LJ).
[16] *Suicide Act 1961* (UK) s 2(1).
[17] *Pretty v Director of Public Prosecutions and Secretary of State for the Home Department* [2002] 1 AC 800, [11] (Lord Bingham).

helped her to travel to Switzerland to access AD there, and was therefore in breach of several provisions of the ECHR.[18] The House of Lords rejected her claims that the *Suicide Act*, as it applied to a person living with a terminal illness resulting in profound suffering, was a violation of her right to respect for her private life (art 8 ECHR), her right to be free of inhumane treatment and torture (art 3 ECHR) and her right to equal treatment (art 14 ECHR).[19] Ms Pretty's appeal to the European Court of Human Rights ('ECtHR') was also unsuccessful,[20] with the ECtHR giving decisive weight to the margin of appreciation accorded to all States to the Convention.[21] It did, however, recognise that 'preventing the applicant from exercising her choice to avoid an undignified and distressing end to her life constituted an interference with her right to respect for private life' under art 8 of the ECHR.[22] This interpretation of art 8 is consistent with the established jurisprudence of the ECtHR and accords with interpretations of similar provisions in the United States Constitution and the Canadian Charter of Rights and Freedoms which regard the notion of 'private life' as encompassing the right to make decisions about matters affecting a person's bodily integrity and identity.[23]

Subsequently, in *R (on the application of Purdy) v Director of Public Prosecutions* [2009] UKHL 45, the House of Lords, accepting the ECtHR's interpretation of art 8 in the Pretty decision, ruled that the lack of certainty as to whether Mrs Purdy's husband would be prosecuted under the Act were he to assist her to travel to Switzerland to access AD, constituted an interference with her rights under this Article. It ultimately found, however, that this interference was justified in the

[18] In Switzerland the Dignitas Clinic provides assisted dying by virtue of the fact that under the Swiss Criminal Code it is only unlawful to assist a person's suicide if that is done for 'selfish' reasons: *Swiss Criminal Code* (1937) art 115.

[19] See the discussion in M Blake, 'Physician-Assisted Suicide: A Criminal Offence or a Patient's Right?' (1997) 5(Autumn) *Medical Law Review* 294 in which the relevance of these rights to AD are analysed.

[20] *Pretty v UK* [2002] ECHR 427.

[21] In a unanimous judgment the European Court of Human Rights ('ECtHR') found that while her application was admissible, the interference with her art 8 rights could be justified as 'necessary in a democratic society' for the protection of others. The margin of appreciation is discussed by the Council of Europe in 'The Margin of Appreciation' (Web Page) <https://www.coe.int/t/dghl/cooperation/lisbonnetwork/themis/echr/paper2_en.asp>.

[22] *Pretty v UK* (n 20) IV.

[23] See *State of Washington v Glucksberg et al* 138 L Ed 2d 777 (Wash, 1997); but see *Dobbs v Jackson Women's Health Organisation* 597 US 215 (2022); and in Canada, *Carter v Canada* [2015] 1 SCR 331.

public interest.[24] Notably, Lord Hope emphasised that the courts were not the appropriate avenue for legal change on AD:

> It must be emphasised at the outset that it is no part of our function to change the law in order to decriminalise assisted suicide. If changes are to be made, as to which I express no opinion, this must be a matter for Parliament.[25]

Consistent with this position of judicial reluctance, the House of Lords held that the Director of Public Prosecutions was required to develop a policy on the prosecution of assisted suicide cases. That policy was published by the then Director of Public Prosecutions Kier Starmer in 2010 in response to this ruling.[26]

In the third case of significance, *R (on the application of Nicklinson and another) v Ministry of Justice,*[27] the UK Supreme Court (the successor to the House of Lords) considered the *Suicide Act*'s compatibility with art 8 in circumstances where a person has made 'a voluntary, clear, settled and informed decision to commit suicide', but who cannot because of their physical incapacity. The case concerned three individuals living with permanent and severe disabilities, who could not end their lives except through the refusal of all nutrition and hydration. In the earlier Court of Appeal hearing,[28] the claimants had argued that the common law should provide a defence of necessity in euthanasia cases.[29] This argument sought to establish that actions which would otherwise constitute murder (because the person assisting had caused the death of the person intending to do so)[30] or assisted suicide, were exempted on the grounds that bringing about death was

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[24] The House of Lords therefore accepted the ECtHR ruling in the *Pretty* case as to the scope of the right to respect for private and family life.

[25] *R (on the application of Purdy) v Director of Public Prosecutions* [2009] UKHL 45, [26].

[26] Crown Prosecution Service ('CPS'), *Code for Crown Prosecutors* (26 October 2018). As published in 2010 the Code identified the involvement of a health professional in another's suicide as being a reason in favour of prosecution, although that was later clarified in 2014 amendments. The publication of the Code was associated with an increased level of prosecutorial discretion being introduced into s 2(4) of the *Suicide Act 1961* (UK). Data associated with the effect of the Code and its role in supporting access to AD in Switzerland is discussed in Alexandra Mullock and Jonathan Lewis, 'Assisted Dying, Vulnerability, and the Potential Value of Prospective Legal Authorisation' (2025) 33 *Medical Law Review* 1, 9.

[27] *R (on the application of Nicklinson and another) v Ministry of Justice* [2015] 1 AC 657.

[28] *R (Nicklinson) v A Primary Care Trust* [2013] EWCA Civ 961.

[29] The applicants relied on the earlier case of *Re A (Conjoined Twins: Surgical Separation*) [2000] 4 All ER 961. The case is discussed in Sally Sheldon and Stephen Wilkinson, 'On the Sharpest Horns of a Dilemma': Re A (Conjoined Twins)' (2001) 9(3) *Medical Law Review* 201.

[30] Note that in relation to assisting suicide the person providing the assistance is not necessarily regarded as having caused the death of the person: *AG v Able* [1984] QB 795. However, it is a requirement for murder that the person be the cause of the death. This is the common conduct element (or actus reus) for all homicide offences. See also *Criminal Code Compilation Act 1913* (WA) ss 268, 270.

necessary in the best interests of the patient in order to alleviate their suffering. Following the Court of Appeal's unanimous rejection of this argument it was subsequently abandoned in the Supreme Court proceedings which focused on the *Suicide Act* provisions and their compatibility with the *HRA*. While Lord Neuberger agreed that the Supreme Court had the institutional authority to make a declaration of incompatibility under the *HRA*:

> The interference with the Applicants' article 8 rights is grave, the arguments in favour of the current law are by no means overwhelming … no compelling reason has been made out for the court simply ceding any jurisdiction to Parliament.[31]

The Court ultimately concluded not to make such a declaration on the basis that this was the remit of Parliament.[32] Again, Lord Neuberger set out reasons as to why it was 'institutionally inappropriate at this juncture' for the court to intervene. He set out four reasons, the first, notably, that

> the question whether the provision of section 2 should be modified raises a difficult, controversial and sensitive issue, with moral and religious dimensions, which undoubtedly justifies a relatively cautious approach from the courts.[33]

Importantly, his third reason was that Parliament was due to shortly debate the issue; a reference to Labour MP Lord Falconer's Assisted Dying Bill 2014 which ultimately failed to progress due to a lack of time for debate associated with the 2015 General Election. This Bill was subsequently revamped in Labour MP Rob Marris's Assisted Dying (No 2) Bill (2015) (defeated at its Second Reading)[34] and Crossbencher Baroness Meacher's Assisted Dying Bill (2021) (which ultimately failed when parliamentary session time ran out while it was in the Committee stage).[35]

This snapshot of the historical consideration of legalising AD in the UK indicates the courts' persistent maintenance of the view that this was Parliament's

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[31] *R (on the application of Nicklinson and another) v Ministry of Justice* (n 27) [111].

[32] Although one of the consequences of the *Nicklinson* decision is that the DPP prosecutorial guidance was revisited to clarify the position of health professionals' involvement. The change is to the effect that health professionals are more likely to be prosecuted for an offence under the *Suicide Act* should there be a pre-existing relationship of care between the health professional and the deceased person: CPS (n 26) as amended in 2014.

[33] *R (on the application of Nicklinson and another) v Ministry of Justice* (n 27) at [116].

[34] There were 330 against and 118 in favour. See Rowena Mason, 'Assisted Dying Bill Overwhelmingly Rejected by MPs', *The Guardian* (online, 12 September 2015) <https://www.theguardian.com/ society/2015/sep/11/mps-begin-debate-assisted-dying-bill>.

[35] John Keown, 'Physician-Assisted Suicide: Improving the Quality of the Debate' (Report, Policy Exchange, 12 March 2023) 12.

responsibility. It was recently made clear that were this to happen, it would be through a private members' bill.[36] This of itself is a point worth noting, given the existence of the *HRA* (UK). Whereas the Supreme Court of Canada's role in the interpretation of the Canadian Charter of Rights and Freedoms was central to the introduction of the Medical Assistance in Dying ('MAID') laws,[37] the UK Supreme Court is of the view that judicial intervention, via a declaration of incompatibility, is not the appropriate way to proceed.

The fact that a legislative route to the legalisation of assisted dying has been carved out enables a timely comparison with the Western Australian legislation, which was passed in 2019 and came into force in 2021, following the successful passing of the Victorian legislation.[38] Realistically, Australian states were bound to Parliamentary intervention were assisted dying to be realised. While Victoria, the ACT and Queensland boast human rights legislation[39] — potentially providing 'legal hangers' for rights associated with AD — this legislation has not particularly featured in the AD discourse in those jurisdictions.[40] The remarkable legal landscape change in Australia – which has seen all States and the ACT legalise AD over a period of eight years[41] — was preceded by a plethora of private members' bills in most jurisdictions dating back many years.[42] The gamechanger appeared to be the then Victorian Premier's endorsement of the Victorian AD Bill in 2017,[43] a recognition of the importance of the support of one of the two major political

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[36] Now Prime Minister Sir Kier Starmer committed to making parliamentary time for a vote on changing the law in March 2024, and confirmed in July 2024 that this would happen 'by way of a private member's bill': Sam Francis, 'Starmer sticks by promise of assisted dying free vote', *BBC News* (online, 12 July 2024) <https://www.bbc.com/news/articles/cy0857z0v5no>.

[37] As a result of the decision in *Carter v Canada* (n 24), which overruled the 20-year-old decision in *Rodriguez v British Columbia (AG)* [1993] 3 SCR 519.

[38] *Voluntary Assisted Dying Act 2017* (Vic) which came into force on 19 June 2019.

[39] *Charter of Human Rights and Responsibilities Act 2006* (Vic); *Human Rights Act 2019* (Qld); *Human Rights Act 2004* (ACT).

[40] Neither the Legal and Social Issues Committee, Parliament of Victoria, *Inquiry into End-of-Life Choices* (Parliamentary Paper No 174, June 2016) nor the Queensland Law Reform Commission, *A legal framework for voluntary assisted dying* (Report No 79, May 2021) references their jurisdiction's human rights legislation in any detail. Also note that WA was the second Australian jurisdiction to introduce AD legislation and there is no WA Human Rights Act.

[41] Victoria's Act was passed in 2017. Most recently the ACT passed AD legislation in 2024 following the Commonwealth's repealing of the ban on territories power to introduce laws legalising euthanasia and assisted suicide in 2022: *Restoring Territory Rights Act 2022* (Cth).

[42] For a review of the historical attempts to legalise AD in Australian jurisdictions see Lindy Willmott et al, '(Failed) Voluntary Euthanasia Law Reform in Australia: Two Decades of Trends, Models and Politics' (2016) 39(1) *University of New South Wales Law Journal* 1.

[43] Melissa Davey, 'Daniel Andrews recounts harrowing deaths as MPs debate voluntary assisted dying', *The Guardian* (online, 17 October 2017) <https://www.theguardian.com/society/2017/oct/17/daniel-andrews-recounts-harrowing-deaths-as-mps-debate-voluntary-assisted-dying>.

parties in Australia.[44] While the private members' bills did not gain particular traction in the Australian jurisdictions, the commitment to this avenue in the UK has, on this occasion, proven successful in this instance, with Labour MP Kim Leadbeater presenting the TAIB to Parliament in 2024. Although there have been suggestions that it is unlikely that the House of Lords would overturn a decision of the House of Commons, particularly considering the clear and demonstrable public support for AD, scholars have expressed the view that the House of Lords may well make amendments to the TIAB which would then need to be approved by the House of Commons.[45]

This commentary now moves to consider several key provisions of the TIAB, essentially those associated with accessing the proposed AD scheme. It is in this regard that some useful comparisons can be drawn with the *WAVADA*, a jurisdiction which has now had a number of years to reflect upon, and collect data in connection with, its own scheme.

III KEY ACCESS PROVISIONS IN THE TIAB AND COMPARISONS WITH THE *WAVADA* SCHEME

This commentary identifies three core areas in connection with a person's ability to access the AD statutory schemes. These have been selected on the basis that they relate to statutory provisions which set out key preconditions and processes associated with the schemes. The commentary deliberately does not engage with other, very real, factors which are relevant to access such as a person's socio-economic status, whether they are living in urban as opposed to regional or rural areas, and the availability of resources (such as the drugs and appropriately qualified health care professionals). These are identified in the scholarship and grey literature as influential in accessing AD schemes.[46] It will also not be engaging with the decisional criteria associated with access, essentially those parts addressing decisional capacity, voluntariness and understanding. These

[44] See the discussion in Willmott et al (n 42).

[45] Mark Elliott, 'Would it be constitutionally improper for the House of Lords to block the Assisted Dying Bill?', *Public Law for Everyone* (Web Page, 20 June 2025) <https://publiclawforeveryone.com/2025/06/20/would-it-be-constitutionally-improper-for-the-house-of-lords-to-block-the-assisted-dying-bill/>.

[46] Eg Casey M Haining, Lindy Willmott and Ben P White, 'Accessing Voluntary Assisted Dying in Regional Western Australia: Early Reflections from Key Stakeholders' (2023) 23(4) *Rural and Remote Health* 8024. These impediments to access have been identified in the various Reports of the Voluntary Assisted Dying Boards in WA, Victoria and Queensland. For examples see Victoria State Government, Department of Health, *Voluntary Assisted Dying Board Report Annual Report July 2023 to June 2024* (Report, June 2024) 7; WA State Government, Department of Health (n 5) under 'Workforce Sustainability'.

aspects are common to the legality of health care decisions more broadly[47] and this commentary is not looking to engage with this more generalised debate, particularly the issue of coercion in relation to AD, which has been consistently identified in the political discourse as a matter of concern, the UK debates being evidence of this.[48]

A *Eligibility Criteria*

1 *Residency*

Section 1 of the TIAB provides that for a person to access the scheme the person must be ordinarily resident in England and Wales and has been resident for at least the last 12 months since the date of the first declaration under the TIAB. There is a further requirement that the person is registered with a general medical practice in England or Wales.[49]

Residency requirements are relatively common in AD schemes worldwide, and are certainly a common feature of the various Australian schemes (although the Queensland legislation is more relaxed on this point).[50] It is acknowledged that this is in order to constrain 'health tourism' — such as that associated with the Swiss Dignitas Clinic.[51] Health tourism has also been associated with surrogacy. While it is seen as problematic in this context because of particular ethical issues and legal challenges in relation to parentage,[52] these are not associated with AD — a point developed below. The requirement of registration with a practice is less

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[47] As noted by Ricciardo (n 6) 175. Also note the discussion in Mullock and Lewis (n 26).

[48] Colin Gavaghan, 'The assisted dying debate has been about safety not sanctity — here's why I think the bill passed the test', *The Conversation* (online, 21 June 2025) <https://theconversation.com/the-assisted-dying-debate-has-been-about-safety-not-sanctity-heres-why-i-think-the-bill-passed-the-test-259476>; and see discussion in Mullock and Lewis (n 26) in which the authors interrogate understandings of vulnerability in the literature and argue that this can co-exist with respect for autonomy.

[49] Terminally Ill Adults (End of Life) Bill (2025) (UK) s 1(1)(d) ('TIAB').

[50] *Voluntary Assisted Dying Act 2021* (Qld) s 10(1)(e).

[51] For example, data from 'Dignity in Dying' indicates that since the UK Prosecutorial Policy on AD was introduced several hundred UK citizens have been assisted to travel to Dignitas in Switzerland to access AD: 'Dignitas British membership at all-time high with 80% increase in last decade', *Dignity in Dying* (Web Page, 2 March 2023) <https://www.dignityindying.org.uk/news/dignitas-assisted-dying-switzerland/>.

[52] See Raywat Deonandan, 'Recent Trends in Reproductive Tourism and International Surrogacy: Ethical Considerations and Challenges for Policy' (2015) 8 *Risk Management and Healthcare Policy* 111; and discussion of the issue in Janelle Miles and Kate McKenna, 'Australia's complex patchwork of surrogacy laws is leaving some children in legal limbo', *ABC News* (online, 2 May 2025) <https://www.abc.net.au/news/2025-05-02/commercial-surrogacy-australia-international-legal-challenges/105238124>.

common and may well be associated with the status of UK's National Health Service as the main provider of medical services.[53]

AD legislation does, like other Australian schemes, contain a residency requirement. Section 16(1)(b)(ii) of the *WAVADA* requires that the applicant be regarded as ordinarily resident in Western Australia ('WA') for at least 12 months. There is a right of appeal in relation to the residency requirement which has been considered in, to date, three decisions of the WA State Administrative Tribunal ('WASAT').[54] In a recent publication considering these decisions, the author notes that the members of WASAT adopted a holistic approach to the question as to whether the applicants should be able to access the *WAVADA* scheme, notwithstanding their long absences from WA.[55] It will be argued later in this commentary that these decisions, and the article, give valuable insight into the underlying purpose of the *WAVADA*.

2 *Qualifying Health Conditions*

The TIAB requires that the applicant have a 'clear, settled and informed wish to end their own life'[56] and that the applicant must have been diagnosed with a terminal illness (an inevitably progressive illness or disease which cannot be reversed by treatment) and be expected to die within the next six months.[57]

Timeframes associated with death of those with terminal illness is a relatively common qualification for accessing AD schemes, although some schemes have expanded their qualifying criteria to include people who are not terminally ill. In the Netherlands and Belgium, this has been the case for some time, with the implication that persons enduring intolerable mental suffering not associated with terminal illness qualify for access to AD in those countries.[58]

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[53] It has been suggested that AD services under the TIAB (n 49) could be provided by the NHS; alternatively that there might be services provided by a separate provider but overseen by the NHS: Mason (n 34).
[54] *AB and CD* [2024] WASAT 6; *EF, GH AND IJ and KL* [2024] WASAT 18; *HM v Co-ordinating Practitioner, HM* [2024] WASAT 23.
[55] Ricciardo (n 6).
[56] TIAB (n 49) s 1(2)(a).
[57] Ibid s 2.
[58] *Termination of Life on Request and Assisted Suicide (Reviews Procedures Act)* (the Netherlands); *Wet betreffende de euthanasie* [*Belgian Euthanasia Act of 2002*] (Belgium).

As is the case in other Australian jurisdictions,[59] the *WAVADA* scheme sets out two timeframes for accessing AD. A person is eligible if they have a medical condition which is advanced and progressive and will, on the balance of probabilities result in death in six months, but this is extended to 12 months where the person has a neurodegenerative condition.[60] It is a further condition of eligibility that the disease, illness or medical condition is 'causing suffering to the person that cannot be relieved in a manner that the person considers tolerable'.[61] This reference to the experiential suffering of the applicant is also a requirement of other AD laws globally.[62] The absence of this from the TIAB is, again, a point of difference which, in the author's view, suggests an approach to the legalisation of AD in England and Wales which is different to that in WA (and indeed other Australian jurisdictions), a point which will be expanded upon in Part IV.

Notably, both regimes specify that the fact that a person has a disability or has been diagnosed with a mental illness does not, itself, provide a basis for accessing the schemes.[63]

B *Process of Approval*

1 *First Stage*

The first stage of the process of approval merits particular consideration as a 'gateway' to accessibility. Under the TIAB the process of access commences with a 'first declaration' which must be witnessed.[64] The first assessment of eligibility is carried out by the first 'registered medical practitioner' (co-ordinating doctor — 'COD')[65] 'as soon as reasonably practicable' after the declaration. A report must then be completed and given to the assessed person detailing reasons as to why the eligibility criteria are or are not satisfied.[66] If satisfied, the COD must refer the assessed person to an independent doctor ('ID').[67] The first doctor with whom the applicant has the consultation is under no duty to raise the option of AD but

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[59] See Katherine Waller et al, 'Voluntary Assisted Dying in Australia: A Comparative & Critical Analysis of State Law' (2023) 46(4) *University of New South Wales Law Journal* 1421 for a comprehensive discussion of the differences between the various Australian state AD laws.
[60] *Voluntary Assisted Dying Act 2019* (WA) s 16(1)(c) ('*WAVADA*').
[61] Ibid s 16(1)(c)(iii); TIAB (n 49) s 2(3).
[62] For example see Canadian Medical Assistance in Dying ('MAID') laws referring to 'suffering that cannot be alleviated under conditions the person considers acceptable': *Medical Assistance in Dying Act*, RSC 2016 c 7 (Canada). See also *End of Life Choice Act 2019* (NZ) s 5(1)(c).
[63] *WAVADA* (n 60) s 16(2).
[64] TIAB (n 49) s 7.
[65] Ibid s 8.
[66] Ibid s 9(5).
[67] Ibid s 9(3)(c)

can raise it if 'appropriate'.[68] If it is raised it must be done in conjunction with explaining all appropriate other options including palliative care.[69] If a medical practitioner is 'unwilling or unable' to conduct the initial discussions then that person 'must ensure' the applicant is directed to where they 'can obtain information and have the preliminary discussion.'[70]

Under the *WAVADA*, a 'clear and unambiguous' request made during a medical consultation is termed a 'first request'.[71] If that request is accepted, that practitioner becomes the coordinating practitioner and is required to make an assessment as to eligibility. In comparing the analogous provisions of the *WAVADA* a clear difference is that this permits medical professionals to administer the scheme by virtue of the reference to the Health Practitioner Regulation National Law (WA), which as a consequence includes both medical doctors and nurse practitioners.[72] This, it is argued later in this commentary, has implications for accessing the relevant schemes.

There are, however, similarities. For example, the *WAVADA*[73] states that the medical practitioner can discuss AD as long as the person is also informed about other 'treatment options'.[74] A further alignment includes the *WAVADA* provision which requires that where a medical practitioner does not want to engage with the request as a matter of conscientious objection, unavailability or 'some other reason',[75] they must provide the applicant information relating to accessing AD.[76]

2 *Subsequent Stages*

The TIAB requires an ID, once passed on a report by the COD, to carry out the second assessment 'as soon as reasonably practicable after the first period of reflection for the assessed person has ended (a period of seven days following the

[68] Ibid s 5(1), (2).
[69] Ibid s 5(2), (5).
[70] Ibid s 5(6).
[71] *WAVADA* (n 60) s 18.
[72] See ibid s 5 in which a 'medical practitioner' is defined as a 'person registered under the Health Practitioner Regulation National Law in the medical profession'.
[73] Ibid s 10(3).
[74] The ability of a practitioner to raise the possibility of AD was a point of contention in the political debates associated with the *WAVADA*: Western Australia, *Parliamentary Debates*, Legislative Council, 26 September – 5 December 2019. Under s 8 of the *Voluntary Assisted Dying Act 2017* (Vic) the practitioner is not permitted to raise this as a possible end of life choice. This was recognised in Victoria State Government, Department of Health (n 46) as a barrier to accessing VAD under that Act (at 39).
[75] *WAVADA* (n 60) s 20.
[76] Ibid s 20(4)(b).

day of the COD's Report).[77] The IC is required to make a report[78] and then supply the Report to the Voluntary Assisted Commissioner ('VAC')[79] after which the VAC must refer 'as soon as reasonably practicable' to the Assisted Dying Review Panel ('Panel') for the determination of the person's eligibility.[80] If the certificate of eligibility is granted there then ensues a 'second period for reflection' which lasts for 14 days unless the COD reasonably believes that the person's death is likely to occur within a month in which case the period of reflection is 48 hours.[81] If the Panel refuses to grant a certificate of eligibility, an appeal is possible although confined to narrow grounds, essentially procedural rather than substantive.[82] The appeal is heard by the Commissioner who must consider the appeal without a hearing.[83]

Under the *WAVADA*, if the coordinating practitioner assesses the patient as eligible then they are required to refer the patient to another medical practitioner for a second assessment of eligibility.[84] If the patient's eligibility at this second stage is confirmed, the patient may make a written request to access the scheme,[85] following which the patient can make a final request to the coordinating practitioner. Within two business days of receiving the request the coordinating practitioner must carry out a final review which involves notifying the Voluntary Assisted Dying Board of the final request and confirming the patient's eligibility and other details.[86]

Under both schemes there are three assessments of the patient's eligibility. The main difference is that under the *WAVADA* all the assessments are carried out by individual medical practitioners. Secondly the timeframes permit a rather quicker progression of the request; a final request for access to AD can be made at the end of the 'designated period' (which is nine days from when the patient made the first request),[87] although exceptions to this are built in where the person is likely

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[77] TIAB (n 49) s 10(1), (3). If the ID makes a report stating that they are not satisfied then they 'may, if requested to do so … refer that person to a different registered medical practitioner …': TIAB s 13(2).
[78] Ibid s 11(5).
[79] Established under s 4.
[80] Ibid s 16(2).
[81] Ibid s 19.
[82] Ibid s 18(2): the grounds are that the first panel's decision (a) contains an error of law; (b) is irrational; or (c) is procedurally unfair.
[83] Ibid s 18(3).
[84] *WAVADA* (n 60) s 30.
[85] Ibid s 42(1).
[86] Ibid divs 5, 6: other details include, eg, if the patient was assisted by an interpreter. The form must be forwarded to the Board within two business days of completion.
[87] Ibid s 48.

to die or lose decision-making capacity before that time.[88] Practitioners are also required to complete their reports as to eligibility within two business days of assessment and also to notify the patient within this timeframe.[89]

There is also a difference in connection with the ability of the applicants to challenge decisions by practitioners that they do not meet the eligibility criteria. Under the *WAVADA* there is a ground of appeal relating to 'legal matters' but not medical determinations.[90] As such there is a right of review in relation to decisions concerning the residence criterion, whether the person has decision-making capacity and whether the person is acting voluntarily and without coercion.[91] One author has defended the role of medical practitioners in making 'legal' decisions noting that this is as an appropriate approach given that 'health practitioners are required to make a host of decisions which involve legal standards'.[92]

C *Administration of the Substance*

Section 25(11) of the TIAB requires the co-ordinating doctor to be present with the patient at the time of taking the approved substance. It states that the doctor need not be in the same room as the patient but does need to 'remain with the person'.[93] Under the TIAB only self-administration of the substance is permitted.[94] Indeed the TIAB provides that the coordinating doctor 'may assist that person to ingest or otherwise self-administer the substance'[95] but that this does not authorise the doctor to 'administer an approved substance to another person with the intention of causing that person's death'.[96] It states that the decision to self-administer the approved substance and the final act of doing so must be taken by the person to whom the substance has been provided.[97]

It is on the issue of administration of the lethal substance that there is a significant difference when looking at the *WAVADA*. Firstly, there is no requirement of the medical practitioner being present at the time of administration of the substance. Secondly, and most importantly, the WA legislation, like all current AD schemes in

[88] Ibid s 48(3).
[89] See ibid s 40(2).
[90] Ricciardo (n 6).
[91] *WAVADA* (n 60) s 84(1)(a)(ii)–(iii).
[92] Ricciardo (n 6) 175.
[93] TIAB (n 49) s 25(11), (12).
[94] Ibid s 25(7), (8).
[95] Ibid s 25(8)(b).
[96] Ibid s 25(10).
[97] Ibid s 25(9).

Australia bar Victoria, permits a choice of self-administration or practitioner administration.[98] The WA Voluntary Assisted Dying Board notes that 94.9% of those accessing VAD over the 2023–2024 period chose practitioner administration.[99] This is consistent with, for example, evidence from jurisdictions such as Canada. The most recent Annual Report on MAID notes that

> MAID was administered by a practitioner in nearly all cases. In 2023, MAID was self-administered in fewer than five instances. While self-administration of MAID is permitted in all jurisdictions in Canada (except for Quebec), very few people have chosen this option since 2016.[100]

As will be suggested below, the limitation to self-administration in the TIAB has both conceptual and practical implications.

IV THE TIAB AND *WAVADA*: DISTINCT UNDERLYING PREMISE EQUATES TO DIFFERENTIAL ACCESS?

This analysis of the various provisions relating to accessing AD under the TIAB and *WAVADA* reveals a key difference in conceptual approaches to AD more generally. It is suggested that the TIAB in its current form continues to identify AD with the law relating to suicide and is thus focused on the provision of significant safeguards in relation to accessing the scheme.[101] As such it is not recognised as a genuine end-of-life choice, but rather as a limited exemption to an existing criminal offence. This, it is argued, contrasts with the *WAVADA* which is underpinned by core moral principles associated with autonomy, dignity and the reduction of suffering.[102]

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[98] Under s 46(c)(i) of the *Voluntary Assisted Dying Act 2017* (Vic), practitioner administration is limited to patients who are unable to self-administer or digest the substance.

[99] WA State Government, Department of Health (n 5) 6.

[100] Health Canada, *Fifth Annual Report on Medical Assistance in Dying in Canada* (Report, 2023) 16–17.

[101] MP Kim Leadbeater, the sponsor of the TIAB, has consistently touted that the safeguards in the scheme are the 'strongest in the world': Jessica Elgot, 'Kim Leadbeater: assisted dying bill will still have world's strongest safeguards', *The Guardian* (online, 11 February 2025) <https://www.theguardian.com/society/2025/feb/11/kim-leadbeater-assisted-dying-bill-worlds-strongest-safeguards>. However this has been criticised as overly narrowing the scope of the scheme: see the discussion in Eduardo Reyes, '"Safety" v autonomy', *The Law Society Gazette* (online, 11 April 2025) <https://www.lawgazette.co.uk/features/safety-v-autonomy/5122984.article>.

[102] See a statement of the Principles in *WAVADA* (n 60) div 2 s 4. The reference to these concepts is also reflected in other jurisdictions. For example, access to MAID requires the person to be experiencing 'unbearable or mental suffering from the illness, disease, disability or state of decline …': see discussion in Health Canada (n 100) 6.

A *Differing Characterisations of AD*

The political discourse leading up to the Western Australian Parliament's debate of the AD Bill was characterised, above all, by reference to the spirit of compassion underpinning the legislation.[103] On the passing of the Bill on 10 December 2019, the then WA Health Minister, Roger Cook, stated that West Australians had 'chosen compassion and the right to choose'.[104] At the earliest possible place in the *WAVADA* the principles governing the Act are set out, and these notably reference the 'equal value' of every human life, 'autonomy in respect of end of life choices', and the need to 'minimise the person's suffering'.[105] It is submitted that the inclusion of these principles is an important interpretative mechanism. It is notable that the TIAB contains no underlying statement of principles and in this sense is very 'legal' in its approach to AD. This is, it is argued, a reductionist approach in that it is acknowledged in the scholarship,[106] and indeed by the fact that both pieces of legislation were considered as a 'conscience' vote, that the law in this area is inextricably linked to core values underpinning humanity.[107] The focus on legal safeguards in the TIAB diminishes this fundamental dimension.

The absence of any reference to the subjective experience of the person seeking to access AD under the TIAB reinforces this legalistic approach. This is in contrast to the *WAVADA* which, as noted, refers to the disease, illness or medical condition 'causing suffering to the person that cannot be relieved in a manner that the person considers tolerable'.[108] The inclusion of the personal experience as a central qualifying criterion is reflected in all Australian AD legislation,[109] and indeed other global models.[110]

The significance of the applicant's subjective experience more generally to the operation of the *WAVADA* scheme has been recognised in three decisions of the

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[103] See, eg, in WA, *Parliamentary Debates*, Legislative Counsel, 26 September 2019, where Stephen Dawson MLC repeatedly refers to compassion, citing examples given to the Joint Select Committee on End-of-Life Choices, Parliament of Western Australia, *Report: My Life, My Choice* (Report, August 2018) 23.
[104] 'Western Australia legalises voluntary assisted dying after 'momentous process', *The Guardian* (online, 11 December 2019) <https://www.theguardian.com/society/2019/dec/11/western-australia-legalises-voluntary-assisted-dying-after-momentous-process>.
[105] See *WAVADA* (n 60) div 2 s 4(1)(d).
[106] See the various papers featured in John Keown (ed), *Euthanasia Examined: Ethical, Clinical and Legal Perspectives* (Cambridge University Press, 1985).
[107] First expressed formally in *United Nations Declaration of Human Rights*, GA Res 217A (III), UN GAOR, UN Doc A/810 (10 December 1948) following the atrocities of World War II.
[108] *WAVADA* (n 60) s 16(c)(iii).
[109] *Voluntary Assisted Dying Act 2017* (Vic) s 9; *Voluntary Assisted Dying Act 2021* (Qld) s 10.
[110] Above n 62.

SAT dealing with appeals on residency criteria.[111] These decisions, in determining whether a person is 'ordinarily resident' in WA for the purposes of accessing the scheme, emphasised the importance of the applicant's personal and subjective attachment to WA. As the author of a recent study of these decisions notes:

> Allowing people who are ordinarily resident in WA to make those choices [to spend significant periods of time away from their usual home], and then also choose to be at home for medical reasons and end of life care, is consistent with the principles under pinning the VAD Act (including respect for autonomy and the provision of high quality care).[112]

The legalistic approach to AD in the TIAB is further reflected in the fact that the legality of AD is addressed through amendments to the *Suicide Act*.[113] As such it can be legislatively characterised as an exemption to an existing offence — it states that '[a] person is not guilty of an offence …' — rather than establishing a separate legislative scheme focused on end-of-life choices. This can be contrasted with the *WAVADA*, which explicitly states that a person utilising the provisions of the legislation is not committing suicide, thereby establishing it as a stand-alone statutory scheme providing specific end-of-life choices.[114]

B *Implications for Access*

The earlier section of this commentary identified specific provisions in the TIAB associated with access to the scheme. It is argued here that these provisions are consistent with a conception of AD as an exception to existing offences rather than a separate framework providing an additional end-of-life choice. For example, the TIAB only permits self-administration of the substance in bringing about death of the person through AD. In this respect it reinforces its association with suicide. Under the *WAVADA*, as noted above, applicants for AD have a choice between practitioner administration and self-administration. It should be noted that in Victoria, practitioner administration is only permissible where the applicant is unable to self-administer or digest the substance,[115] a restriction which has been

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[111] Above n 54.
[112] Ricciardo (n 6) 163.
[113] TIAB (n 49) s 32.
[114] *WAVADA* (n 60) s 12.
[115] Section 46(c)(i) of the *Voluntary Assisted Dying Act 2017* (Vic) states that a 'practitioner administration permit' only applies if 'the person is physically incapable of the self-administration or digestion of the voluntary assisted dying substance'.

associated with the proportionally lower numbers of people participating in that jurisdiction's statutory scheme and identified as an access challenge.[116]

A second example is the limitation in the TIAB of the professionals involved in the assessment of the person requesting access to the scheme. This is confined to medical doctors which is inherently limiting the operation of the scheme. Under the *WAVADA* medical professionals include both medical doctors and nurse practitioners,[117] meaning that both can assess patients, and supply and administer the lethal substance.

A third example is the sheer complexity of the approval scheme under the TIAB. It has been noted above that this incorporates significant periods of 'reflection' which implicitly extend the process of approval, particularly significant given that the legislation is only concerned with those who have a life expectancy of six months or less. The involvement of a second tier of decision-makers in the approval scheme — the Panel[118] — and the limited and legalistic grounds associated with challenging eligibility decisions are further evidence of this complexity.

It is argued that these provisions which are posited as safeguards will ultimately provide obstacles to those wanting to access the scheme in their dying weeks. The *WAVADA*, in its textual provisions, provides a more accessible scheme. And yet, the most recent Annual Report of the Voluntary Assisted Dying Board identifies difficulties of access to the WA scheme as its main challenge. The Annual Report cites the low numbers of applications for training by practitioners, as well as persistent issues of a lack of education around the scheme, as reasons for access problems.[119] The delays in processing applications have meant that those seeking to access the scheme have died before having the opportunity to utilise it.[120] It is logical to suppose that if this is a problem with a scheme which is comparatively more accessible, the TIAB scheme will experience more significant challenges.

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[116] Victoria State Government, Department of Health (n 46) 34.
[117] By virtue of the fact that *WAVADA* (n 60) references the status of medical practitioners under the Health Practitioner Regulation National Law.
[118] To include a social worker, lawyer and psychiatrist in its membership.
[119] WA State Government, Department of Health (n 5).
[120] Ibid.

V CONCLUSION

This commentary commends the progress which has been made with the passing of the TIAB. The failure to conceive of AD as a genuine end-of-life choice, however, has resulted in a perversion of language, whereby the narrative of 'safeguards' manifests as barriers to access. The TIAB as it stands presents a range of hurdles which applicants need to clear before being able to access the promise of a chosen death, at a time when they are probably experiencing considerable if not profound physical and existential suffering. Until AD is reimagined in terms of its broader social and moral context, accessing the scheme proposed by the TIAB is likely to be challenging.

MINORS' ACCESS TO GENDER-AFFIRMING HEALTHCARE IN AUSTRALIA: CURRENT REVIEWS AND THEIR CLINICAL, LEGAL AND POLICY CONTEXTS

AIDAN RICCIARDO *

In 2025, two concurrent reviews were established to consider the provision of gender-affirming healthcare to minors in Australia: a state-based review in Queensland and a national process led by the National Health and Medical Research Council. These reviews emerged in the context of prolonged legal and clinical uncertainty, intensified by the growing politicisation of this topic in Australia and globally. This article examines the origins of these two review processes, their institutional authority, and their capacity to provide a robust foundation for future practice and access to care. It argues that the national process is capable of delivering a coherent and credible framework to guide gender-affirming care for minors, whereas Queensland's review risks entrenching uncertainty through jurisdictional fragmentation. National guidelines offer a pathway to address the existing challenges by providing an evidence-based foundation for clinical practice, legal and regulatory certainty, and fair access to care for those who need it.

I INTRODUCTION

In recent years, minors' access to gender-affirming healthcare has increasingly become the subject of media coverage and public discussion.[1] This discussion has been fuelled by the decision in the English case of *Bell v The Tavistock and Portman NHS Foundation Trust* ('*Bell*'),[2] and by the *Independent Review of Gender Identity Services for Children and Young People* commissioned by the English National Health Service and led by Hilary Cass.[3] It also coincides with broader politicisation and marginalisation of transgender people across social, legal, and political spheres globally.[4]

In 2025, both the Australian Government and the Queensland Government announced reviews into gender-affirming treatment for minors, including puberty suppression (sometimes called 'stage 1 treatment') and gender-affirming feminising or masculinising hormonal therapy (sometimes called 'stage 2 treatment').[5] The Queensland Government has commissioned an independent review of puberty suppression and gender-affirming hormone therapies in Queensland's public paediatrics gender services,[6] and the Australian Government has tasked the National Health and Medical Research Council ('NHMRC') with undertaking a comprehensive review of the *Australian Standards of Care and*

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[1] Gabrielle Wolf, 'Gender-affirming Medical Treatment for Minors: International Legal Responses to an Evolving Debate' (2024) 47(3) *University of New South Wales Law Journal* 744, 746.

[2] *Bell v The Tavistock and Portman NHS Foundation Trust* [2020] EWHC 3274 ('*Bell*'), and on appeal, *Bell v The Tavistock and Portman NHS Foundation Trust* [2021] EWCA Civ 1363 ('*Bell Appeal*').

[3] Hilary Cass, *Independent Review of Gender Identity Services for Children and Young People: Final Report* (Report, April 2024) ('*Cass Review*').

[4] See, eg, Myles Williamson, 'A Global Analysis of Transgender Rights: Introducing the Trans Rights Indicator Project (TRIP)' (2024) 22(3) *Perspectives on Politics* 799, 799, 814; Paula Gerber, *Sex, Gender & Identity: Trans Rights in Australia* (Monash University Publishing, 2025) 40–62.

[5] Both puberty suppression and gender-affirming hormones are regarded as falling under the umbrella of 'gender-affirming treatment'. These treatments are best not conceptualised as 'stages', as this incorrectly implies (1) that an individual must have commenced an earlier 'stage' before accessing a later one, and (2) that all individuals will progressively access each from of treatment. Treatment pathways vary according to individual needs and circumstances. See Michelle M Telfer et al, *Australian Standards of Care and Treatment Guidelines for Trans and Gender Diverse Children and Adolescents* (version 1.4, The Royal Children's Hospital Melbourne, 2023) 5.

[6] Queensland Health, *Independent Review of Stage 1 and Stage 2 Hormone Therapies in Queensland's Public Paediatrics Gender Services* (Web Page, 30 July 2025) <https://www.health.qld.gov.au/research-reports/reports/review-investigation/hormone-therapies-review>.

Treatment Guidelines for Trans and Gender Diverse Children and Adolescents,[7] and with developing new national guidelines.[8]

In this piece I first briefly set out the backdrop of events which have led to these reviews, before considering the context and scope of each. I then argue that while both inquiries reflect a shift toward a more structured framework for the delivery of gender-affirming care for minors — a development with the potential to support greater clarity and consistency — the NHMRC review provides a more promising foundation for coherent reform. By promoting nationally consistent, evidence-based clinical guidance, the NHMRC process may help to clarify standards of care, reduce legal uncertainty for clinicians and their patients, and insulate treatment decisions from political criticism. In contrast, the Queensland review may ultimately contribute to jurisdictional inconsistency and fragmentation in clinical standards across the country.

II BACKGROUND

Questions about whether, and in what circumstances, minors and their parents can consent to gender-affirming treatment have been extensively litigated in Australian courts over the past two decades.[9] A number of decisions have clarified the role of the courts in these treatment decisions, with a key development being the recognition that, in certain circumstances, gender-affirming treatment could be provided to minors without court involvement.[10] In the clinical context, the *Australian Standards of Care and Treatment Guidelines for Trans and Gender Diverse Children and Adolescents* were developed and published by clinicians at the Royal Children's Hospital Gender Service in Melbourne in 2018,[11] and have since informed the provision of care at all Australian paediatric gender services.[12]

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[7] Telfer et al (n 5).

[8] Mark Butler, 'Health Care for Trans and Gender Diverse Australian Children and Adolescents' (Media Statement, 31 January 2025) <https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/health-care-for-trans-and-gender-diverse-australian-children-and-adolescents>.

[9] See, eg, Malcolm K Smith, 'The Requirement for Trans and Gender Diverse Youth to Seek Court Approval for the Commencement of Hormone Treatment: A Comparison of Australian Jurisprudence with the English Decision in Bell' (2022) 31(1) *Medical Law Review* 47; Aidan Ricciardo, 'Minors' Capacity to Consent to Puberty Supressing Treatment' (2022) 38(1) *Journal of Professional Negligence* 38, 39; Wolf (n 1).

[10] See, eg, *Re Jamie* (2013) 278 FLR 155; *Re Kelvin* (2017) 57 Fam LR 503; *Re Matthew* [2018] FamCA 161; *Re Imogen (No 6)* (2020) 61 Fam LR 344; *Re A* (2022) 11 QR 1.

[11] Telfer et al (n 5).

[12] AusPATH and Transcend Australia, *Briefings on Trans Healthcare: Responding to the Cass Review's Recommendations* (Report, 2024) 19.

However, despite these developments, clinical and legal uncertainty has persisted.

Meanwhile, events in the United Kingdom ('UK') from 2020 onwards significantly shaped discourse in Australia. In *Bell*, the English High Court held that children under the age of 16 were unlikely to be competent to consent to puberty-suppressing treatment.[13] The judgment recommended that applications be made to the court before such treatment could proceed.[14]

Although the English High Court's decision in *Bell* was ultimately overturned and was never binding in Australia,[15] it attracted significant attention and led some Australian health services to take a more cautious approach to providing gender-affirming treatment to minors. In Western Australia, for example, the Perth Children's Hospital initiated a review of its Gender Diversity Service in response to the decision in *Bell*.[16] During the review period, the hospital adopted a practice of requiring court authorisation before providing gender-affirming treatment, even in cases where Australian law clearly did not mandate court authorisation as a procedural safeguard (ie, the Hospital required court authorisation even where the minor was '*Gillick* competent' *and* their parents consented to the treatment).[17]

On appeal, the English Court of Appeal overturned the first-instance *Bell* decision, holding that it was inappropriate for the High Court to issue generalised guidance on minors' capacity to consent to gender-affirming treatment.[18] The Court of Appeal noted that such guidance was inconsistent with Lord Scarman's observations in *Gillick v West Norfolk and Wisbech Area Health Authority*, which cautioned against determining capacity by reference to a 'judicially fixed age limit'.[19] The appellate decision affirmed that questions of competence should be determined on a case-by-case basis by clinicians, consistent with the *Gillick* test.[20]

During the course of the *Bell* litigation, the National Health Service in England commissioned the *Independent Review of Gender Identity Services for Children and Young People*, led by Dr Hilary Cass (the 'Cass Review'). The final report, released

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[13] *Bell* (n 2) [127].
[14] Ibid [148]–[152].
[15] *Bell Appeal* (n 2).
[16] *Re G2* [2021] FCWA 98, [26]–[30].
[17] Ibid. Per *Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC 112 (*'Gillick'*), a minor becomes competent to make a particular healthcare decision for themselves when they display sufficient emotional maturity and intelligence to fully understand the proposed treatment.
[18] *Bell Appeal* (n 2) [91].
[19] Ibid [88], quoting *Gillick* (n 17) 186–8.
[20] *Bell Appeal* (n 2) [76]–[80].

in early 2024, recommended changes to the structure and delivery of gender identity health services for minors in the UK. Key recommendations included the establishment of regional multidisciplinary services and a more cautious approach to the use of puberty suppression and gender-affirming hormones, particularly outside research settings.[21] While the Cass Review focused only on the UK context, its recommendations nevertheless ignited debate in Australia, where questions were raised about their applicability in local health frameworks.

The Australian Professional Association for Trans Health ('AusPATH') and Transcend Australia noted that many of the Cass Review's recommendations reflect practices which are already embedded within Australian paediatric gender services.[22] Indeed, Australian clinics operate with reference to national standards of care, with multidisciplinary teams that provide holistic, individualised care.[23] Many Australian clinicians and researchers have contended that the Cass Review should not be used to guide care for trans young people in Australia, including in a recent article which argues that the Cass Review 'does not give credible evidence-based guidance':[24]

> The Cass Review's internal contradictions are striking. It acknowledged that some trans young people benefit from puberty suppression, but its recommendations have made this currently inaccessible ... It found no evidence that psychological treatments improve gender dysphoria, yet recommended expanding their provision. It found that NHS provision of [gender-affirming medical treatment] was already very restricted, and that young people were distressed by lack of access to treatment, yet it recommended increased barriers ... It dismissed the evidence of benefit from [gender-affirming medical treatment] as "weak", but emphasised speculative harms based on weaker evidence. The harms of withholding [gender-affirming medical treatment] were not evaluated. The Review disregarded studies observing that adolescents who requested but were unable to access [gender-affirming medical treatment] had poorer mental health compared with those who could access [it]. Despite finding that detransition and regret appear uncommon, the Review's recommendations appear to have the goal of preventing regret at any cost.[25]

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[21] *Cass Review* (n 3) 20–45.
[22] AusPATH and Transcend Australia (n 12).
[23] Ibid 2; Telfer et al (n 5).
[24] Julia K Moore et al, 'Cass Review Does Not Guide Care for Trans Young People' (2025) 223(7) *Medical Journal of Australia* 331, 334.
[25] Ibid 331.

After the Interim Report of the Cass Review was released, the New South Wales ('NSW') Ministry of Health commissioned the independent Sax Institute to update an earlier 'Evidence Check' which reviewed international and national evidence on the effectiveness and safety of gender-affirming treatment for minors. Released in 2024, the Sax Institute's updated report concluded that while the overall quality of evidence remains limited, the new evidence 'reinforced' previous findings that puberty-suppressing treatment was generally 'safe, effective and reversible'.[26] In relation to feminising or masculinising gender-affirming hormone therapy ('GAHT'), similar limitations were observed in the evidence, but the Sax Institute noted that the 'studies reporting positive mental health outcomes following GAHT outnumber those with neutral or negative findings' and that 'serious adverse outcomes associated with GAHT are rare'.[27]

The brief context outlined in this Part indicates that tensions around minors' access to gender-affirming treatment in Australia have not developed in isolation, but have been shaped by court proceedings, professional discourse and formal reviews. It is against this backdrop that the two Australian reviews announced in 2025 must be situated and understood.

III QUEENSLAND REVIEW

A *Political and Policy Background*

In October 2024, Queensland held a state election that brought a change of government, with the Queensland Liberal National Party ('LNP') forming government. In the period leading up to the state election, the LNP adopted an increasingly critical stance on the provision of gender-affirming care to young people. This was evident both in formal party resolutions and in statements made by senior figures.

At the party's annual convention in June 2024, an 'overwhelming majority' of party members voted in favour of a motion to ban the use of puberty blockers for children and adolescents.[28] The resolution signalled strong sentiment within the party membership, but during the 2024 election campaign itself, the LNP did not release a comprehensive policy platform on gender-affirming care. When asked

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[26] Sax Institute, *Evidence for Effective Interventions for Children and Young People with Gender Dysphoria: Update* (Evidence Check Report, February 2024) 10.
[27] Ibid 11.
[28] Madura McCormack and Taylah Fellows, 'LNP Convention Day 1: Lawrence Springborg Eyes Likely Election Win', *Courier Mail* (online, 6 July 2024) <https://www.couriermail.com.au/news/queensland/qld-politics/lnp-convention-day-1-lawrence-springborg-eyes-likely-election-win/news -story/f1909f7cdfa3fc316b22078978ee0023>.

by media outlets, the party declined to clarify whether it would impose a ban on puberty blockers or outline the extent of any proposed restrictions.[29]

Earlier, in 2023, LNP frontbencher Tim Nicholls (then Opposition Health Minister) raised concerns in Parliament about puberty-suppressing treatment and the provision of gender-affirming care generally.[30] His comments suggested concern that gender-affirming care was being overused or insufficiently monitored,[31] and foreshadowed later party positions when he became the Health Minister following the LNP's election victory.

By early January 2025, the new LNP government announced that Tim Nicholls had directed Queensland Health to halt works relating to an expansion of its paediatric gender services.[32] The expansion plans were underway as part of actioning the recommendations from a 2024 independent review delivered to the previous Labor government. That review was commissioned as an external clinical service evaluation of the Queensland Children's Gender Service ('QCGS'). Conducted by an independent multidisciplinary panel, the evaluation examined governance, clinical pathways, data and outcomes against national and international guidelines.[33] The panel found QCGS care to be safe, evidence-based and consistent with current guidelines.[34] It found 'no evidence of children, adolescents or their families being hurried or coerced into making decisions about medical intervention',[35] and described a typical caseload in which roughly one-third of assessed patients are discharged without the need for medical treatment, one-third are undergoing further clinical management and assessment, and one-third receive puberty blockers or gender-affirming hormones with ongoing support.[36] The report made 25 recommendations, including staffing increases and the development of a statewide networked service to improve access and reduce wait times.[37] The (then) Labor government

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[29] Ben Smee and Andrew Messenger, 'David Crisafulli Faces Questions About LNP's Transgender Plans After Party Official's Email Revealed', *The Guardian* (online, 10 October 2024) <https://www.theguardian.com/australia-news/2024/oct/09/david-crisafulli-lnp-transgender-queensland-state-election>.
[30] Queensland, *Parliamentary Debates*, Legislative Assembly, 13 June 2023, 1780–5 (Tim Nicholls).
[31] Ibid 1784–5.
[32] Jordan Hirst, 'Queensland Government Stops Expansion of Gender Service', *QNews* (online, 7 January 2025) <https://qnews.com.au/queensland-government-stops-expansion-of-gender-service/>.
[33] Queensland Health, *Queensland Children's Gender Service: External Clinical Service Evaluation* (Report, July 2024).
[34] Ibid 5–11.
[35] Ibid 7.
[36] Ibid 6–7.
[37] Ibid 12–16.

accepted the evaluation and announced the implementation of its recommendations,[38] though under the new government this work was stopped in accordance with Tim Nicholl's directive to Queensland Health in early January 2025.[39]

Just weeks after that directive, in late January 2025, the Queensland Government announced that it would commission an independently-led 'broad review of the evidence for Stage 1 and Stage 2 hormone therapies for children in Queensland' (the 'Queensland Review').[40] The Government's media release did not make reference to the Sax Institute's updated 'Evidence Check' furnished to the NSW Ministry of Health the year prior, but noted that 'Queensland has not yet undertaken its own review of the evidence' relating to puberty suppression and gender-affirming hormonal treatment for minors.[41] In the same announcement, the Queensland Government issued an 'immediate pause' on Queensland Health's intake of new patients under 18 years for puberty suppression and gender-affirming hormonal treatment. Following judicial review, the Queensland Supreme Court set aside that decision to impose the pause on new patients,[42] although the pause has since been reinstated under a new ministerial direction.[43]

B *Scope of the Queensland Review*

The Queensland Review is led by an independent external consultant — Professor Ruth Vine — and a panel of reviewers with varied expertise in psychiatry, endocrinology, ethics, law, and social work.[44] The reviewers have been tasked with 'assessing the current evidence base and ethical considerations for the use

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[38] Shannon Fentiman, 'Independent Evaluation Finds Queensland Paediatric Gender Services Safe and Evidence-Based' (Media Statement, 19 July 2024) <https://statements.qld.gov.au/statements/ 100859>.
[39] Hirst (n 32).
[40] Tim Nicholls, 'Independent Review into Puberty Blockers' (Media Statement, 28 January 2025) <https://statements.qld.gov.au/statements/101903>.
[41] Ibid.
[42] *AB v Chief Executive of Queensland Health* [2025] QSC 277.
[43] Minister for Health and Ambulance Services (Qld), *Treatment of Gender Dysphoria in Children and Adolescents with Hormone* Therapy (QH-MD-002, 28 October 2025).
[44] Queensland Health (n 6). It is worth noting that the Queensland Government has faced criticism for not including on the review panel anyone with lived experience, nor anyone with clinical expertise relating to the provision of gender-affirming care: see Freya Kerwick, *Queensland Trans Health Review Fact Sheet* (Fact Sheet, Trans Justice Project, 30 June 2025) <https://transjustice.org.au/wp-content/uploads/2025/06/Queensland-Trans-Health-Review-Fact-Sheet.pdf> 5.

of puberty suppression (Stage 1) and gender-affirming (Stage 2) hormones for children and adolescents ... in Queensland's public hospital system'.[45]

The Terms of Reference set out that the Queensland Review's scope includes consideration of:

- the quality and outcomes of available medical and clinical evidence for the use of Stage 1 and Stage 2 hormones for children and adolescents with gender dysphoria; …
    - the strength of the evidence base for using … hormones to treat gender dysphoria;
    - the ethical considerations and safeguards applied when prescribing and administering … hormones;
    - the legal and ethical considerations and social impacts on clinical practice and decision-making and informed consent;
    - the psychological, psycho-social and biological management including for Stage 1 and Stage 2 hormones, and whether these are considered to be reversible or irreversible; and
    - the short, medium and longer-term effects of Stage 1 and Stage 2 hormones [for] children and adolescents …
- models of governance to appropriately monitor access and oversight if the use of Stage 1 and Stage 2 hormones are endorsed for children and adolescents with gender dysphoria; and
- mechanisms for ongoing clinical audit, long term follow-up, data reporting and research if the use of Stage 1 and Stage 2 hormones are endorsed for children and adolescents with gender dysphoria.[46]

[45] Queensland Health, 'Terms of Reference: Independent Review of the Evidence Base and Advice Regarding Policy Options for the use of Puberty Suppression (Stage 1) and Gender Affirming (Stage 2) Hormones for Children and Adolescents with Gender Dysphoria in Queensland's Public Hospital System' (Terms of Reference, 2025) <https://www.health.qld.gov.au/__data/assets/pdf_file/ 0033/1433697/Terms-of-Reference.pdf> 1 ('Queensland Review Terms of Reference').

[46] Ibid 1–2.

The Queensland Review has been directed to consider existing literature, as well as national and international reviews, including the Cass Review, the Sax Institute 'Evidence Check', and an evidence brief published by the New Zealand Ministry of Health in 2024 on the 'Impact of Puberty Blockers in Gender-Dysphoric Adolescents'.[47] It was also directed to conduct interviews with a sample of stakeholders and to invite written submissions.[48] The Terms of Reference expressly set out that the Queensland Review is 'not designed or intended to result in recommendations regarding the use of Stage 1 or Stage 2 hormones for children and adolescents with gender dysphoria'.[49] Rather, it will provide written advice that 'may inform' government policy and implementation decisions.[50] The final report is due to the Director-General of Queensland Health by 30 November 2025.[51]

IV NATIONAL REVIEW

On 31 January 2025 — just three days after the Queensland Review was announced — the Australian Government requested the NHMRC to develop new national clinical practice guidelines for the care of trans and gender diverse children and adolescents with gender dysphoria.[52] Amongst its other functions, the NHMRC develops and approves guidelines that address a wide range of topics in health and medicine, including specific areas of clinical practice. However, this represents the first time that the NHMRC has undertaken guideline development in this area. The *Australian Standards of Care and Treatment Guidelines for Trans and Gender Diverse Children and Adolescents* (ie, those guidelines which have come to inform the provision of care in all Australian paediatric gender services) were developed by clinicians and have not been approved by the NHMRC.[53]

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[47] New Zealand Ministry of Health, *Impact of Puberty Blockers in Gender-Dysphoric Adolescents* (Evidence Brief Report, November 2024).

[48] The submission period closed on 29 July 2025. The questions posed by the Queensland Review (accompanied by the UWA Centre for Health Law and Policy's responses to those questions) can be seen in Aidan Ricciardo et al, Submission to Queensland Health, Independent Review of 'Stage 1' and 'Stage 2' Hormone Therapies in Queensland's Public Paediatrics Gender Services (21 July 2025) <https://api.research-repository.uwa.edu.au/ws/portalfiles/portal/532593650/CHLP_submission_to_Queensland_Health_s_independent_review_of_gender_affirmation_therapies_for_young_people.pdf>.

[49] Queensland Review Terms of Reference (n 45) 2.

[50] Ibid 2–3.

[51] Ibid 4.

[52] Butler (n 8).

[53] NHMRC, *National Clinical Practice Guidelines for the Care of Trans and Gender Diverse People Under 18 with Gender Dysphoria* (2025) <https://www.nhmrc.gov.au/health-advice/guidelines-care-trans-and-gender-diverse-people>, discussing Telfer et al (n 5).

The new guidelines are intended to provide a clear and nationally consistent framework, supported by rigorous evidence review and consultation. The guidelines will be developed in accordance with the NHMRC's Standards for Guidelines,[54] using the GRADE approach ('an internationally recognised approach to rate the certainty of evidence and the strength of recommendations').[55] These frameworks require systematic appraisal of the available evidence, transparent and documented decision-making, and structured management of conflicts of interest.[56] The NHMRC process also mandates the establishment of a multidisciplinary guideline development committee, with members appointed on the basis of their varied clinical and professional expertise, alongside representatives with lived experience and guideline end-users.[57]

The published timeline spans over more than three years from the date the process was announced. Evidence reviews will take place from September 2025 to September 2026, with interim recommendations on puberty blockers to be developed between February and August 2026. Further development of recommendations will continue to September 2027, with public consultation planned for September to November 2027. The guidelines are scheduled for release in March 2028.[58]

V COMPARATIVE ASSESSMENT OF THE TWO REVIEW PROCESSES

This Part compares the Queensland Review and the NHMRC process, focusing on their framing, institutional authority, and implications for policy coherence. This comparative assessment highlights how the two processes differ in scope, perceived legitimacy, and capacity to provide effective guidance on gender-affirming care for minors. The analysis below demonstrates that the NHMRC process, by virtue of its scope and institutional authority, is more likely to resolve existing tensions, whereas the Queensland Review may further compound them.

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[54] 'Standards for Guidelines', *NHMRC* (Web Page, 2016) <https://www.nhmrc.gov.au/guidelinesforguidelines/standards>.
[55] 'Guidelines', *NHMRC* (Web Page) <https://www.nhmrc.gov.au/guidelines>.
[56] Ibid.
[57] *National Health and Medical Research Council Act 1992* (Cth) s 39.
[58] NHMRC, *National Clinical Practice Guidelines for the Care of Trans and Gender Diverse People Under 18 with Gender Dysphoria,* 'Guideline Development' (Web Page, 2025) <https://www.nhmrc.gov.au/health-advice/guidelines-care-trans-and-gender-diverse-people/guideline-development>.

A *Framing and Objectives*

The two reviews are framed differently and serve different policy functions. The Queensland Review is an evidence review focused on one state system, expressly not designed to produce recommendations on the use of gender-affirming treatment for minors. The NHMRC process is a guideline development exercise directed to producing national clinical practice recommendations that will standardise care for minors across Australia. On purpose alone, the NHMRC process is better positioned to answer the questions that have driven much of the uncertainty and public debate — what clinicians should do, and on what evidentiary basis — in a way that is nationally coherent.

The Queensland Review sets out broad questions about evidence quality, ethics, safeguards, informed consent and governance, and will furnish information to government. That may be useful for state policy and service planning, but without the mandate to make clinical recommendations it is unlikely to resolve the questions that clinicians, health services, and consumers most need answered.

B *Authority and Perceived Legitimacy*

The NHMRC is a statutory authority often tasked with guideline development and approval as one of its core functions, operating within a well-established framework for evidence appraisal, conflict of interest management and robust public consultation.[59] That institutional setting carries procedural legitimacy that has real potential to create much-needed clinical and legal certainty in this context. The Queensland Review body's independence and process may be sound, but as a jurisdiction-specific ad hoc review body it lacks the same system-level authority to settle standards of care. In this sense, the NHMRC review is positioned to provide the most authoritative and enduring basis for clinical decision-making and policy development.

The relative legitimacy of the Queensland Review may also be undermined by the political circumstances surrounding its announcement. At the threshold, the necessity of the exercise is doubtful, and the sequence of events leading to its announcement raise questions about the Government's motivation for commissioning a review. As explained in Part III, Queensland Health had only recently received an external clinical evaluation which concluded that care was safe, evidence-based and consistent with current guidelines, and which set out recommendations to improve capacity and access. In early January 2025, the

[59] NHMRC (n 54).

Government announced that it had paused delivery of those recommendations. Then, in late January 2025, it announced the Queensland Review and concurrent pause on the intake of new patients. In this instance, the policy shift (ie, pausing the delivery of recommendations and the intake of new patients) *preceded* the evidence checking exercise (ie, the Queensland Review). This sequence suggests that the Queensland Government may be treating the Queensland Review as a proxy for a pre-determined position rather than a process to genuinely resolve existing uncertainty. This suggestion is strengthened when considering that the Queensland Review's endpoint is only advisory in nature — a written report that 'may inform' policy and implementation decisions,[60] with the Terms of Reference noting that it is 'not designed or intended to result in recommendations' about the use of hormonal treatment.[61]

C *Consistency and Certainty*

Both the Commonwealth and state governments play a significant role in shaping health policy.[62] In the provision of gender-affirming healthcare for minors, states are typically responsible for service delivery and are closest to operational issues, but the legal, clinical and ethical questions that arise transcend jurisdictional boundaries. Indeed, it is acknowledged that many areas of health policy require national coherence, which can be achieved through mechanisms such as NHMRC-led guideline development, national frameworks, and intergovernmental agreements that set shared standards across jurisdictions.[63] In such contexts, clarity and consistency are essential to ensure equitable access, minimise jurisdictional variability, and support clinical confidence. Gender-affirming healthcare for minors exemplifies this need and represents a classic case for national stewardship.

The guidelines to be developed through the NHMRC process have real potential to promote consistent practice and to be persuasive in resolving any future clinical or legal uncertainties. This national approach is also well-aligned with the nature of the policy issue; clinical questions about gender-affirming care for minors are not unique to any single Australian state, and their resolution requires shared standards rather than jurisdictional patchwork. Citing this reason, the

[60] Queensland Review Terms of Reference (n 45) 2.
[61] Ibid.
[62] Karen Wheelwright, 'Commonwealth and State Powers in Health: A Constitutional Diagnosis' (1995) 21(1) *Monash University Law Review* 53, 57–71.
[63] Ibid 53–7.

Commonwealth Health Minister noted the following in a press conference after announcing the NHMRC review:

> I've indicated to [the Queensland Health Minister] that I don't think it would be appropriate for Queensland to continue with their stated intention to undertake an evidence review in this area of care. These issues should be nationally consistent, and in my view, should be driven by the preeminent authority, which is the NHMRC.[64]

Despite this communication, the Queensland Government opted to proceed with its review. The Queensland Review is, therefore, a narrow single-jurisdiction exercise that operates in parallel to the national NHMRC process. If the Queensland Government relies on the Queensland Review to develop policy that diverges from future national guidance, it would undermine the objective of a coherent national framework. Conflicting state and national positions would not only entrench inconsistency but also expose clinicians and patients to heightened legal and clinical uncertainty.

Given the nature of the issues and the risks of fragmented state policy, the NHMRC process is best placed to provide the coherent framework that this area of care demands. Any government action taken on the basis of the Queensland Review could represent a departure from the opportunity to achieve national consistency.

VI Conclusion

The two concurrent review processes — the Queensland Review and the NHMRC process — reflect divergent approaches to addressing uncertainty surrounding minors' access to gender-affirming care in Australia. While the Queensland Review may generate useful jurisdiction-specific insights, its advisory nature, political framing, and lack of a mandate to make clinical recommendations limit its capacity to provide the kind of authoritative guidance required to stabilise practice. In contrast, the NHMRC process is well-placed to deliver national, evidence-based guidelines.

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[64] Mark Butler, 'Minister for Health and Aged Care: Press Conference on Health Care for Trans and Gender Diverse Children and Adolescents, and Botox' (Transcript, 31 January 2025) <https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/minister-for-health-and-aged-care-second-press-conference-31-january-2025>.

Minors' access to gender-affirming healthcare involves a range of complex clinical, ethical, and legal considerations. Fragmented approaches risk creating further uncertainty for clinicians in an already fraught environment, and access to appropriate treatment should not depend on jurisdictional happenstance. National guidelines offer a pathway to address the existing challenges by providing a clear and consistent foundation for clinical practice and access to care.

THE PRINCIPLE OF NECESSITY IN CONTEMPORARY AUSTRALIAN HEALTH LAW: A VALID VEHICLE FOR HEALTH CARE DECISION-MAKING, OR A DEFUNCT DOCTRINE?

RICHARD MADDEVER*

Since Re F (Mental Patient: Sterilisation) [1990] 2 AC 1, the 'doctrine of necessity' has been considered a legal basis for doctors to provide treatment to patients who lack capacity to make decisions for themselves, at least in the United Kingdom. While the language of 'necessity' is still used in Australian hospitals, the doctrine has received only scarce judicial and academic attention domestically, leaving doubt about its standing recognition under Australian law. In this doctrinal analysis, I consider the medical treatment legislation relevant to each state and territory as well as the key cases, and seek to answer these three questions: (1) Does the doctrine of necessity still exist within Australian civil law? (2) If it does, is it a sound basis for health care professionals to make treatment decisions for patients who cannot consent? And, (3) does it even matter?

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I INTRODUCTION

It has long been entrenched in the law that no medical or surgical treatment may be provided to a competent patient without their informed consent, lest the intervention amount to assault.[1] However, there will inevitably be times when a patient is unable to make decisions for themselves. In these situations where a patient has reduced decision-making ability,[2] the courts have held that it is appropriate for a health professional to act in the patient's best interests, without consent, as a matter of 'necessity'. This doctrine of necessity evolved in the United Kingdom ('UK') courts, with the House of Lords crystallising its position in *Re F (Mental Patient: Sterilisation)* ('*Re F*') that 'it will not only be lawful for doctors, on the ground of necessity, to operate on or give other medical treatment to adult patients disabled from giving their consent; it will also be their common law duty to do so'.[3]

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[1] *Secretary, Department of Health and Community Services v JWB and SMB* (1992) 175 CLR 218, 310 ('*Marion's Case*'); *Rogers v Whitaker* (1992) 175 CLR 479; *F v R* (1983) 33 SASR 189. See generally *Schloendorff v Society of New York Hospital* 211 NY 125 (NY, 1914); *Malette v Shulman* (1990) 67 DLR (4th) 321 (Ontario Court of Appeal).

[2] Historically the law has referred to a patient's 'capacity'. However, the emerging trend in health care and disability services favours the term 'decision-making ability' with this strengths-based language being more inclusive and patient-centric. It is anticipated that this is the language which will be used in the new WA *Guardianship Act* following the review that is currently underway. See Law Reform Commission of Western Australia, *Project 114 Guardianship and Administration Act 1990 (WA)* (Discussion Paper Vol 1, December 2024).

[3] *Re F (Mental Patient: Sterilisation)* [1990] 2 AC 1, 55–6 (Lord Brandon) ('*Re F*').

However, 'necessity' is not an invention of health law. Rather, it originated first as a defence to past criminal conduct. Later, the same rationale was applied to tort cases in civil courts, with the defendant party arguing that their past wrongful conduct should be excused based on this 'doctrine' or 'principle' of necessity. In Australian and UK law, these principles were well aligned. *Re F* was the first time that necessity had been considered applicable to future conduct, marking a significant deviation from the prior case law. The civil law doctrine of necessity has since been considered only a few times by Australian courts, leaving it 'unclear how far the extended principle of necessity articulated by Lord Goff of Chieveley can be relied upon in Australia'.[4]

In the leading High Court of Australia decision, *Secretary, Department of Health and Community Services v JWB and SMB* ('*Marion's Case*'), McHugh J remarked that that 'the approach of their Lordships [in *Re F*] is not consistent with the common law of Australia'.[5] These remarks have been cited by the Guardianship and Administration Board of Western Australia ('WA'), which commented further that it would not be appropriate to use the doctrine of necessity as justification for imposing 'a restraint as part of a regime of behaviour management, and which falls short of medical management, without the consent of a guardian'.[6]

Additionally, every Australian state and territory has its own legislation dealing with urgent treatment decisions (these include the Mental Health Acts,[7] and the Guardianship and other Acts which provide for urgent treatment without consent, which I will collectively refer to as the 'Medical Treatment Acts'[8]) as well as a legislated criminal defence of emergency in most jurisdictions.[9] In circumstances where legislation has been passed which covers the same ground as the common law, the principle of parliamentary sovereignty ordinarily

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[4] Nick O'Neill and Carmelle Pesiah, 'Substitute Consent to Medical and Dental Treatment' in Nick O'Neill and Carmelle Pesiah (eds), *Capacity and the Law* (Sydney University Press, 2011) [12.2.1].
[5] *Marion's Case* (n 1) 310.
[6] *Re BCB; Application for Guardianship Order* (2002) SR (WA) 338, [33] ('*Re BCB*'), cited in *Re BTO* (Full Board of the Guardianship and Administration Board of WA, Barker J, Members McCutcheon and Child, 14 October 2004) ('*Re BTO*').
[7] *Mental Health Act 2014* (WA); *Mental Health Act 2015* (ACT); *Mental Health Act 2016* (Qld); *Mental Health and Wellbeing Act 2022* (Vic); *Mental Health and Related Services Act 1998* (NT); *Mental Health Act 2009* (SA); *Mental Health Act 2013* (Tas).
[8] *Guardianship Act 1987* (NSW); *Health Care Decision Making Act 2023* (NT); *Guardianship and Administration Act 2000* (Qld); *Consent to Medical Treatment and Palliative Care Act 1995* (SA); *Guardianship and Administration Act 1995* (Tas); *Medical Treatment Planning and Decisions Act 2016* (Vic).
[9] *Criminal Code Act 1995* (Cth) s 10.3; *Criminal Code 2002* (ACT) s 41; *Criminal Code 1899* (Qld) s 25; *Criminal Code Act 1983* (NT) s 33; *Criminal Law Consolidation Act 1935* (SA) s 15E; *Criminal Code Act Compilation Act 1913* (WA) s 25.

requires that the statute prevails. Yet, doctors in Australian hospitals still to this day talk about the 'doctrine of necessity' when contemplating whether they can provide treatment to a patient with reduced decision-making ability, rather than using the urgent treatment language from the legislation. Surveys have highlighted that junior doctors' knowledge of legal issues, particularly regarding advanced care directives and substitute decision-making for people without decision-making capacity, is limited, and there is a need for further education.[10] However, it would only be worthwhile educating doctors on this nuance of law if the difference actually mattered.

Therefore, this paper sets out to answer the following three questions:

(1) Does the doctrine of necessity still exist within the Australian civil law?

(2) If it does, is it a sound basis for health care professionals to make treatment decisions for patients who cannot consent?

(3) Does it matter?

In answering these questions, it is appropriate to first look back through the evolution of the doctrine of necessity, highlighting the areas where the case law leaves uncertainty, and then consider whether there is any work which the common law doctrine may yet be able to do which is not covered by the statutes.

II ORIGINS OF THE DOCTRINE OF NECESSITY

A *Necessity as a Defence to Crime*

'Necessity' is a common law defence originating in the British criminal law, later being imported to the civil law where it has primarily been applied to cases in tort. *Stephen's Digest of the Criminal Law* ('*Stephen's Digest*')[11] is often considered the starting point for necessity:

> An act which would otherwise be a crime may in some cases be excused if the person accused can show that it was done only in order to avoid consequences which could not otherwise be avoided, and which, if they had followed, would have inflicted upon him or upon others whom he was bound to protect inevitable and irreparable evil, that no more was done than was reasonably necessary for that

[10] See, eg, Jamie Bryant et al, 'Junior Medical Officers' Knowledge of Advance Care Directives and Substitute Decision Making for People Without Decision Making Capacity: A Cross Sectional Survey' (2022) 23 *BMC Medical Ethics* 74.

[11] Sir James Fitzjames Stephen, *A Digest of the Criminal Law (Crimes and Punishments)* (MacMillan, 4th ed, 1887 ('*Stephen's Digest*').

> purpose, and that the evil inflicted by it was not disproportionate to the evil avoided. The extent of this principle is unascertained.[12]

The two cases which established the defence of necessity in Australian law are *R v Davidson*[13] and *R v Loughnan*.[14]

In *R v Davidson*, Dr Davidson was charged with 'unlawfully' performing four abortion procedures and contemplating a fifth. Justice Menhennitt directed the jury to consider the defence of necessity, based on the definition from *Stephen's Digest*, and the jury ultimately acquitted Dr Davidson on all five charges, finding that the crime of abortion was necessary to avoid the imminent perils of mental harm or death befalling each of those five mothers.

The case of *R v Loughnan* was not a medical case, but further refined the defence of necessity. The facts were that Mr Loughnan escaped from Pentridge Prison in Victoria, was subsequently arrested by police, and then charged with offences relating to his escape, which he appealed on the basis that his escape was a matter of necessity. The majority judgment by Young CJ and King J explored the defence of necessity from its origins to date, including both Sir James Stephen's definition and its application in *R v Davidson*.[15] The majority summarised Stephen's definition as a three-part test:[16]

> (1) The criminal act must have been done in order to avoid certain consequences which would have inflicted irreparable evil upon the accused or upon others whom he was bound to protect;
>
> (2) The accused must honestly believe on reasonable grounds that he was placed in a situation of imminent peril;
>
> (3) The acts done to avoid the imminent peril must not be out of proportion to the peril to be avoided.

This became the basis of the defence of necessity in the Australian criminal law and remains so to date. However, the decisions by the UK courts in *Re F* and *Re T (Adult: Refusal of Medical Treatment)* ('*Re T*')[17] took a different approach, leading to the evolution of the doctrine into a tool for forward decision-making, culminating in the decision of *Re A (Children) (Conjoined Twins: Surgical*

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[12] *R v Davidson* [1969] VR 667, 669–70 (Menhennitt J) ('*R v Davidson*'), citing *Stephen's Digest* (n 11) ch 3 art 32.
[13] Ibid.
[14] *R v Loughnan* [1981] VR 443 ('*R v Loughnan*').
[15] *R v Davidson* (n 12).
[16] *R v Loughnan* (n 14) 448 (Young CJ, King J).
[17] *Re T (Adult: Refusal of Treatment)* [1992] EWCA Civ 18 ('*Re T*'); *Re F* (n 3).

Separation) ('*Re A*').[18] While arising in an extraordinary set of circumstances, *Re A* saw the Court of Appeal affirm the position in *Re F* regarding the doctrine of necessity as authority.

B *Evolution from Criminal Law Defence to Civil Law Doctrine*

1 *Re F*

Ms F was a 36-year-old woman who lived with considerable cognitive impairment such that she needed to reside full-time in a care facility, where she had found companionship with another, male, resident. In the interests of supporting Ms F to live the fullest life possible, her mother and her care team did not want to prevent her from forming close personal relationships. However, they anticipated the possibility that their relationship might progress to a sexual one. They were concerned that Ms F might not have the capacity to understand the changes that might occur to her should she fall pregnant, and certainly would not have the ability to care for a baby. Further, she would not be able to reliably use contraception and, in any event, all contraception has a risk of failure. Therefore, Ms F's mother sought to explore the possibility of medical sterilisation.[19] Her treating medical practitioners agreed that sterilisation was in Ms F's best interests, however as Ms F was also unable to weigh up the risks and benefits of the surgery, she lacked the capacity to make decisions about her care. As the health service was not certain of the legal basis on which the procedure may be performed, it applied to the court for orders authorising the invasive treatment.

In considering the origins of the principle of necessity, Lord Goff described a range of circumstances where the defence may apply, noting that although in the past the principle had only been relied upon in circumstances of emergency, 'emergency is however not the criterion or even a pre-requisite; it is simply a frequent origin of the necessity which impels intervention'.[20] Therefore, the 'elderly person who suffers a stroke which renders him incapable of speech or movement'[21] requires health care intervention as a matter of necessity just as much as the person pulled from the path of an oncoming vehicle.[22] The basis for this principle is that the law expects that doctors and other health care workers will use 'their best endeavours' to provide treatment to any person who is unable to make decisions for themselves, for 'otherwise they would be deprived of

[18] *Re A (Children) (conjoined twins: surgical separation)* [2001] 2 WLR 480 (EWCA) ('*Re A*').
[19] *Re F* (n 3).
[20] Ibid 24.
[21] Ibid 76 (Lord Goff).
[22] Ibid 74 (Lord Goff).

medical care which they need and to which they are entitled'.[23] Subsequently, however, in many cases, 'it will not only be lawful for doctors, on the ground of necessity, to operate on or give other medical treatment to adults disabled from giving their consent; it will also be their common law duty to do so'.[24]

In articulating the doctrine of necessity insofar as it provided a justification for the health service to take a future action to sterilise Ms F, Lord Goff held:

> [T]o fall within the principle, not only (1) must there be a necessity to act when it is not practicable to communicate with the assisted person, but also (2) the action taken must be such as a reasonable person would in all the circumstances take, acting in the best interests of the assisted person.[25]

In considering the facts of the case, the Court in *Re F* held that the doctors and other health care staff could provide Ms F with routine (and emergency) care on the basis of necessity,[26] however the doctrine of necessity did not extend to sterilisation procedures. Therefore, it was necessary for the court to make orders authorising such a procedure (and multiple judges discussed the court's jurisdiction to make such orders).

Traditionally, the principle underpinning the defence of necessity was that, in the heat of the moment where there is little time to think and an imperative to act urgently to avoid some peril, the wrongful collateral harm caused by such action may be excusable.[27] However, the way the Court used the doctrine in *Re F* as a vehicle for rendering lawful a future event marked a significant evolution of the doctrine, and potentially opened the door for it to be used in a variety of health care situations. Further, this determination by the House of Lords established that it was the weighing up of the competing harms, not the urgency, that enlivened the doctrine of necessity as a vehicle for decision-making under common law. On this basis, their Lordships were willing to conclude that this justification of necessity should hold as authority for routine as well as emergency treatment.[28]

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[23] Ibid 4 (Lord Brandon).
[24] Ibid.
[25] Ibid 25 (Lord Goff).
[26] Ibid 25-6 (Lord Goff).
[27] See, eg, *Stephen's Digest* (n 12).
[28] Ibid 26.

2 *Re T*

Miss T was a 20-year-old pregnant woman and Jehovah's witness who was brought into hospital following a car accident.[29] At the time Miss T arrived at hospital, her medical condition was such that she was conscious and alert, and did not require urgent medical treatment. At this time, she told nurses and doctors that she did not want any blood transfusions due to her religious beliefs. Subsequently, it was discovered that her baby was very unwell and an emergency caesarean section was performed, however the baby was stillborn. Following this procedure, Miss T's condition deteriorated significantly and she was admitted to the intensive care unit ('ICU'); she did not have capacity to make decisions about her care at this time. While Miss T was in the ICU, her father and her partner (the father of her baby) together applied to the court for orders authorising a blood transfusion, which were granted. Miss T received the transfusion and her condition improved; after she had recovered, she appealed the court's order on the basis that it was against her known wishes.

The Court of Appeal on considering the appeal cited the decision in *Re F*,[30] in particular the holding that there must be 'a necessity to act when it is not practicable to communicate with the assisted person'.[31] In developing this point, Staughton LJ described three possible scenarios in which a person's previous consent or refusal may not be valid, and therefore give rise to the need to reconsider the decision: first, because their consent or refusal was given as a result of 'undue influence';[32] second, because the consent was not made with reference to the 'particular circumstances in which it turns out to be relevant';[33] or third, because the person's 'understanding and reasoning powers may be seriously reduced by drugs or other circumstances, although she is not actually unconscious'.[34]

The Court considered that the facts in *Re T* fell within the second group of scenarios. At the time that Miss T communicated her refusal of any blood transfusions, it was clear that she had an interest in preserving her life, and it was reasonable to consider there might be a number of alternative treatment options which the medical team could use. Miss T had not at that time been asked to consider that her refusal of blood products could result in her death. However, at

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[29] *Re T* (n 17).
[30] Ibid [54] (Staughton LJ) citing *Re F* (n 3) 75 (Lord Goff).
[31] Ibid.
[32] Ibid [56] (Staughton LJ).
[33] Ibid [58] (Staughton LJ).
[34] Ibid [59] (Staughton LJ).

the time that the declaration was sought by Miss T's family, the circumstances were very different and it was clear on the medical evidence that Miss T may not survive without a transfusion. As it was never put to Miss T that her refusal of treatment would hasten her death, it was reasonable for the court to make the orders (and doctors to rely on them) authorising life-sustaining treatment as a matter of necessity.

It appears that this case was more focused on the issue of informed consent (and informed refusal of treatment) than the doctrine of necessity as a vehicle for medical decision-making. Having established that the circumstances had changed sufficiently since the patient's previous refusal of consent for a blood transfusion was made that a new decision was now required, it was reasonable to apply the doctrine of necessity as stated in *Re F* and provide treatment in the patient's best interests.[35]

The Court noted that it will not always be an option for the hospital or family to find a judge and for a court to make a determination before the window for taking action has passed, 'so the medical profession, in the future as in the past, must bear the responsibility unless it is possible to obtain a decision from the courts'.[36] This statement implies that wherever there is an imperative to make decisions about a patient who cannot consent, the onus falls to the doctor (or other health care practitioner in a position to take action for the benefit of the patient) to make a decision, ostensibly by applying the doctrine of necessity as stated in *Re F*.

3 *Re A*

The case of *Re A*[37] involved the incredibly rare event of conjoined twin babies. Doctors had advised that the two girls, who were joined at the hip, were unlikely to survive if they remained conjoined. This is because the smaller twin's heart was barely functional, and her life was being sustained only by the shared circulation with the larger twin. However, the larger twin's heart was not strong enough to sustain them both indefinitely; her heart was under constant strain and at some point it would fail, leaving them both to perish. Surgeons proposed that it might be possible to separate the twins, saving the larger twin and enabling her the chance at life; however it would almost certainly lead to the death of the smaller twin, whose heart would not be strong enough to sustain her.

[35] Ibid [62] (Staughton LJ).
[36] Ibid [61] (Staughton LJ).
[37] *Re A* (n 18).

Previously the Court had held that the doctrine of necessity did not extend to circumstances where the accused's actions led to the death of another person. Yet, inaction in the present case would lead to the death of two. Lord Justice Brooks relied upon the doctrine of necessity, citing again the principle as stated by Sir James Stephen, and concluding (as did Walker and Ward LJJ, in separate judgments and for different reasons), that the exceptional circumstances and the interests of both children required that the proposed surgical separation procedure be authorised by the court.

The application of the doctrine by this Court, including the weighing-up of competing interests, has been criticised as 'crude' and 'ad-hoc'[38] by commentators and, in any event, the factual scenario is so remarkably rare that the judgment offers very little, if any, utility to future courts in future applications of the doctrine. Therefore, the judgments in *Re T* and *Re F* are largely recognised as being the foundation of the lawful authority for health practitioners to provide treatment to patients with diminished decision-making ability under UK common law, especially in emergencies.

III Subsequent Treatment of Necessity as Authority for Decision-Making by Australian Courts

There are many similarities between Australian and UK law; we share similar values, similar social structures and public authorities, similar legal institutions and the same rule of law. Therefore, it is not uncommon for decisions made in UK courts to influence decisions made in Australian courts. UK case law can be imported into Australian law when an Australian court has made a decision citing the wording or rationale of a previous UK decision as its basis. If cited by a state Supreme Court, the decision is binding in that State; positive treatment by the High Court of Australia will make the principles applicable across Australia.

When it comes to the doctrine of necessity as discussed in *Re F* and *Re T*, Australian courts have been reluctant to accept the UK courts' framing outright. *Marion's Case*,[39] a 1992 decision by the High Court of Australia, presented the opportunity for the High Court to engage with the principles from *Re F*, however it appears to me that the Court strategically evaded that discussion. The WA Guardianship Board subsequently commented that *Marion's Case* was therefore

[38] Meredith Blake, 'Doctors Liability for Homicide under the WA Criminal Code' (2011) 35 *UWA Law Review* 287, 291 with reliance on Ian Kennedy, 'Patients, Doctors and Human Rights' in Blackburn and Taylor (eds), *Human Rights for the 1990s: Legal, Political and Ethical Issues* (Mansell Publishing, 1993) 90–1.

[39] *Marion's Case* (n 1).

evidence that the doctrine of necessity did not exist in Australia as a vehicle for making health care decisions.[40]

However, *Re F* was later discussed favourably by the New South Wales ('NSW') Supreme Court in *Hunter and New England Area Health Service v A by his Tutor T* ('*Hunter and New England Area Health Service v A*'),[41] suggesting that these principles may be relevant at least in NSW. The High Court has also mentioned *Re F* in *Binsaris v Northern Territory* ('*Binsaris*') [42] and *The King v Anna Rowan — a Pseudonym* ('*Anna Rowan*'),[43] but in language which suggests the High Court either does not recognise the doctrine of necessity as framed by the UK courts, or only recognises it in a very limited way. This leaves some uncertainty about the common law basis for necessity within Australian law — an ambiguity that would be best resolved by turning to the legislation. However, for the sake of completeness, I will discuss these cases in more detail below.

A *Marion's Case*

Marion was a 14-year-old girl living in the Northern Territory with significant neurological, mental, cognitive and physical disabilities. Marion's doctors recommended that her ovaries and uterus be removed to stabilise hormonal fluctuations, and eliminate consequential stress and behavioural responses associated with menstruation and any potential future pregnancy. Marion's parents agreed with the medical recommendation and had consented to the procedure. However, the hospital was uncertain whether medical sterilisation could proceed on the basis of the parents' consent alone. Therefore, the parents and hospital applied to the court for orders authorising the procedure.[44]

The majority judgment of the High Court in *Marion's Case* was concerned only with the question of whether sterilisation procedures required the consent of the court. Justice McHugh summarised the decision in *Re F* thus:

> In *re F*, the House of Lords held that sterilisation of an incompetent child was justified if it was necessary or in the public interest and that it would be in the public interest if the procedure was in the best interests of the child. Their Lordships held that it will be in the best interests of the patient if a doctor has formed the opinion that sterilisation should be carried out provided that that opinion

[40] See, eg, *Re BCB* (n 6) 345; *Re BTO* (n 6).
[41] *Hunter and New England Area Health Service v A by his Tutor T* [2009] NSWSC 761 ('*Hunter and New England Area Health Service v A*').
[42] *Binsaris v Northern Territory* (2020) 270 CLR 549 ('*Binsaris*').
[43] *The King v Anna Rowan – a Pseudonym* (2024) 278 CLR 470 ('*Anna Rowan*').
[44] *Marion's Case* (n 2) 218.

> corresponds with a respectable body of medical opinion among those experienced in the field. Their Lordships (Lord Griffith dissenting on this point) held that the involvement of a court was highly desirable as a matter of good practice although it was not necessary as a matter of law.[45]

My interpretation of the cautionary treatment of *Re F* by the High Court in *Marion's Case* is that it was specific to the issue of the 'lawfulness' of sterilisation, and not a decision about the principle of necessity. The Court drew a distinction between 'therapeutic' and 'non-therapeutic' decisions,[46] holding that non-therapeutic decisions such as sterilisation could only be authorised by orders of the court in exercising its *parens patriae* jurisdiction.[47] This is an inherent jurisdiction of the court to make orders protecting the welfare of a child which, as clarified by the High Court in this decision, extended to the circumstances in question. After considering the relevant legislation in the Northern Territory (and other Australian jurisdictions) the High Court concluded that parental consent alone was insufficient to authorise the parents or guardians to sterilise a child. Such a procedure required the authorisation of the Family Court of Australia, to make the procedure lawful.[48]

Importantly, the judgments in *Marion's Case* did not involve any meaningful discussion of the principle of necessity at all. The only time the principle properly arose was in Justice McHugh's separate judgment, when discussing the serious harm that might befall Marion if sterilisation was not performed, and therefore the 'necessity for appropriate "treatment"'.[49] Therefore, nothing in *Marion's Case* reads down or excludes the doctrine of necessity as either a defence, or a tool for decision-making, in the Australian health care context. It appears likely that the lack of discussion of necessity by the Court was strategic, so as to avoid needing to engage with the expanded scope proposed by the House of Lords in *Re F*.

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[45] *Marion's Case* (n 2) 323 (McHugh J).
[46] Ibid 243 (Mason CJ, Dawson, Toohey and Gaudron JJ), summarising Nicholson CJ in *Re Marion* (1990) 14 Fam LR 427, 439–40. See also 250.
[47] *Re Marion* (1990) 14 Fam LR 427 (Full Court), 439–41 (Nicholson CJ, dissenting). The High Court in *Marion's Case* overturned the majority decision of the Full Court, and Nicholson CJ's dissenting judgment was given neutral if not favourable treatment by the High Court.
[48] *Marion's Case* (n 1) 230 (Mason CJ, Dawson, Toohey and Gaudron JJ).
[49] Ibid 321 (McHugh J).

B *Re BCB and Related Guardianship Board of WA Decisions*

The case of *MW*[50] concerned an application for guardianship orders in respect of a 64-year-old woman who had considerable intellectual disability and mental health issues for which she required ongoing care and treatment. The State Administrative Tribunal considered the decision of the Full Board of the Guardianship and Administration Board in *Re BCB*,[51] affirmed in *Re BTO* (unreported):[52]

> In short, the Board there noted that the English House of Lords *in Re F (Mental Patient: Sterilization)* [1990] 2 AC 1, recognised that in certain situations a medical practitioner may act in accordance with a "principle of necessity" and treat a patient without obtaining the consent of that patient. However, some doubt about the recognition of such a principle under Australian law was expressed in some of the judgments in the High Court decision in the case colloquially known as *Marion's case* (1992) 175 CLR 218. As a result, in *Re BCB* the Board thought it unwise to conclude that the general law applicable in Western Australia presently permitted a medical practitioner or any other health professional to provide treatment without a patient's consent. With this approach to the law we respectfully agree.[53]

In the discussion of *Marion's Case* above, I suggested that the *ratio* in that case was not so much concerned with the doctrine of necessity as a vehicle for decision-making so much as it was a question of whether judicial approval was needed before a sterilisation procedure could be performed on a minor. Indeed, the doctrine of necessity was given very little discussion by the High Court in its decision. While it may have been open to the Guardianship and Administration Board of WA to consider that the absence of robust discussion about the principle amounted to cautionary treatment, there have been subsequent Australian cases considering the doctrine that suggest the principle remains very much alive.

C *Hunter and New England Area Health Service v A*

Mr A was an older man who had been brought into a hospital emergency department in NSW in a critically unwell state. He was found to be suffering from septic shock and respiratory failure, as a result of which he was unconscious and unable to make decisions about his treatment. He was admitted to the ICU and given emergency treatment, however his condition continued to worsen and he

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[50] *MW* [2005] WASAT 205 ('*MW*').
[51] *Re BCB* (n 6).
[52] *Re BTO* (n 6).
[53] *MW* (n 50) [43].

developed renal failure. At this stage, Mr A was being kept alive by mechanical ventilation and dialysis. It transpired that, 11 months earlier, Mr A had written a document in which he stated that he would refuse dialysis, and on discovering this fact, the hospital applied to the court for orders that the life sustaining dialysis treatment be withdrawn, in complying with Mr A's last known wishes.[54]

The Court held that the treatment already being provided to Mr A, who on arrival to hospital was borderline unconscious and unable to consent to the treatment, must have been provided on the basis of necessity, applying the principle as stated in *Re F* and cited with approval in *Re T*. Therefore treatment was lawfully, and appropriately, commenced. And, given that the document revealed it was against the patient's wishes to receive dialysis, it was appropriate to withdraw that treatment, as 'the principle of necessity does not apply where, among other things, the proposed action "is contrary to the known wishes of the assisted person, to the extent that he is capable of rationally forming such a wish"'.[55]

The willingness of the NSW Supreme Court to apply *Re F* and find that the early treatment of Mr A was lawful under the doctrine of necessity rather than any statutory authority or other principle is suggestive that the defence remains available to Australian health professionals acting in good faith in the performance of their duties.

Different commentators have considered the above cases and each come to different conclusions as to which is the leading authority in Australia. Rankin argues that *Loughnan* is the leading Australian authority for the doctrine of necessity,[56] as does McSherry.[57] Blake discusses the 'more developed jurisprudence in the UK'.[58] Then, the Australian authorities, too, differ: the WA Guardianship Board (above) was concerned only with *Marion's Case*, while the NSW Supreme Court in *Hunter and New England Area Health Service v A* referred only to *Re F* and *Re T* without mention of the earlier Australian cases. In *Binsaris*[59] and *Anna Rowan*,[60] two recent cases which will be discussed later in this paper,

[54] *Hunter and New England Area Health Service v A* (n 40) [1]–[2] (McDougall J).
[55] Ibid [34] (McDougall J) citing *Re F* (n 4) 76 (Lord Goff).
[56] Mark Rankin, 'Abortion Law in NSW: The Problem with Necessity' (2018) 44(1) *Monash University Law Review* 32, 47–51.
[57] Bernadette McSherry, 'The Doctrine of Necessity and Medical Treatment' (2002) 10 *Journal of Law and Medicine* 10.
[58] Blake (n 38) 293.
[59] See, eg, *Binsaris* (n 42) 566.
[60] See, eg, *Anna Rowan* (n 43) 497.

the Court refers only to *Re F* and Virgo in 'Defences in Tort'.[61] While Virgo discusses necessity at some length, in my view the elements of the doctrine are framed in such a way as to lend themselves most readily to citation as they are stated in *Loughnan* and *Re F*. Regardless of the semantics as to which case is most readily quotable, the above is a summary of the development of the common law doctrine to date.

D *Binsaris v Northern Territory*

Mr Binsaris was a detainee at the Don Dale Youth Detention Centre in the Northern Territory who suffered collateral injury when tear gas was deployed by corrections officers, without lawful authorisation, to quell a riot. The prison officers argued that the deployment of tear gas was a matter of necessity. The High Court considered the historical evolution of the liability of public officers, from an initial standpoint of being personally liable for their own decisions, to the state bearing their liability vicariously, to the evolution of 'a defence of public necessity'[62] so that officers were able 'to make the hard choice of sacrificing the interests of some in order to preserve the greater interests of others'.[63] In the course of this discussion, the Court referred to Virgo and *Re F*, however simply rejected the prison officers' argument without discussing the doctrine in great detail. While *Binsaris* remains in the spotlight for other reasons, its usefulness in the current discussion is limited to the implied acknowledgement by the High Court that the defence of necessity likely still exists under Australian common law.

E *The King v Anna Rowan — a Pseudonym*

In *Anna Rowan*, a woman living with intellectual disability had faced several charges relating to sexual offences in company with another person over the course of a number of years. The accused appealed their conviction on the basis that the trial judge had not put it to the jury to consider the 'defence of duress'.[64] The High Court briefly explored the relationship between the defences of 'duress' and 'duress of circumstances' as subtypes within the defence of 'necessity', but ultimately concluded it was 'not necessary to explore this doctrinal development' as it was not raised by either party in their submissions.[65]

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[61] Graham Virgo, 'Justifying Necessity as a Defence in Tort Law' in Dyson, Goudkamp and Wilmot-Smith (eds), *Defences in Tort* (Bloomsbury Publishing, 2015) 135, 146–7.
[62] *Binsaris* (n 42) 567 (Gageler J).
[63] Ibid.
[64] *Anna Rowan* (n 43) 470.
[65] Ibid 489 (Gageler CJ, Gordon, Jagot and Beech-Jones JJ).

Edelman J, agreeing in a separate judgment, discussed the distinction between claiming necessity as though it were an excuse for wrongful conduct, and relying on the principle of necessity as a justification for causing harm so as to avoid a greater evil.[66] The cases of *R v Rogers*[67] and *R v Loughnan*[68] were cited as examples of how the distinction between excuse and justification are often 'muddled'.[69] This somewhat esoteric distinction was only drawn in the course of the lead-in to the discussion of 'duress of circumstances', which Edelman J engaged in more readily than the majority:

> The common law of Australia has not yet embraced any unification of the excuses of duress and necessity, nor has it yet recognised duress of circumstances as a species of necessity alongside duress by human threat. Duress as a defence has remained confined to pressure arising from human threats. Necessity has been left as a shadowy, uncertain defence often treated as though it were only a justification but sometimes also recognised as an excuse. Ultimately, however, from the perspective of justice generally, Woolf LJ was correct to say that "[w]hether 'duress of circumstances' is called 'duress' or 'necessity' does not matter. What is important is that, whatever it is called, it is subject to the same limitations as to 'do this or else' species of duress."[70] Hence, with a keen eye to justice, when the Victorian Parliament abolished the common law defences of duress and necessity, it created statutory excuses of duress and necessity, with nearly identical elements.[71]

These cases offer little to our current discussion of necessity for the purposes of providing treatment beyond acknowledging that necessity exists within the common law. However, the High Court's comments that statutory defences should be preferred over common law ones raises a question of whether the Court would make similar comments in respect of the civil law doctrine. For our purposes, I believe the take-away message from this case is that, when it comes to necessity, the language of the legislation should be preferred over the common law wherever possible.

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[66] Ibid [79]–[80] (Edelman J).
[67] *R v Rogers* (1996) 86 A Crim R 542 ('*R v Rogers*').
[68] *R v Loughnan* (n 14).
[69] *Anna Rowan* (n 43) 498–9 (Edelman J).
[70] *R v Conway* [1989] QB 290, 297 (citation in original).
[71] *Anna Rowan* (n 43) 501.

IV Australian Legislation on Necessity and Medical Decision-Making for Patients with Reduced Decision-Making Ability

A *Statutory Authority for Substituted Medical Decision-Making*

Each Australian state and territory has its own legislation governing treatment of patients who do not have the ability to make decisions for themselves. For matters relating to patients who are unable to make decisions primarily due to a mental health issue, the Mental Health Acts[72] (eg *Mental Health Act 2014* (WA) s 25) set out criteria for a psychiatrist to make orders that the person undergo treatment either in a hospital, or in the community, without requiring the patient's consent, as long as all those criteria are met. In all other cases where a person needs urgent treatment and does not have the ability to make decisions about their treatment, the Medical Treatment Acts[73] are the relevant legislation.

In WA, the *Guardianship and Administration Act 1990* (WA) provides at s 110ZI that, where a person needs urgent treatment and does not have the ability to make decisions about their treatment, and it is not practicable to contact a substitute decision-maker, then the health professional may provide that urgent treatment without consent. If a person needs treatment other than urgent treatment, then the Act directs the health professional to contact a substitute decision-maker, being the first person on the hierarchy provided in s 110ZD who is an adult and willing to make a decision in respect of the patient's treatment.

There are similar provisions for urgent treatment without consent in the relevant legislation for each jurisdiction, with the exception of the Australian Capital Territory ('ACT'). In the ACT, the relevant Act simply states 'this part [consent to treatment without formal representation] does not affect any common law right of a health professional to provide urgent medical treatment without consent'.[74] Interestingly, the ACT Health *Consent for Healthcare Treatment Guideline* directly refers to the 'principle of necessity' and articulates the criteria for relying upon the principle in similar terms as are used in the legislation in other states and territories.[75]

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[72] See above n 7.
[73] See above n 8.
[74] *Guardianship and Management of Property Act 1991* (ACT) s 32N.
[75] ACT Health, Canberra Health Services, 'Section 4: Healthcare Treatment Without Consent', *Consent for Healthcare Treatment Guideline* (Guideline, 21 May 2024) 12 <https://www.canberrahealthservices.act.gov.au/__data/assets/word_doc/0011/1981388/Consent-for-Healthcare-Treatment-.docx>.

B *Statutory Criminal Defences*

While this paper is primarily concerned with the civil law doctrine of necessity, given the adage 'treatment without consent is assault' it is possible that some health practitioners would also be concerned with criminal liability. Therefore, a brief discussion of the statutory criminal defences is also warranted.

In McSherry's commentary on the case of *Re A*[76] she considered that, had the case taken place in Australia, it could have been dealt with appropriately within the scope of the defence of 'sudden or extraordinary emergency' found within the model Criminal Code.[77] The Australian Model Criminal Code Officers' Committee proposed the statutory defence, an example of which is found in the *Criminal Code Act 1995* (Cth) s 10.3.[78] This defence now appears in the Commonwealth,[79] ACT,[80] QLD,[81] NT,[82] SA[83] and WA[84] Criminal Codes, as well as the *Crimes Act 1958* (Vic).[85] There is no comparable section in the Crimes Acts in NSW or Tasmania. Interestingly, when the Victorian legislature introduced this statutory defence into its legislation in 2014, it also expressly 'abolished' the common law defence of necessity.[86] It is probable that, if a situation arose which was so dire or required such prompt action as to be considered an 'emergency', then any health practitioner providing treatment with due care and skill in the best interests of their patient is likely to be able to rely on these statutory defences, just as McSherry suggests.

Section 259 of the WA Criminal Code separately provides that a person is

> not criminally responsible for administering [or (2), not administering or ceasing to administer], in good faith and with reasonable care and skill, surgical or medical treatment (including palliative care)
>
> (a) to another person for that other person's benefit; or

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[76] *Re A* (n 18).
[77] McSherry (n 57) 14.
[78] Criminal Law Officers Committee of the Standing Committee of Attorneys-General, *General Principles of Criminal Responsibility*, Ch 2 (Dec 1992), 67; *Criminal Code Act 1995* (Cth) s 10.3.
[79] *Criminal Code Act 1995* (Cth) s 10.3.
[80] *Criminal Code 2002* (ACT) s 41.
[81] *Criminal Code 1899* (QLD) s 25.
[82] *Criminal Code Act 1983* (NT) s 33.
[83] *Criminal Law Consolidation Act 1935* (SA) s 15E.
[84] *Criminal Code Act Compilation Act 1913* (WA) s 25.
[85] *Crimes Act 1958* (Vic) s 322R.
[86] *Crimes Act 1958* (Vic) s 322S. These changes were introduced in the Crimes Amendment (Abolition of Defensive Homicide) Bill 2014 (Vic) as part of a suite of amendments which also clarified the defences of self-defence, duress and intoxication in relation to all offences, as part of the government's action in addressing the growing issue of family violence.

> (b) to an unborn child for the preservation of the mother's life, if the administration of the treatment is reasonable, having regard to the patient's state at the time and to all the circumstances of the case.

Blake notes that, until the decision in Rossiter,[87] 'section 259 was construed and interpreted as a defence of medical necessity, a defence which has been traditionally understood as being about circumstances, not the exercise of personal autonomy'.[88] Further, this section does not mention 'consent' as relevant to this section, or the offences that a doctor may wish to rely upon this section as a defence from.[89] It is arguable that consent and capacity may be relevant to the consideration of whether 'the administration of the treatment is reasonable'. The door appears to be left open to the defence of necessity here, as opposed to the 'sudden emergency' defence elsewhere in the Code.[90] However, such ambiguities are not sufficiently robust for any practitioner to want to rely on these provisions when making urgent treatment decisions, when there is a more appropriate avenue under the Medical Treatment Acts.

V Interaction Between Common Law and Legislation

A fundamental principle of Australian law (as indeed in all common law jurisdictions) is that of parliamentary supremacy: that when legislation is inconsistent with the common law, the legislation overrides to the extent of the inconsistency. The doctrine of necessity originated as a defence in both criminal and tort law, and through *Re F* became particularly important for guiding decision-making in health care, at least in the UK. However, the very existence of the Medical Treatment Acts and the statutory criminal defences impliedly overrules the doctrine of necessity insofar as it applies to proceedings in each participating jurisdiction.

A doctor may well find himself asking 'but why would I oblige myself to rely upon the more onerous requirements of the statutes when I could simply rely on the common law' — a question answered by Gleeson CJ in *R v Rogers*:

> The corollary of the notion that the defence of necessity exists to meet cases where the circumstances overwhelmingly impel disobedience to the law is that the law cannot leave people free to choose for

[87] *Brightwater Care Group (Inc) v Rossiter* [2009] WASC 229 ('*Rossiter*').
[88] However, since *Rossiter* (n 87), the section has been seen more as a defence to protect the patient's autonomy. It achieves this by protecting the health professionals who dutifully abide their patient's wishes even when doing so may lead to the patient's death. See Blake (n 38) 308.
[89] Namely wounding, grievous bodily harm, and murder. See Blake (n 38) 300.
[90] *Criminal Code Act Compilation Act 1913* (WA) s 25.

> themselves which laws they will obey, or to construct and apply their own set of values inconsistent with those implicit in the law. Nor can the law encourage juries to exercise a power to dispense with compliance with the law where they consider disobedience to be reasonable, on the ground that the conduct of an accused person serves some value higher than that implicit in the law which is disobeyed.[91]

The doctor cannot choose to prefer his own approach to the situation by applying the doctrine of necessity if doing so would be inconsistent with the values of the legislation. So, in circumstances where the legislature has set out a clear procedure for making treatment decisions in respect of the patient with diminished decision-making ability, it would be contrary to the spirit of the law to choose to do anything else. As every Australian jurisdiction has mental health and medical treatment legislation (acknowledging there is interjurisdictional variation in the wording), the Parliament of each state and territory expects health professionals to abide by its statutory rules.

However, that conclusion must be caveated on the understanding that, as the doctrine of necessity (insofar as it exists in Australia) operates defensively, the circumstances enlivening its consideration must necessarily arise from a breach of the law.

Although I have been unable to conceive of any examples where a health professional may need to act urgently, but in circumstances which fall outside of the scope of the legislation, it must theoretically be possible for such a circumstance to arise, and therefore it is probable that the defence of necessity still exists to be relied upon in such unexpected situations.

VI Remainder of Necessity at Common Law

Even though the High Court made its decision in *Anna Rowan* on another basis, the Court's discussion of necessity in that case leaves little doubt as to the continued existence of a common law defence of necessity in the criminal law, notwithstanding the establishment of the alternative statutory defences. The case of *Binsaris* clearly leaves the door open to necessity potentially being relied upon in future civil matters, even if it was not held to be applicable to the unique facts of that case. Given that, based on these cases, it is likely that necessity still exists in the common law, the challenge becomes finding situations which could fall

[91] *R v Rogers* (n 67) 546 (Gleeson CJ; Clarke JA and Ireland J agreeing).

outside the scope of the statutory provisions so as to leave a gap which would give rise to consideration of the common law doctrine.

In my view, the following circumstances may warrant consideration of necessity:

(i) the patient is unable to provide consent for medical treatment (the *Re F* problem);

(ii) the patient's condition has deteriorated, and their most recent consent (or refusal) is inconsistent with the practitioner or family's belief about the need for treatment (the *Re T* problem);

(iii) the patient is unable to make decisions due to an acute-on-chronic mix of mental health and physical health issues, leaving uncertainty as to which statutory scheme should apply;

(iv) the patient is acting in a way that jeopardises the health and safety of the treating practitioner, other patients, staff and visitors, and immediate treatment is required to make the situation safe.

A *The Re F Problem*

In this first situation, treatment has been recommended for the patient, however the patient does not have capacity to make decisions about their own care, as was originally the case in *Re F*. The statutory schemes in the Medical Treatment Acts effectively provide a system for health care practitioners to determine whether the treatment is so urgent that it is not practicable to seek a substitute decision-maker, and therefore may provide treatment in the patient's best interests without consent, or whether the treatment can wait until attempts can be made to seek input from a substitute decision-maker in accordance with the legislation.[92] Where the medical treatment is in respect of patients who lack decision-making ability due primarily to a mental illness, this is provided for in the Mental Health Acts. Either way, it is most appropriate that health care practitioners apply the statutory schemes rather than the common law doctrine in these circumstances.

B *The Re T Problem*

In this second situation, the patient has expressed a wish (for example, to decline blood transfusions), but the clinical situation has changed, and the people who would be their substitute decision-makers now have different views on the situation. In these circumstances, the court seeks to protect the patient's

[92] See, eg, *Guardianship and Administration Act 1990* (WA) ss 110ZD, 110ZI.

autonomy; a patient has the right to refuse treatment even if in doing so they may knowingly hasten their own death.[93] However, in *Re T* the circumstances were such that the clinical situation had changed so drastically that the patient's previous refusal of consent could no longer apply to the new situation, and they had never had the opportunity to reconsider their refusal with the new information that doing so could lead to their death. If such a situation were to be repeated in the future, it would be appropriate for the senior clinician (usually a consultant medical practitioner) to determine whether the situation had changed so significantly that the new situation was outside of the scope of the patient's contemplation at the time they previously communicated their decision. If the situation is not substantially different, and the present circumstances were contemplated by the patient at the time they communicated their decision, the clinician should respect the patient's decision. If possible (for example, during an elective surgery), the decision should wait until the patient is able to make the decision for themselves. However, if the situation is so substantially different that the patient could not have contemplated the new circumstances at the time of their original decision, and so urgent that it cannot wait, it may be reasonable for the clinician to make an urgent treatment decision under the Medical Treatment Acts, as above. The legislation would likely still cover these situations, so it would still not be appropriate to rely on the common law doctrine of necessity here.

C *An Acute-on-Chronic Mix of Mental and Physical Health Issues*

The circumstances of a patient presenting with a 'mixed picture' of underlying physical or mental health issues together with new, acute issues at the fore will always be challenging. A patient presenting with purely psychiatric issues would warrant contemplation of the Mental Health Acts, while the Medical Treatment Acts would be more relevant for a patient presenting with physical health issues or longstanding disability. It is important to note that the Medical Treatment Acts will be the 'default' legislation when considering a patient with reduced decision-making ability. The Mental Health Acts will only be enlivened when the patient has 'a mental illness for which the person is in need of treatment' and 'because of that mental illness, there is (i) a significant risk to the health and safety of the person, or the safety of another person, (ii) a significant risk of serious harm to the person, or to another person; or (iii) a significant risk of the person suffering serious physical or mental deterioration'.[94] If these criteria (along with the other criteria for making an order under a Mental Health Act) are met, then

[93] *Re T* (n 17).
[94] See, eg, *Mental Health Act 2014* (WA) s 25.

the practitioner should consider treating the patient under the Mental Health Act for this episode of care. However, if these criteria are not clearly met, but there is still concern that the patient's ability to make decisions about their health care is impaired, then the Medical Treatment Acts should still be considered in the alternative. Either way, it is once again most appropriate for practitioners to act in accordance with the relevant legislation, rather than by attempting to rely upon the common law doctrine of necessity.

D *A Patient Jeopardising the Health and Safety of Others*

One situation was discussed by Kelly, Cockburn and Madden,[95] when responding to a query by senior emergency department doctors about their obligations towards belligerent or dismissive patients who *may* have head injuries. Their hypothetical scenario involved a 29-year-old man who fell from a bicycle, wearing a helmet, with no *obvious* signs of head injury, who was aggressive towards staff. Their conclusion was that, as a starting point, the adult patient must be assumed to have capacity to make decisions about their care. Therefore, if the patient is not showing any signs of reduced decision-making ability which could be due to a head injury, intoxication, or other cause, then they are entitled to refuse further assessment or treatment and leave the hospital of their own volition. Indeed, it is the policy of most (if not all) Australian public health services that if a patient is acting so aggressively that they cannot be de-escalated or treated safely, then it is reasonable for health practitioners to refuse to treat that patient until they are no longer a threat to staff safety.[96] However, what if the belligerent or dismissive patient did have signs of a head injury?

In *Neal v Ambulance Service of NSW*,[97] Mr Neal was wandering the streets at approximately 2 am one Friday morning when he was happened upon by police. They noticed dried blood on his head and were concerned that he had suffered a head injury, and called an ambulance. However, on attempting to examine the injury, and touching the 'egg on his head',[98] the ambulance officers were pushed away by Mr Neal saying words to the effect of 'I haven't given you permission to

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[95] Anne-Maree Kelly, Tina Cockburn and Bill Madden, 'When Patients Behave Badly: Consent, Breach of the Duty of Care and the Law' (2021) 33(1) *Emergency Medicine Australasia* 172.
[96] See, eg, WA Health, *Refusal or Withdrawal of Care for a Patient Exhibiting Aggressive or Violent Behaviour Policy* (Policy Document no MP0174/22, 24 October 2022) <https://www.health.wa.gov.au/About-us/Policy-frameworks/Work-Health-and-Safety/Mandatory-requirements/Refusal-or-Withdrawal-of-Care-for-a-Patient-Exhibiting-Aggressive-or-Violent-Behaviour-Policy>.
[97] *Neal v Ambulance Service of NSW* [2008] NSWCA 346.
[98] Ibid [15].

examine me'.[99] The paramedics explained to Mr Neal that he had suffered a head injury, and needed to go to hospital for further assessment and investigation by medical practitioners, and asked him several times to come to hospital. However, Mr Neal refused each time, pushing the paramedics' hands away and not cooperating with their assessment.[100] Ultimately, the paramedics determined that Mr Neal understood the possibility he had a serious head injury, and had the ability to make the decision to decline to be transported to hospital, so there was no lawful basis for the paramedics to do otherwise. As it happens, the police still took Mr Neal to the police watchhouse as he was intoxicated, where he continued to be 'combative'.[101] While at the police station, officers woke Mr Neal and spoke with him every half an hour to check on his welfare, as per protocol.[102] At one stage later that morning Mr Neal was found to be unrousable, and an ambulance was called to urgently convey him to hospital. Shortly after arriving in the emergency department, a CT-scan was ordered which found a significant extradural haematoma requiring surgery. Mr Neal suffered a variety of ongoing disabilities following the injury, and took action against the State of NSW through its police and ambulance officers for their failure to take him directly to hospital, despite his refusal.

In considering all the circumstances, the Court asked the following hypothetical question: even if paramedics had taken Mr Neal to hospital — without his consent and against his wishes — would he have engaged with the doctors and nurses there, agreed to be examined, undergone blood tests, and remained still for radiological imaging? The Court found that the 'only available inference is that he would not willingly have gone to hospital and submitted to medical assessment'.[103]

I would add to this: even if the paramedics had wanted to convey Mr Neal to hospital without his consent and against his clear wishes, how would they have achieved this practically? Would they have enlisted the support of police officers to restrain Mr Neal to the ambulance stretcher using rescue straps or handcuffs? Would they have collaborated to pin Mr Neal down and inject him with a sedative medication? Would they have anaesthetised Mr Neal completely and inserted a breathing tube to be able to take him to hospital entirely unconscious? The act of sedating a patient is fraught with risk, and not a decision to be made lightly. There

[99] Ibid [14].
[100] Ibid [18].
[101] Ibid [43].
[102] Ibid [55].
[103] Ibid [49].

is always a very real possibility that the patient could become seriously unwell, or even die, as a result of this sedation.[104] At its core, the doctrine of necessity may excuse one harm if it is done to avoid a greater harm. However, in circumstances where Mr Neal was on the roadside at 2 am, walking, talking and explicitly refusing care, it is hard to see how any of these alternative situations could possibly be seen as the lesser harm. Indeed, the best approach to an aggressive patient who is declining care may well be to simply state the medical advice, to explain that staff do not feel safe around them, and to invite them to return if their condition deteriorates (or their mood improves).

Instead, I suggest an alternative example which may enliven consideration of necessity. Perhaps a patient has been brought in by ambulance unwell, and unconscious, due to some suspected physical health issue. They have been received into the emergency department where breathing tubes have been inserted to keep their airways patent, intravenous cannulas have been inserted with medications and fluids, urinary catheters in place as they are unconscious and otherwise liable to soil themselves, and investigations like blood tests and scans are underway to determine the cause of their illness. Suddenly, they wake up, disoriented, confused, likely angry, ready to fight anyone and everyone in sight, demanding to be discharged. This could be a result of their illness, or it may be a normal physiological response to stress, or perhaps they are simply angry. Regardless, it is likely very frightening to staff and other patients, who may fear for their safety. There may be a brief window of opportunity to attempt to verbally de-escalate the situation, but what if that does not work? Given the established presumption that all adult patients have decision-making ability, there is an argument that this now-awake patient ought to be left simply to discharge themselves from hospital (or security could be called to remove them). However, I know few, if any, senior doctors who would be agreeable to letting a patient who was just a few minutes ago unconscious and unwell simply walk out the door, cannulas and lines still connected, while waiting for the results of investigations ordered out of concern for a serious medical condition needing treatment. In this situation, there may instead be an argument, as Kelly and colleagues suggest, for sedating this patient without their consent. The argument would be that the harm caused by such action, being the insult to the patient's autonomy, and the treatment risk inherent to the procedure, would be less than the harm avoided, being the risk of death or disability from whatever illness caused the patient to be brought into hospital in such an unwell state, the risk of serious harm to

[104] Kelly, Cockburn and Madden (n 95) 7.

themselves caused by improper removal of their breathing tubes and catheters, and the real risk that the patient may harm staff or other patients.

As the patient's condition may not have been fully established at this point, it is difficult to say that the sedation would amount to 'urgent treatment' within the meaning of the Medical Treatment Acts,[105] therefore the only other doctrine of law which could conceivably authorise the intervention may be 'necessity'. This would most likely be necessity as a defence against the criminal charge of assault, where these circumstances would arguably fall within the scope of the statutory defences of 'emergency' without evoking the common law defence. Further, in WA specifically, the legislature has provided an exemption for using 'such force as is reasonably necessary in order to prevent a person whom he believes, on reasonable grounds, to be mentally impaired from doing violence to any person or property'.[106] Separately from the criminal defences, we must consider the civil actions and defences. If the actions of health care practitioners in this situation are undertaken in the patient's best interests, and in good faith, then it is highly unlikely that the patient will suffer any harm actionable by way of medical negligence. Therefore, the only remaining cause of action may be in tort for trespass against the person (battery), for treatment or sedation without consent. It is in defence of this action in tort that the civil law doctrine of necessity may be relied upon by the hospital and its practitioners to justify their intervention.

This is the only circumstance I was able to conceive which fell outside the scope of the Medical Treatment Acts, leaving space for the common law doctrine of necessity to operate: to defend a practitioner who has treated, sedated or restrained a patient, in order to prevent that patient from causing harm to other patients, staff, or themselves, but where the patient did not have a mental illness or the Mental Health Act did not otherwise apply.

VII CONCLUSION

Despite various commentators' uncertainty as to the existence of the doctrine of necessity in Australia, the NSW Supreme Court's application of *Re F* and *Re T* in *Hunter and New England Area Health Service v A*, together with the High Court's discussions of the doctrine in *Binsaris* and *Anna Rowan*, demonstrate that the doctrine is still alive in the Australian common law. However, given the existence of the Mental Health Acts, Medical Treatment Acts, and statutory criminal

[105] Or the 'surgical and medical treatment' exception in the WA Criminal Code: see *Criminal Code Act Compilation Act 1913* (WA) s 259. See also Blake (n 38).
[106] *Criminal Code Act Compilation Act 1913* (WA) s 243.

defences, there is such a narrow window for the common law doctrine to operate that, in practical terms, there is almost no work left for the doctrine to do. For these reasons, I agree with the WA Guardianship and Administration Board's assessment that it is 'unwise to conclude that the general law applicable in Western Australia presently permitted a medical practitioner or any other health professional to provide treatment without a patient's consent'[107] (even if I disagree with their suggestion that *Marion's Case* is the basis of this conclusion).

Therefore, health care practitioners contemplating the treatment of patients with reduced decision-making ability should use the language of their local statute. For example, doctors in WA should refer to 'the *Guardianship Act*'[108] rather than 'the doctrine of necessity'. It is possible that when health care practitioners say 'necessity' they are actually referring to the legislation already, and simply say 'necessity' out of habit, or brevity, but this is a poor practice. While the language of the legislation is in some ways similar to the doctrine, the statutory framework differs in more ways than mere semantics.

For example, 'emergency' was not a criterion or even a pre-requisite to the contemplation of necessity,[109] and it was also not a requirement that health care practitioners considered the views of substitute decision-makers. However, under the various Medical Treatment Acts, it is only permissible to provide treatment without consent if the need for treatment is so 'urgent' that it would not be practicable to seek the patient's views or the views of a substitute decision-maker, such as a parent, sibling or adult child of the patient.[110] In circumstances where the treatment is not so 'urgent', a substitute decision-maker must be contacted. Referring broadly to the 'doctrine of necessity' rather than the legislation risks missing opportunities to involve family in these critical health care decisions, which the legislation was specifically designed to facilitate. As necessity cannot be relied upon where the values inherent in the relevant action are 'inconsistent with those implicit in the law',[111] and patient autonomy is an important value in the Medical Treatment Acts, there is even an argument that failing to engage in consultation with the patient's family could even invalidate the application of the doctrine.

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[107] *MW* (n 50) [43].
[108] *Guardianship and Administration Act 1990* (WA).
[109] *Re F* (n 3) 75 (Lord Goff).
[110] See, eg, *Guardianship and Administration Act 1990* (WA) s 110ZD. This requirement has also been conserved in the new Victorian guardianship legislation: *Medical Treatment Planning and Decisions Act 2016* (Vic) s 55(3).
[111] *R v Rogers* (n 67) 546 (Gleeson CJ; Clarke JA and Ireland J agreeing).

So, in response to the questions posed in the introduction:

(1) What is the current status of the common law doctrine of necessity in Australia?

The doctrine of necessity still technically exists within Australian civil law, and likely also exists within the criminal law, however the scope for its application in most jurisdictions is limited by the existence of the Mental Health Acts, Medical Treatment Acts, and statutory criminal defences.

(2) Can the doctrine of necessity be relied upon by health care practitioners when providing treatment to patients with impaired decision-making ability?

The principle of parliamentary sovereignty requires that, where legislation is inconsistent with the common law, the legislation must prevail. Therefore, as Medical Treatment Acts and Mental Health Acts in each state and territory establish statutory frameworks for making health care decisions in respect of patients with impaired decision-making ability, health care practitioners should refer to the language of their local legislation when making any treatment decisions. It is not appropriate to refer to the common law doctrine of necessity in situations appropriately covered by the legislation.

(3) Does it matter?

Yes, it matters. The Medical Treatment Acts establish a criterion of 'urgency' where Lord Goff in *Re F* did not consider this to be a factor.[112] In circumstances where treatment is required and there is enough time to seek a substitute decision-maker (eg, the situation is not 'urgent'), the Medical Treatment Acts require health care practitioners to do so,[113] which also was not a requirement in *Re F*. If health care practitioners continue to use the old language of 'necessity' there is a risk that opportunities to seek input from substitute decision-makers may be missed, contrary to the values inherent in the legislative scheme and therefore, ironically, contrary to the principles underpinning necessity itself.[114]

[112] See, eg, *Guardianship and Administration Act 1990* (WA) s 110ZI(1)(a). Note that in the recent review of the Victorian guardianship legislation, the language of 'urgency' was also conserved: *Medical Treatment Planning and Decisions Act 2016* (Vic) s 53(1).
[113] See above n 110.
[114] *R v Rogers* (n 67) 546 (Gleeson CJ; Clarke JA and Ireland J agreeing).

THE NDIS TRANSFORMATION FROM DISCRETION TO RULES: LEGISLATIVE REBUTTAL AND ADMINISTRATIVE JUSTICE

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Australia's National Disability Insurance Scheme ('NDIS') offers a compelling case study of the tension between discretion and rules. This article argues that the 2024 NDIS reforms represent a 'legislative rebuttal': a systematic hardening of discretionary soft law into binding rules to blunt the application of principles established by judicial and merits review. This shift creates two competing consequences: programmatic invisibility, a legally mandated structural blindness to the holistic needs of participants; and a paradox of legibility, where the precision of the new rules creates targets for legal challenge. Reflecting on the long shadow of the Robodebt Royal Commission, the article concludes that the NDIS reforms reveal a subtle but potent pathology of executive power: not illegal defiance of administrative law, but its lawful circumvention by recasting accountability from substantive fairness to procedural compliance.

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I INTRODUCTION

In 2024, a comprehensive legislative overhaul fundamentally recast Australia's National Disability Insurance Scheme ('NDIS'), replacing the scheme's original discretionary, principles-based architecture with a prescriptive, rules-based framework. This article argues that these reforms exemplify what I term 'legislative rebuttal': the strategic conversion of flexible standards and soft-law guidance into binding legal instruments to reverse, and largely foreclose, the interpretive space courts and tribunals had used to protect individualised justice.[1] In plainer terms, the reforms moved decision-making from judgement within standards to classification under lists. The change is lawful, system-wide, and designed to endure. This transformation matters because it reveals how modern welfare states can lawfully circumvent accountability mechanisms when judicial oversight proves too effective at protecting citizen rights. Unlike the outright illegality of the Robodebt scheme,[2] which collapsed under judicial scrutiny, the NDIS reforms demonstrate a more sophisticated and potentially more enduring approach: achieving similar ends through legitimate legislative means. This makes the NDIS reforms a template for recalibrating the balance between executive efficiency and individual rights within the bounds of legality.[3]

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[1] On the operation of soft law in National Disability Insurance Scheme ('NDIS') administration prior to the reforms, see Terry Carney et al, 'National Disability Insurance Scheme Plan Decision-Making: Or When Tailor-Made Case Planning Met Taylorism & the Algorithms?' (2019) 42(3) *Melbourne University Law Review* 780, 786–7, documenting how National Disability Insurance Agency ('NDIA') Operational Guidelines directed assessments despite their non-binding status. On the separation of powers in the Australian administrative law context and legislative responses to judicial decisions, see, eg, John McMillan, 'Re-Thinking the Separation of Powers' (2010) 38(3) *Federal Law Review* 423.

[2] *Royal Commission into the Robodebt Scheme* (Final Report, July 2023) vol 1, xxix: 'Robodebt was a crude and cruel mechanism, neither fair nor legal, and it made many people feel like criminals. ... It was a costly failure of public administration, in both human and economic terms.'

[3] This article focuses on what is lost through the legislative rebuttal, but this should not diminish recognition of what might be gained. The reforms potentially benefit participants whose needs align with standardised categories, those lacking advocacy resources, and future participants who require a sustainable scheme. A complete evaluation would require longitudinal data not yet available. This article's critical perspective reflects concern that the mechanisms chosen to

The transformation of the NDIS sits in a longer Australian trajectory. Earlier disability programmes, including the Disability Support Pension and Carer Payment, experienced similar shifts toward prescriptive rules during the 1980s and 1990s, driven by concerns about expenditure growth.[4] This was not an isolated tuning of eligibility; it marked a structural re-imagination of disability benefits from open-textured judgement to quantified impairment scoring.[5] The NDIS reforms extend this pattern beyond income security payments to comprehensively case-managed disability services, representing a decisive policy choice to prioritise actuarial certainty over contextual judgement across the entire disability support landscape. Systemic design flaws compounded the fiscal imperative for reform: the original scheme's expansive discretionary language created what the 2023 Independent Review described as an 'unbalanced' system that had become the 'only lifeboat' as state-level foundational supports were allowed to deteriorate.[6] In this context, some form of intervention was politically and fiscally inevitable.[7] Furthermore, the similarities between these NDIS reforms and the progressive constraint of discretion in Australian migration law are striking.[8] As Stephen Gageler documented long before he became Australia's Chief Justice, migration law underwent decades of codification designed to limit judicial creativity, replacing discretionary decision-making with prescriptive rules.[9] More recent scholarship by Grant Hooper has examined how this 'codification on steroids' created new sites of contestation through the very precision it introduced.[10] The NDIS reforms follow a parallel trajectory, though in a different substantive domain, raising fundamental questions about the evolving

achieve legitimate goals may produce unintended consequences that ultimately undermine those very goals.

[4] See the comprehensive history provided in Terry Carney, 'Vulnerability: False Hope for Vulnerable Social Security Clients?' (2018) 41(3) *University of New South Wales Law Journal* 783, 793–800. I am grateful to the anonymous reviewer for making this insightful and important point.

[5] See discussion of the *Social Security (Tables for the Assessment of Work-related Impairment for Disability Support Pension) Determination 1997* (Cth) and subsequent iterations in Terry Carney, 'Disability Support Pension: Towards Workforce Opportunities or Social Control?' (1991) 14(2) *University of New South Wales Law Journal* 220; Carney, 'Vulnerability: False Hope for Vulnerable Social Security Clients?' (n 4).

[6] *Working Together to Deliver the NDIS: Independent Review into the National Disability Insurance Scheme* (Final Report, Commonwealth of Australia, Department of the Prime Minister and Cabinet, October 2023) 243–9 ('*Independent Review*').

[7] Ibid 295.

[8] I am grateful to the anonymous reviewer for drawing this critical connection.

[9] Stephen Gageler, 'Impact of Migration Law on the Development of Australian Administrative Law' (2010) 17(2) *Australian Journal of Administrative Law* 92, 96–8.

[10] Grant Robert Hooper, 'Three Decades of Tension: From the Codification of Migration Decision-Making to an Overarching Framework for Judicial Review' (2020) 48(3) *Federal Law Review* 401, 403.

relationship between legislative prescription, executive administration, and judicial oversight in the modern Australian administrative state. Put simply, the NDIS reforms follow a well-worn path in Australian welfare and migration law: codification constrains holistic discretion but creates new justiciable margins, shifting contest from contextual judgement to boundary-policing.

The pre-reform NDIS architecture embodied deep tensions.[11] Its broad 'reasonable and necessary' standard created vast discretionary space that generated both inconsistency and opportunity for judicial creativity.[12] When the National Disability Insurance Agency ('NDIA') failed to operationalise this discretion fairly and consistently,[13] courts and tribunals responded by developing what I term the 'NDIS review jurisprudence': a coherent body of principles emphasising individualised assessment, holistic support, and collaborative decision-making.[14] Yet this judicially-crafted framework, while protecting individual rights, exacerbated the very problems — rising costs, administrative complexity, and perceived inequity — that ultimately triggered legislative intervention. The 2024 amendments represent a systematic reversal of these judicial principles through three mechanisms: (1) transforming administrative guidelines into binding legislative instruments; (2) creating categorical exclusions that replace factual inquiry with classification; and (3) mandating fragmented assessment through an 'accepted impairment' gateway that fragments the person into discrete, governable categories.[15] These mechanisms share a common logic: eliminating the interpretive space where judicial creativity operated by hardening soft law into prescriptive rules.

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[11] Allan Ardill and Brett Jenkins, 'Navigating the Australian National Disability Insurance Scheme: A Scheme of Big Ideas and Big Challenges' (2020) 28(1) *Journal of Law and Medicine* 145, 147–8; Sue Olney and Helen Dickinson, 'Australia's New National Disability Insurance Scheme: Implications for Policy and Practice' (2019) 2(3) *Policy Design and Practice* 275, 277.

[12] *National Disability Insurance Scheme Act 2013* (Cth) s 34. See also Alyssa Venning et al, 'Adjudicating Reasonable and Necessary Funded Supports in the National Disability Insurance Scheme: A Critical Review of the Values and Priorities Indicated in the Decisions of the Administrative Appeals Tribunal' (2021) 80(1) *Australian Journal of Public Administration* 97, 98.

[13] *Independent Review* (n 6) 32.

[14] The term 'NDIS review jurisprudence' is used in this article to refer to the coherent body of principles developed by the Administrative Appeals Tribunal and the Federal Court in interpreting the *National Disability Insurance Scheme Act 2013* (Cth) ('NDIS Act'), particularly the 'reasonable and necessary' criteria in s 34. It is 'jurisprudence' in the *functional* sense of being a series of published decisions that create a principled gloss on the statutory scheme.

[15] See overview of reforms provided at 'Summary of Legislation Changes', *NDIS* (Web Page, 18 September 2025) <https://ndis.gov.au/changes-ndis-legislation/summary-legislation-changes>. The principal amendments relevant to this paper are contained in the *National Disability Insurance Scheme Amendment (Getting the NDIS Back on Track No 1) Act 2024* (Cth) ('NDIS Amendment Act').

This transformation generates two profound consequences. First, it creates what I term 'programmatic invisibility': a legally mandated inability to perceive participants' holistic needs, forcing decision-makers to view complex human experiences through rigid categorical boundaries. Drawing on James C Scott's analysis of state 'legibility',[16] I argue that the reforms exemplify how administrative systems simplify complex realities for bureaucratic control, creating what Scott calls 'fiscal forests': administratively legible but humanly impoverished representations.[17] Second, and paradoxically, the attempt to insulate decision-making through precise rules creates a 'paradox of legibility'. By codifying every categorical boundary, the reforms inadvertently transform each new rule into a potential site for fresh legal contestation. While the durability and scope of this resistance remain uncertain, and past experience with rule-based disability programmes suggests caution, early Administrative Review Tribunal ('ART') decisions reveal adaptation to the new constraints through purposive statutory construction and vigorous merits review where rules permit.

This article develops these arguments through four parts. Part II examines the original discretionary model (2013–2023), showing how broad standards created space for both administrative failure and judicial creativity, and how the Administrative Appeals Tribunal ('AAT') developed coherent principles to give substantive content to the aspirations of the *National Disability Insurance Scheme Act 2013* (Cth) ('NDIS Act'). Part III analyses the 2024 reforms as a systematic legislative rebuttal, documenting how the transformation of soft law into hard rules reversed each principle of the NDIS review jurisprudence while simultaneously responding to legitimate concerns about sustainability and consistency. Part IV explores the consequences: how the reforms produce programmatic invisibility while simultaneously generating sites of resistance through the paradox of legibility. The conclusion considers broader implications for administrative justice, acknowledging the genuine design flaws that necessitated reform while questioning whether the chosen mechanisms adequately balance consistency with the contextual, individualised judgement essential to complex human needs.

[16] See James C Scott, *Seeing Like a State: How Certain Schemes to Improve the Human Condition Have Failed* (Yale University Press, 1st ed, 1998) 2.
[17] Ibid 23.

II THE PROMISE AND PERIL OF DISCRETION: THE NDIS (2013–2023)

A *The Architecture of Discretion: Legislating for Flexibility*

From its inception, the NDIS was defined by a central, and ultimately unstable, tension; its reliance on broad discretionary standards created the very interpretive space that would later allow courts to challenge the agency's implementation. The 2024 NDIS reforms represent an inversion of this dynamic, using formal legal rules to diminish the policy space where decision-maker creativity thrived. The scheme's enabling legislation, the NDIS Act eschewed prescriptive detail in favour of broad principles.[18] The legislative cornerstone was the 'reasonable and necessary' standard, a phrase that created vast discretionary space while embedding deep value conflicts into the scheme's operation.[19] NDIA planners and Local Area Coordinators exemplified Lipsky's 'street-level bureaucrats':[20] frontline workers whose discretionary decisions effectively become policy.[21] The resulting inconsistencies were not administrative errors but predictable outcomes of delegating broad discretion to workers managing high demand with finite resources.[22] To manage demand and work pressures, street-level bureaucrats develop 'rules of thumb, local custom and practice, informal interpretations' and other coping mechanisms.[23] For the individuals subject to these practices, the result can be decisions that feel 'almost random and senseless'.[24] The gap between the scheme's legislative promise and its implementation fuelled conflicts that drove participants to AAT appeals.[25] The NDIS review jurisprudence can be understood not just as a judicial response to agency failure, but as a higher-level attempt to impose coherence and principle upon the unavoidable discretion exercised at the street level.[26]

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[18] See Mhairi Cowden and Claire McCullagh (eds), *The National Disability Insurance Scheme: An Australian Public Policy Experiment* (Springer Singapore, 2021) 5; Eloise Hummell et al, 'Agendas of Reform: Continuity and Change in Australia's National Disability Insurance Scheme (NDIS)' (2024) *Social Policy and Society* 1, 1–2.
[19] Venning et al (n 12).
[20] See generally Michael Lipsky, *Street-Level Bureaucracy: Dilemmas of the Individual in Public Services* (Russell Sage Foundation, 1980).
[21] Mike Rowe, 'Going Back to the Street: Revisiting Lipsky's Street-Level Bureaucracy' (2012) 30(1) *Teaching Public Administration* 10, 11, citing Lipsky (n 20) 3.
[22] Michele Foster et al, '"Reasonable and Necessary" Care: The Challenge of Operationalising the NDIS Policy Principle in Allocating Disability Care in Australia' (2016) 51(1) *Australian Journal of Social Issues* 27, 29–31; Venning et al (n 12); Lipsky (n 20) xii.
[23] Rowe (n 21) 12.
[24] Ibid 14.
[25] *Independent Review* (n 6) 32.
[26] Venning et al (n 12) 97.

To understand how this discretionary space was structured and contested, we must map the 'architecture of administration' comprising the scheme.[27] The scheme operated through a three-tiered hierarchy: the NDIS Act, limited binding *National Disability Insurance Scheme (Supports for Participants) Rules 2024* (Cth) ('NDIS Rules'), and extensive non-binding Operational Guidelines.[28] This architecture deliberately concentrated operational power in the 'soft law' guidelines. Cross's analysis confirms that decision-makers almost always followed these guidelines, giving them practical force despite their soft law status.[29] This created a 'structural incongruity'; the NDIS Act embodied a collaborative, participant-led philosophy, while merits review remained rooted in an adversarial judicial paradigm.[30] Early studies confirmed these tensions were designed into the policy.[31] The statute did not define key statutory terms, including the important 'reasonable and necessary supports' criterion. Most operational detail was in the sprawling body of internal Operational Guidelines, a form of 'soft law' that, while not legally binding, directed assessments and funded supports.[32] This architecture was inherently unstable, creating what Venning et al describe as a conflict between 'imagined rights versus fair and sustainable administration of entitlements'.[33] The result was not principled flexibility but widespread inconsistency, with reports of drastically increasing internal reviews and external AAT appeals, leading to a system that many participants found cumbersome and difficult to navigate without significant advocacy support.

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[27] Elizabeth Fisher, 'Why Doctrinal Administrative Lawyers Need to Think More About Policy' (2023) 29(4) *Australian Journal of Administrative Law* 254, 254.

[28] Prior to the 2024 reforms, these Guidelines were kept up to date and available on a dedicated 'microsite' (<https://ourguidelines.ndis.gov.au>). The microsite was taken down as of 4 September 2025, and current Guidelines are available at 'Our Guidelines', *NDIS* (Web Page, 24 October 2025) <https://www.ndis.gov.au/our-guidelines>. See generally Javier Cross, 'The Administrative Appeals Tribunal and the Drake Doctrine: How the AAT Treats Government Policy in NDIS Decisions as to Reasonable and Necessary Supports' (2022) 29(1) *Australian Journal of Administrative Law* 60; Thomas Liu, 'The Participant in the National Disability Insurance Scheme: A Paradigm Shift for Administrative Law' (2019) 97 *AIAL Forum* 81; Hummell et al (n 17) 2.

[29] See Cross (n 28).

[30] Liu (n 28) 97.

[31] See Louise P Bygrave and Ron McCallum, 'The National Disability Insurance Scheme and Administrative Decision-Making: Unique Challenges and Opportunities' (2020) 26 *Australian Journal of Administrative Law* 191.

[32] *Independent Review* (n 6) 30.

[33] Ibid 32; Venning et al (n 12) 98.

B *Aspiration versus Reality: Inequity and Administrative Failure*

As the scheme matured, these ambiguities crystallised into intractable disputes, carrying the practice of the NDIA further from its collaborative, person-centred promises. Venning et al's analysis of AAT decisions shows disputes clustered around fundamental questions: the responsibilities between the NDIS and other government services, the scope of NDIS services, and the legitimacy of supports related to social participation and therapeutic goals.[34] Carney et al documented how the NDIA's adoption of 'Taylorist' administrative practices (the application of scientific management principles through algorithmic standardisation) had started to undermine individualised planning well before the 2024 legislative reforms.[35] Their analysis revealed that by 2016, the NDIA was using legacy data and questionnaires to generate typical 'reference packages' that served as presumptive starting points,[36] with planners under pressure to meet 'hugely ambitious' targets to produce 500 plans daily by 2018–19.[37] This fundamentally altered the planner-participant relationship, transforming collaborative planning into a process of algorithmic categorisation.[38]

These structural tensions were compounded by significant distributional inequities that undermined the scheme's egalitarian aspirations. The original model's reliance on subjective assessment and open-textured language inadvertently favoured participants with what sociologists term 'social capital': access to knowledgeable advocates, health professionals, and family support networks capable of navigating complex bureaucratic processes.[39] A 2018 evaluation by Mavromaras et al documented stark disparities, including one case where effective advocacy transformed a participant's package from $600 to $32,000.[40] Geographic location proved equally determinative; participants in rural and remote areas faced both service unavailability (with over one-third of mature participants in remote areas not accessing daily activity supports despite having budgets) and systematically smaller plan sizes, yet these market failures

[34] Venning et al (n 12) 99–100.
[35] Carney et al (n 1) 782–3.
[36] Ibid 794.
[37] Ibid 785.
[38] Ibid 787.
[39] Gemma Carey, Eleanor Malbon and James Blackwell, 'Administering Inequality? The National Disability Insurance Scheme and Administrative Burdens on Individuals' (2021) 80(4) *Australian Journal of Public Administration* 854, 868; Kostas Mavromaras et al, *Evaluation of the NDIS* (Final Report, National Institute of Labour Studies, Flinders University, February 2018) 198–200.
[40] Mavromaras et al (n 39) 248.

were persistently attributed to participant 'choice' rather than thin markets.[41] Cultural and linguistic diversity created additional barriers, exacerbating socio-economic or geographical disadvantage.[42] Thus this reliance on broad discretion did not lead to principled flexibility but instead produced deep systemic inequities, as outcomes began to depend less on need and more on a participant's social capital and capacity for advocacy. This 'postcode lottery' was a key criticism of the previous state-based disability services system that the federal NDIS was supposed to address.[43]

C *The Judicial Response: Forging the NDIS Review Jurisprudence*

External review became crucial as the NDIA struggled to fairly operationalise the scheme's rights-based mandate. As Venning et al note, judges stepped in to ensure that the scheme delivered on its promise to 'redress unfairness' and recognise 'the equal right of all persons with disabilities to live in the community'.[44] This intervention was achieved by the incremental development of 'NDIS review jurisprudence' through insistently and consistently aligning the interpretation and application of the NDIS Act with its purposes. The AAT and Federal Court did not routinely invoke the *Drake* exception (which allows for departure from lawful government policy where its application would produce unjust results),[45] so much as exercise their standard authority to reach different conclusions *within*

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[41] *Independent Review* (n 6) 287–291. See generally Sarah Veli-Gold et al, 'The Experiences of People with Disability and Their Families/Carers Navigating the NDIS Planning Process in Regional, Rural and Remote Regions of Australia: Scoping Review' (2023) 31(4) *Australian Journal of Rural Health* 631; Luke Wakely et al, 'The Lived Experience of Receiving Services as a National Disability Insurance Scheme Participant in a Rural Area: Challenges of Choice and Control' (2023) 31(4) *Australian Journal of Rural Health* 648; Alexandra Prowse et al, 'Lived Experience of Parents and Carers of People Receiving Services in Rural Areas under the National Disability Insurance Scheme' (2022) 30(2) *Australian Journal of Rural Health* 208; Stuart Wark, Lia Bryant and Tyson Morales-Boyce, '"Thin Markets": Recruitment and Retention of Disability Staff to Support Effective Post-parental Care Planning in Rural Australia' (2023) 20(4) *Journal of Policy and Practice in Intellectual Disabilities* 428.

[42] See generally, Angeline Ferdinand et al, 'Culturally Competent Communication in Indigenous Disability Assessment: A Qualitative Study' (2021) 20(1) *International Journal for Equity in Health* 68; Deborah Warr et al, *Choice, Control and the NDIS: Service Users' Perspectives on Having Choice and Control in the New National Disability Insurance Scheme* (Community Report, Melbourne Social Equity Institute, 2017); Corinne Cortese et al, 'Hard-to-Reach: The NDIS, Disability, and Socio-Economic Disadvantage' (2021) 36(6) *Disability & Society* 883.

[43] Mhairi Cowden and Claire McCullagh, 'The Philosophy of the NDIS' in Mhairi Cowden and Claire McCullagh (eds), *The National Disability Insurance Scheme: An Australian Public Policy Experiment* (Springer Singapore, 2021) 123, 131.

[44] Venning et al (n 12) 98. See also Joel Townsend, 'No Narrow or Pedantic Approach: The NDIS and AAT Jurisdiction' (2023) 34 *Public Law Review* 327, 336.

[45] Cross (n 28) 67–8.

the broad statutory guidance the NDIS Act provided.[46] Where the NDIA's Operational Guidelines remained within the statutory framework, decision-makers applied them as relevant considerations while maintaining independent judgement; where NDIA positions ventured beyond or contradicted the NDIS Act's beneficial purposes, tribunals simply applied the statute itself.[47] This represented conventional merits review rather than dramatic departures from policy. However, the systematic pattern of such decisions, which consistently privileged individualised assessment over bureaucratic standardisation, gave substantive content to the NDIS Act's principles and constrained the NDIA's tendency toward rigid, cost-focused administration. The NDIS review jurisprudence can therefore be understood as a judicial defence of *mētis*: the 'practical knowledge, informal processes, and improvisation' of participants and their support networks, against the state's abstract, schematic plans.[48] Where the NDIA sought to apply simplified categories, the judiciary insisted on the kind of particular, context-bound knowledge that, Scott argues, is essential for a functioning social order.[49]

This NDIS review jurisprudence crystallised around four foundational principles. First, the principle of indivisible funding, established in *McGarrigle v NDIA*,[50] holds that once a support is deemed reasonable and necessary, it must be fully funded.[51] The Federal Court rejected the NDIA's attempt to partially fund supports, finding it would introduce 'means testing by a backdoor route into the NDIS,' contrary to the scheme's social insurance model.[52] Second, the principle of intense factual assessment, articulated in *NDIA v WRMF*,[53] requires rigorous, evidence-based inquiry into the individual's circumstances.[54] The Full Federal Court rejected categorical exclusions for certain supports, insisting the 'reasonable and necessary' determination demands intense fact finding based on unique participant needs, not generic policy application.[55] Third, the principle of holistic and relational support, established in *NDIA v KKTB*,[56] requires viewing participant support needs as an integrated whole.[57] The Full Federal Court

[46] Ibid 60–1.
[47] Cross (n 28); Venning et al (n 12).
[48] Scott (n 16) 6, 350.
[49] Ibid 311.
[50] *McGarrigle v National Disability Insurance Agency* (2017) 252 FCR 121 ('*McGarrigle*').
[51] Ibid [94], affd *National Disability Insurance Agency v McGarrigle* [2017] FCAFC 132.
[52] *McGarrigle* (n 50) [62] (Mortimer J).
[53] *National Disability Insurance Agency v WRMF* (2020) 276 FCR 415 ('*WRMF*').
[54] Ibid [152].
[55] Ibid.
[56] *National Disability Insurance Agency v KKTB* (2022) 295 FCR 379 ('*KKTB*').
[57] Ibid [136]

endorsed the AAT's right to assess an 'overall requested level' of support as a single package, directly rebutting administrative fragmentation.[58] This principle was taken further in AAT decisions like *RXFR and NDIA*,[59] where the ART's analysis focused not just on the child applicant but on the profound disabilities affecting the entire family unit.[60] Considering the applicant's needs in this context, the ART found that the care required exceeded reasonable family expectations under s 34(1)(e) of the NDIS Act.[61] Finally, the principle of collaborative process, articulated in *QDKH v NDIA*,[62] requires review processes to be collaborative and inquisitorial.[63] The Full Federal Court confirmed that the AAT was not confined to supports formally requested at internal review, accepting the parties' reasoning that participants 'may lack the capacity to identify the particular supports they wish to have approved', and that this broad construction 'better serves the beneficial purpose of the NDIS Act' by protecting vulnerable participants from bureaucratic limitations.[64]

These four principles represented more than individual judicial decisions. They constituted a coherent philosophy of administrative justice that privileged substance over form, individual needs over bureaucratic categories, and collaborative problem-solving over adversarial contest. The judiciary had created a common law overlay, consistently applied and further developed in the AAT and ART, that gave meaning to the NDIA Act's abstract principles while constraining the NDIA's tendency toward rigid, cost-focused administration. Yet this judicially managed balance proved unsustainable. The success of the NDIS review jurisprudence in expanding access and ensuring individualised justice created the conditions for its demise. This outcome reflects the fundamental tension in public law between systematic rules and contextual judgement, a tension particularly acute in social welfare schemes needing consistency and responsiveness to individual need.[65] However, where previous studies have

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[58] Ibid.
[59] *RXFR and National Disability Insurance Agency* [2024] ARTA 188 ('*RXFR*').
[60] Ibid [86], [111]–[122].
[61] Ibid [112].
[62] *QDKH, by his litigation representative BGJF v National Disability Insurance Agency* [2021] FCAFC 189 ('*QDKH*'). In *QDKH* both parties agreed that the AAT had made an error of law; the Full Federal Court made consent orders and confirmed the parties' shared understanding of the legal position was correct.
[63] See ibid [7].
[64] Ibid.
[65] Monika Zalnieriute, Lyria Bennett Moses and George Williams, 'The Rule of Law and Automation of Government Decision-Making' (2019) 82(3) *The Modern Law Review* 425, 455.

focused on administrative non-compliance or policy workarounds,[66] the NDIS reforms demonstrate a more sophisticated response: the strategic use of legislative precision to eliminate the interpretive space where judicial creativity operates. This 'legislative rebuttal' represents not merely a technical change but a profound institutional choice to resolve the rules-discretion dialectic through comprehensive statutory prescription rather than administrative judgement.[67] The reforms exemplify the 'institutional turn' in administrative law: a recalibration of decision-making authority between courts, tribunals, and agencies through structural legal change.[68]

D *The Breaking Point: An Unsustainable System*

The pressure for reform came from multiple sources. Rising costs, inconsistent outcomes, and the administrative burden of complex, multi-day hearings generated political demands for standardisation.[69] Reports from the Australian National Audit Office documented persistent non-compliance and poor quality assurance within the NDIA.[70] This dysfunction was compounded by the agency's failure to learn from external review. A 2024 Commonwealth Ombudsman report observed the NDIA's practice of settling cases immediately before AAT hearings, creating a perception that 'the only way the NDIA will fund certain supports ... is if the participant appeals to the Tribunal'.[71] The strategic implications of these settlement patterns merit particular attention. The NDIA's practice of settling cases immediately before hearings was not merely an efficiency measure but a deliberate strategy to minimise the normative force of AAT jurisprudence. As Queensland Advocacy for Inclusion documented, less than 1% of appeals between 2019 and 2021 resulted in published decisions (130 published decisions from 7,532 appeals).[72] The Parliamentary Joint Standing Committee on the NDIS specifically recommended publication of settlement outcomes to address this

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[66] See, eg, Terry Carney, 'Robo-Debt Illegality: The Seven Veils of Failed Guarantees of the Rule of Law?' (2019) 44(1) *Alternative Law Journal* 4; Valerie Braithwaite, 'Beyond the Bubble That Is Robodebt: How Governments That Lose Integrity Threaten Democracy' (2020) 55(3) *Australian Journal of Social Issues* 242; *Royal Commission Into the Robodebt Scheme* (n 2).

[67] Carl E Schneider, 'Discretion and Rules: A Lawyer's View' in Keith Hawkins (ed), *The Uses of Discretion* (Oxford University Press, 1992) 47, 72.

[68] See Yee-Fui Ng, 'Institutional Adaptation and the Administrative State' (2021) 44 *Melbourne University Law Review* 889, 898.

[69] *Independent Review* (n 6) 28–31.

[70] See Mona Nikidehaghani, 'Accounting and Neoliberal Responsibilisation: A Case Study on the Australian National Disability Insurance Scheme' (2024) 37(9) *Accounting, Auditing & Accountability Journal* 128, 132; Hummell et al (n 18) 2.

[71] Commonwealth Ombudsman, *Learning from Merits Review: Best Practice Principles for Agency Engagement with Merits Review* (Report, December 2024) 35.

[72] Queensland Advocacy for Inclusion, *Analysis of NDIS Appeals* (Report, 30 June 2022) 12.

accountability gap, a recommendation the government rejected.[73] These high settlement rates limited the AAT's opportunities to provide guidance to the NDIA on interpretation of legislation. This guidance was sorely needed in a system which, as Brookes and Ballantyne observed, 'there seem[ed] to be significant confusion over the correct interpretation of the legislation and associated instruments across the Agency'.[74] Thus the penetration of AAT principles into NDIS administrative practice remained minimal despite the tribunal's development of coherent jurisprudential guidance.

NDIA dysfunction and implementation tensions were amplified by a fundamental design flaw in the federal architecture: the absence of clarity about boundaries between the NDIS and other service systems. The Applied Principles and Tables of Support ('APTOS'), intended to delineate responsibilities, proved inadequate as state and territory governments allowed mainstream disability supports to deteriorate, leaving the NDIS as what the Independent Review called the 'only lifeboat'.[75] Important programs that had previously supported all people with disability were effectively rolled into the scheme, leaving many Australians with a disability who were not NDIS-eligible without adequate support, and significant uncertainty about which governments or programmes were responsible for services.[76] From this perspective, the government's case for reform rested not only on fiscal sustainability but on legitimate concerns that discretionary decision-making had, in practice, systematically disadvantaged the most vulnerable participants. The 2024 reforms sought to address this through the National Cabinet's commitment to re-establish 'foundational supports' (universal services available to all people with disability regardless of NDIS eligibility) with $2 billion committed over five years as a first phase.[77] This structural recalibration, emphasising that the NDIS should not be the sole source of disability support, formed a crucial part of the reform rationale, attempting to restore the balance between targeted, individualised NDIS supports and broader systemic supports that had been lost during implementation. By 2023, the discretionary model had become politically and administratively unsustainable.

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[73] Ibid 4.
[74] Libby Brookes and Tom Ballantyne, 'Review and Appeal Rights in the NDIS' (2019) 154 *Precedent* 8, 10.
[75] *Independent Review* (n 6) 243–9.
[76] Productivity Commission, *Review of the National Disability Agreement* (Study Report, February 2019) ch 10.
[77] Australian Government, Department of Health, Disability and Ageing, *Foundational Supports for People with Disability* (Policy Framework, 1 October 2025) <https://www.health.gov.au/our-work/foundational-supports-for-people-with-disability>.

The stage was set for a comprehensive legislative rebuttal of the NDIS review jurisprudence.

III THE LEGISLATIVE REBUTTAL: ENGINEERING CERTAINTY

Having mapped the discretionary architecture and the jurisprudence it invited, this Part demonstrates how Parliament dismantled it through what I term 'legislative rebuttal'. Building on Fisher's analysis of how administrative law structures the relationship between policy and legal accountability,[78] this concept distinguishes ordinary legislative amendment from something more fundamental. While amending a statute to correct judicial interpretation is a normal democratic process,[79] legislative rebuttal describes the comprehensive restructuring of an administrative scheme, specifically designed to foreclose entire modes of judicial reasoning. The 2024 NDIS reforms are a textbook example, [80] converting the very texture of decision-making from flexible standards to prescriptive rules, and from contextual principles to rigid categories. This was not a minor policy adjustment; it was an act of administrative re-engineering designed to achieve through legislative instruments what discretionary administration could not. The 2024 amendments represent a systematic narrowing of the NDIS review jurisprudence principles, replacing broad standards with prescriptive rules.[81] These reforms were based on recommendations of the 2023 Independent Review of the NDIS,[82] and respond to the very real problems plaguing the scheme. While the Independent Review identified multiple drivers for reform, including financial sustainability, administrative burden, and participant frustration with inconsistent outcomes,[83] the specific mechanisms chosen reveal an underlying logic of legislative rebuttal. The government could have addressed these concerns through enhanced training, better guidelines, or improved quality assurance. Instead, it chose to

[78] Fisher (n 27).
[79] John Basten, 'Separation of Powers: Dialogue and Deference' (2018) 25 *Australian Journal of Administrative Law* 91, 91.
[80] NDIS Amendment Act (n 15).
[81] See Georgia Van Toorn and Terry Carney, 'Decoding the Algorithmic Operations of Australia's National Disability Insurance Scheme' (2025) 60(1) *Australian Journal of Social Issues* 21 for evidence of how soft law standardisation operated in practice, though their focus on algorithmic systems represents only one mechanism through which standardisation occurs.
[82] *Independent Review* (n 6) i.
[83] Ibid; *Learning from Merits Review* (n 71); Rachael Thompson, 'The National Disability Insurance Scheme Review Process: Weaknesses and Opportunities to Enhance the CRPD' (2022) 28(2–3) *Australian Journal of Human Rights* 266, 272.

eliminate discretion itself, suggesting a deeper objective: constraining the judicial creativity that had expanded access and individualised support.

A *The Strategy: Hardening Soft Law to Dismantle Jurisprudence*

The reform strategy adopted was to transform the NDIA's non-binding Operational Guidelines into legally binding instruments.[84] This strategy represents a classic managerial solution to the 'continuing dilemma' posed by street-level bureaucracy: the impulse 'to manage street-level bureaucrats, to control their independence'.[85] Where the original discretionary model created inconsistency by empowering frontline staff, the 2024 reforms sought to constrain that discretion through formalisation. This can be seen as an attempt to resolve the perennial tension between professional autonomy and bureaucratic control by decisively favouring the latter. The 'hardening' of soft law aimed for consistency, ensuring predictable and uniform outcomes. Consistency is a recognised ideal of good government according to law,[86] and inconsistency was a major motivator for reforming the NDIS. However, the new NDIS Rules, by creating prescriptive lists and mandating specific assessment tools, impose a level of consistency that is at odds with other principles of good administration like 'flexibility', as embodied in the existing 'no fettering' ground of judicial review which requires attention to individual circumstances.[87] The legislative rebuttal represents a choice to prioritise executive-defined consistency over individualised, merits-based justice in the NDIS review jurisprudence.

The transformation involved several key changes. First, the government introduced the NDIS Rules, which created detailed lists of funded and non-funded supports. Second, it amended s 34 of the NDIS Act to include a new 'accepted impairment' gateway, limiting funding to supports addressing needs from the specific impairment for scheme access.[88] The mandatory use of standardised assessment tools replaces individualised professional judgement with algorithmic calculation, creating 'algorithmic grey holes': spaces of automated calculation shielded from legal scrutiny because they were classified as inputs

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[84] NDIS Amendment Act (n 15); *National Disability Insurance Scheme (Supports for Participants) Rules 2024* (Cth).
[85] Rowe (n 21) 16.
[86] Greg Weeks, *Soft Law and Public Authorities: Remedies and Reform* (Hart Publishing, 2016) 156.
[87] See discussion in Mark Aronson, Matthew Groves and Greg Weeks, *Judicial Review of Administrative Action and Government Liability* (Lawbook Co, 7th ed, 2022) 303–6.
[88] Section 34(1)(aa) provides that the CEO must be satisfied that 'the support is necessary to address needs of the participant arising from an impairment in relation to which the participant meets the disability requirements … or the early intervention requirements'.

rather than reviewable decisions.[89] This provides a technological solution to the administrative problem of street-level bureaucracy. The algorithm becomes the new manager, a tool designed to eliminate frontline discretion. This recourse to automation represents a contemporary expression of the historical tension between 'bureaucratisation and professionalisation'.[90] By embedding rules in code, the reforms privilege a highly regulated, formalised mode of policy delivery over the professional, discretionary judgement inherent in the street-level bureaucrat role.

Beyond the frontline, this legislative strategy also closed the interpretive space used to develop the NDIS review jurisprudence. Where the AAT applied the *Drake* doctrine to avoid unjust results produced by rigid application of the guidelines, the new framework eliminated this possibility by making the guidelines legally binding. Where courts insisted on individualised assessment, the new rules mandated categorical determinations. Where tribunals took a holistic view of participant needs, the reforms required a fragmented assessment, impairment by impairment.

B *A Doctrinal Reversal: From Factual Inquiry to Classification*

The 2024 reforms radically recalibrated the ART's task. While independent merits review remains a feature, the legislative rebuttal limits its scope and impact by hardening policy into binding law, constraining the ART's capacity to depart from government policy on substantive grounds. The shift from the collaborative problem-solving seen in *QDKH* to mechanical rule application represents a significant reversal of the NDIS review jurisprudence's participant-centred philosophy, a shift plain to see in the 2025 ART decision of *FSWN and NDIA*.[91] In dismissing an application for naturopathy and yoga supports, the Tribunal Member explicitly acknowledged that the 2024 reforms had fundamentally changed the nature of the review process.[92] Previously, the question of whether naturopathy was 'effective and beneficial' under s 34(1)(d) of the NDIS Act would have been a factual inquiry, likely involving competing expert evidence. However, the ART noted that this was no longer the case.[93] With the introduction of binding rules, which expressly exclude alternative therapies

[89] Van Toorn and Carney (n 81) 31.
[90] Peter Hupe, Michael Hill and Aurélien Buffat, 'Introduction: Defining and Understanding Street-Level Bureaucracy' in Peter Hupe, Michael Hill and Aurélien Buffat (eds), *Understanding Street-Level Bureaucracy* (Bristol University Press, 1st ed, 2015) 3, 6.
[91] *FSWN and National Disability Insurance Agency* [2025] ARTA 114 ('*FSWN*').
[92] Ibid [4].
[93] Ibid [3], [43]–[46].

and yoga therapy,[94] the question of efficacy was no longer 'a fact to be found by the [ART]' but was instead determined by 'statutory instruction'.[95] The Tribunal concluded that the new rules operated to 'deprive the Applicant's case of any substance' from the outset.[96] It also directly addressed the impact on participant autonomy, observing that the principle of 'choice and control' must now be exercised *within* the prescribed categories of approved supports, 'and not outside them'.[97] The ART further noted that the 'decisional freedom' afforded to it by the Full Federal Court in *WRMF* was now 'similarly constrained' by the new legislative framework.[98]

Thus, following the reforms, the question has shifted from evidentiary to classificatory. Furthermore, the new s 34(1)(aa) 'accepted impairment' gateway limits funding to supports addressing needs from the specific impairment granting scheme access. This severs connections between co-existing conditions, forcing decision-makers to see discrete impairments rather than whole persons, and preventing the holistic and contextual evaluation seen in cases like *KKTB* and *RXFR*. This systematic reversal repurposes a core principle of the administrative continuum. Tribunals must 'stand in the shoes' of the primary decision-maker, so hardening policy into prescriptive rules constrains the tribunal's adjudicative space. Once law dictates categorical exclusions, tribunals must apply them regardless of individual merit. The capacity for objective, evidence-based assessment is curtailed by rewriting the rules at their source. The reforms do not eliminate merits review but seek to alter its character: from substantive review of 'reasonableness' and 'necessity' to a more constrained, classificatory review of whether a support fits a prescribed category. Evaluative judgement sensitive to individual circumstances — or indeed any consideration of the individual themself — begins only if a support is first determined to be on the correct list.[99] The effect is not to abolish the umpire, but to shrink the playing field.

C *The Official Rationale: Pursuit of Sustainability and Consistency*

The legislative transformation of the NDIS was not an arbitrary exercise of power, nor can it be described solely (or even primarily) as an attempt to avoid accountability. To understand the legislative rebuttal, one must engage seriously

[94] *National Disability Insurance Scheme (Getting the NDIS Back on Track) Transitional Rules 2024* (Cth) sch 2 ('Transitional Rules').
[95] *FSWN* (n 91) [28].
[96] Ibid [4].
[97] Ibid [56].
[98] Ibid [57].
[99] Ibid [43].

with its official rationale, framed as a response to two intertwined crises: long-term financial sustainability and a lack of fairness caused by systemic inconsistency.

The first imperative was fiscal. The NDIS Review Panel was tasked with making recommendations to secure the scheme's future, reinforced by National Cabinet's decision to implement a Financial Sustainability Framework. The government's position, articulated through the *Independent Review*, was that a well-managed scheme required predictable and manageable budget setting, a core principle of responsible public administration. The proposed new governance structure, with National Cabinet and the Disability Reform Ministerial Council ('DRMC') accountable for the sustainability of the entire disability ecosystem, reflects this imperative.

The second imperative was fairness. The original discretionary model created a "postcode lottery". Participants with similar needs received vastly different outcomes based on their location, planner, or ability to navigate a complex and adversarial appeals process. The NDIS Review voiced the frustration of the disability community, quoting one participant who captured the corrosive effect of this perceived unfairness:

> Arbitrary rules — what is reasonable and necessary to me is not the same as it is to my planner … Being told a service is not reasonable and necessary by your planner but knowing someone (whom is in the exact same situation) else's planner has approved it.[100]

Lived experiences of inequity justified reform. From this perspective, the government's primary solution, elevating key policy parameters from non-binding Operational Guidelines into the NDIS Rules, was presented as the logical cure for both crises. Legally binding rules would deliver consistency, ensuring similar outcomes for similar circumstances and remedying the unfairness of the "postcode lottery". This standardisation would create predictability to control costs and ensure financial sustainability.

Framed this way, the shift from discretion to rules is not a repudiation of justice, but a redefinition prioritising horizontal equity and systemic integrity over bespoke outcomes. It reflects an attempt to rein in what had become an unsustainably expensive and administratively unwieldy system while maintaining an acceptable level of support for participants. It sees centralised managerial control as the solution to the problems of street-level bureaucracy.

[100] *Independent Review* (n 6) 26.

Yet, as the next Part contends, this choice to solve administrative problems through prescriptive rule-making has profound, and paradoxical, consequences. The very mechanisms designed to create a legible and consistent system produce new forms of programmatic invisibility, and simultaneously open up new battlegrounds for legal contestation.

IV AFTERMATH: INVISIBILITY AND NEW BATTLEGROUNDS

Having identified the instruments and design choices that constrain discretion, this Part examines what those choices do in practice and traces their system-level effects in two directions. First, this legislative rebuttal entrenches 'programmatic invisibility': a state where the system cannot see or respond to participants' holistic needs. Second, it creates the potential for a 'paradox of legibility': where codification enables new forms of systemic challenge. Whether this paradox will prove durable or merely represent transitional friction remains uncertain.[101] The experience of income security programmes since the 1990s, which underwent similar transformations from discretionary to rule-based frameworks with minimal subsequent judicial contestation, suggests caution about predicting ongoing robust resistance through purposive statutory construction.[102] Nonetheless, early ART decisions reveal judicial creativity adapting to new constraints, raising the possibility that the precision introduced to foreclose discretion may generate unforeseen sites of legal challenge.

A *Programmatic Invisibility: The State's Simplifying Gaze*

At its core, programmatic invisibility is the direct outcome of the state's drive for what Scott calls 'legibility'. He argues that no administrative system can engage with a complex reality without first subjecting it to a 'heroic and greatly schematized process of abstraction and simplification'.[103] The state's gaze is necessarily a simplifying one; it is not interested in the whole person but only in 'that slice of it that interest[s] the official observer',[104] in this case, a fiscally containable impairment. The NDIS reforms, particularly the 'accepted impairment' gateway and lists of excluded supports, are a textbook example of

[101] The observations here are necessarily preliminary, based on the first year of decisions under the new framework. Longitudinal analysis will be required to assess whether these patterns of resistance persist.
[102] See Carney, 'Vulnerability: False Hope for Vulnerable Social Security Clients?' (n 4), documenting minimal judicial success in challenging the rule-based Disability Support Pension framework post-reform.
[103] Scott (n 16) 22.
[104] Ibid 3.

this process. They force decision-makers to see the participant not as a whole person, but as a collection of governable categories. Scott's Prussian forestry metaphor illuminates this process; complex forests were reduced to timber yields, creating 'fiscal forests' that were perfectly legible but ecologically doomed.[105] Similarly, the NDIS reforms create 'fiscal participants': administratively legible but humanly impoverished representations of complex lives.[106] Thus the new architecture forces decision-makers to view a person as a collection of discrete, siloed impairments, consistent with a model that locates disability as a deficit within the individual. This fragmentation represents the legislative entrenchment of a medical model of disability.[107] This contrasts with the social model of disability, which understands 'disability' as the interaction between an individual's impairment and an inaccessible society.[108] The NDIS review jurisprudence had, through its emphasis on holistic assessment and contextual need, moved the scheme closer to the social model the NDIS claimed to embrace.[109] The reforms, by compelling a narrow focus on the 'accepted impairment', reverse this trajectory.

Tsao and NDIA illustrates the operation of programmatic invisibility.[110] Mr Tsao, who has severe vision impairment, was denied funding for physiotherapy for debilitating back pain and psychiatric support. The ART's reasoning was straightforward; these needs did not arise from his 'accepted disability', the vision impairment that granted him access to the scheme.[111] The new s 34(1)(aa) legally required the ART to ignore that Mr Tsao is a whole person whose back pain affects his mobility just as profoundly as his vision loss. The system could see only the single impairment through which he entered, rendering his other needs programmatically invisible. To have the decision-maker consider support needs relating to his additional disabilities — the existence of which was unchallenged — Mr Tsao would have to repeat the onerous application and assessment process he had already navigated for his 'accepted disability'.[112] *Sparkes and NDIA* replicates this fragmentation, where physiotherapy for physical conditions was

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[105] Ibid 12.
[106] A tendency observed even pre-reform in Carney et al (n 1).
[107] See Fleur Beaupert, Linda Steele and Piers Gooding, 'Introduction to Disability, Rights and Law Reform in Australia: Pushing beyond Legal Futures' (2018) 35(2) *Law in Context* 1.
[108] Mike Oliver, 'The Social Model of Disability: Thirty Years On' (2013) 28(7) *Disability & Society* 1024, 1024.
[109] Samantha Cooms, 'Decolonising Disability: Weaving a Quandamooka Conceptualisation of Disability and Care' (2025) 40(2) *Disability & Society* 235, 238.
[110] *Tsao and CEO, National Disability Insurance Agency* [2025] ARTA 235.
[111] Ibid [67].
[112] Ibid [66].

denied because the applicant's scheme access was based on Autism Spectrum Disorder.[113] Thus the reformed NDIS compels decision-makers to 'see' the participant as a collection of unrelated impairments rather than an integrated human navigating complex, interconnected challenges. The human cost of this administrative neatness is clear: a person's undisputed needs are rendered legally irrelevant, forcing them to endure multiple, onerous application processes to have their whole self recognised by the scheme.

The entrenchment of programmatic invisibility extends beyond individual planning decisions to the review architecture. Previously, the AAT undertook an 'intense factual assessment' of individual circumstances,[114] but the new framework replaces factual inquiry with categorical classification. This shift is exemplified by comparing pre and post-reform decisions. In *MPPZ and NDIA*,[115] Deputy President Mischin conducted a thorough analysis of whether funding for a sex worker was reasonable and necessary, examining evidence about the participant's specific circumstances, therapeutic goals, and support needs. The question was entirely factual: did this participant, in their specific situation, require this support to achieve their goals?[116] Post-reform, nuanced analysis is foreclosed. In *Habib and NDIA*,[117] a health retreat request is dismissed not through factual inquiry but through classification: retreats are on the excluded list.[118] In *Chamberlin and NDIA*,[119] an archery kit is refused because it falls within 'standard recreational equipment'.[120] The ART cannot ask whether this equipment is therapeutically necessary for this person. The decision-maker's role is thus transformed: from an evaluator of human need to a mere taxonomist, tasked only with assigning a requested support to its correct regulatory box.

B *The Paradox of Legibility: How Rules Create Resistance*

The mechanisms designed to entrench programmatic invisibility generate an unexpected consequence: the paradox of legibility. While Scott's work details how subordinate groups resist state power through 'infrapolitics', the subtle, undeclared acts of non-compliance that operate in the gaps of state

[113] *Sparkes and CEO, National Disability Insurance Agency* [2025] ARTA 561.
[114] *WRMF* (n 53) [152].
[115] *MPPZ and National Disability Insurance Agency* [2024] AATA 3563.
[116] Ibid [23].
[117] *Habib and National Disability Insurance Agency* [2025] ARTA 483 ('*Habib*').
[118] Ibid [78], [80]–[82], [160]–[164].
[119] *Chamberlin and National Disability Insurance Agency* [2025] ARTA 582 ('*Chamberlin*').
[120] Ibid [36]–[39].

surveillance,[121] the NDIS reforms reveal a different form of resistance, one uniquely adapted to the modern administrative state. By transforming discretionary soft law into prescriptive hard law, the state makes its power perfectly legible. In doing so, it inadvertently creates clear, hard targets for legal contestation. The lines of the state's own grid become the front lines of legal resistance. What was meant to be a shield becomes a map for strategic litigation.

Rock and Weeks, distinguishing between applicants seeking individual redress and those pursuing systemic reform, articulate a framework for understanding the operation of this paradox in the Australian context.[122] The old NDIS, with its vast body of soft law and case-by-case discretion, was primarily amenable to individual challenges. Each adverse decision was sui generis, based on particular facts. The aggregation of hundreds of AAT decisions created a discernible body of precedent and principle, but each case remained an isolated dispute about individual circumstances. The new system, by codifying exclusionary policies into hard legal rules, transforms them from administrative preferences into legislative instruments susceptible to judicial review on grounds of validity, interpretation, and application. The reforms create new procedural vulnerabilities. Binding NDIS Rules are legislative instruments that must comply with the *Legislative Instruments Act 2003* (Cth), subjecting them to disallowance and enhanced judicial scrutiny. Each prescriptive rule creates a 'jurisdictional fact': a determination that, if wrongly made, can invalidate the entire decision.[123] The paradox of legibility reveals a truth about administrative law; precision and accountability exist in tension. The more precisely executive power is exercised through formal legal instruments, the more it can be seen, challenged, and potentially invalidated by courts maintaining the rule of law.

1 *Resistance in Action: Policing Boundaries and Unbundling Supports*

Early ART decisions reveal a strategy of using purposive statutory construction to resist a purely classificatory logic, ensuring exclusionary rules do not defeat the disability-specific purpose of the NDIS Act. In *QGRY and NDIA*,[124] the ART confronted whether kitchen modifications for a vision-impaired participant constituted excluded 'standard home repairs'.[125] The NDIA advocated for literal

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[121] James C Scott, *Domination and the Arts of Resistance: Hidden Transcripts* (Yale University Press, 1990) 198.
[122] Ellen Rock and Greg Weeks, 'Getting What You Want from Administrative Law' (2023) 108 *AIAL Forum* 88, 90–1.
[123] *Timbarra Protection Coalition Inc v Ross Mining NL* (1999) 46 NSWLR 55, 64 [38].
[124] *QGRY and National Disability Insurance Agency* [2025] ARTA 598.
[125] Ibid [223].

interpretation; modifications to a kitchen are home repairs, which the NDIS Rules exclude. The ART rejected this approach, reasoning that modifications required *because of* disability-related functional deficits cannot be 'standard'.[126] This interpretive move re-establishes the nexus to disability as determinative, pushing back against classification by label alone. This resistance through interpretation extends across multiple categories. In *Eastham and NDIA*, the ART refused to accept that a mobility scooter designed for a person with disability could be classed as a 'standard scooter' under recreational exclusions.[127] Again, the ART focused on purpose and function rather than nomenclature. These decisions demonstrate judicial insistence that exclusionary rules cannot be applied in ways that would defeat the NDIS Act's beneficial purpose — a technique of resistance through statutory construction.

The most sophisticated interpretive resistance involves 'unbundling' requested supports to identify fundable components within excluded categories. *WWWX and NDIA* exemplifies this approach.[128] The ART accepted that swimming lessons generally fall within the excluded category of 'recreational activities'.[129] However, it distinguished between the standard cost of group lessons and the additional expense of one-on-one instruction needed by WWWX. This differential, incurred solely due to disability, was deemed a distinct, fundable support.[130] The ART funded the essential support without directly contravening the exclusionary rule, demonstrating its capacity to work within the statutory constraints while achieving individualised justice.

2 *The Persistence of Merits Review: Where Discretion Survives*

The legislative rebuttal did not eliminate merits review entirely; it corralled it. Where the new rules are silent, particularly regarding the quantum and configuration of non-excluded supports, the ART's robust, evidence-based analysis continues unabated. The contrast with simple classification cases is stark. In *Habib* and *Chamberlin*, the inquiry ends at categorisation; health retreats and archery equipment are excluded, full stop. But for supports not captured by bright-line rules, the ART continues the AAT's tradition of intense factual analysis. Specialist disability accommodation disputes exemplify this. In *Flack and NDIA*[131]

[126] Ibid [224]–[226].
[127] *Eastham and National Disability Insurance Agency* [2025] ARTA 198.
[128] *WWWX and National Disability Insurance Agency* [2024] ARTA 285.
[129] Ibid [324]–[331].
[130] Ibid.
[131] *Flack and CEO, National Disability Insurance Agency* [2025] ARTA 456.

and *CBYW and NDIA*,[132] the ART conducted multi-day hearings examining expert evidence about housing models. The statutory criterion of 'value for money' became the vehicle for traditional merits review: weighing evidence, assessing credibility, and determining the best supports for the participant's needs. Similarly, *XMTW and NDIA* saw the Deputy President undertaking analysis of competing occupational therapy reports about bathroom modifications, with the 'value for money' criterion enabling consideration of design options, safety, and utility.[133]

These cases prove that the legal model of administrative justice endures where rules permit. The ART uses the same methodologies as the pre-reform NDIS review jurisprudence: careful fact-finding, expert evidence evaluation, and reasoned justification for preferring one outcome. This approach's persistence for non-excluded supports creates a two-track system: mechanical classification for rule-based exclusions, detailed merits review for everything else.

3 *The Rule of Law in Transition*

The transition to the new framework has generated contests over rule of law principles. *Deayton v NDIA* represents the Federal Court's defence of legal finality against retrospective rule changes.[134] Mr Deayton had won his AAT case before the reforms, with the AAT remitting the matter to the NDIA with directions to fund supports. The NDIA delayed implementation until after the new NDIS Rules took effect, then argued that the Transitional Rules prevented funding supports now excluded.[135] Justice Hill's rejection was emphatic. Her Honour found the savings provisions deliberately preserved pre-commencement decisions' legal effect.[136] To hold otherwise would produce 'arbitrary or anomalous' outcomes where participants' vested rights depended on administrative processing speed.[137] The decision establishes a clear boundary; final judicial and quasi-judicial determinations create rights that subsequent legislative changes cannot retroactively defeat.

Yet *LFKZ and NDIA*[138] demonstrates this protection's limits. There, a plan approved under old law included certain supports, but a new plan under new rules validly removed them. The ART distinguished *Deayton* on the basis that

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[132] *CBYW and National Disability Insurance Agency* [2025] ARTA 548.
[133] *XMTW and CEO, National Disability Insurance Agency* [2025] ARTA 107.
[134] *National Disability Insurance Agency v Deayton* [2025] FCA 562 ('*Deayton*').
[135] Ibid [131].
[136] Ibid [136].
[137] Ibid [128].
[138] *LFKZ and National Disabilty Insurance Agency* [2025] ARTA 558.

administrative plan approvals, unlike tribunal decisions, create no vested rights. Plans are subject to review and variation; once superseded, they cease having legal effect. These cases delineate the rule of law's boundaries in transitional space: final adjudicative decisions receive protection; administrative decisions remain vulnerable.

The ART has also vigorously defended judicial hierarchy against attempts to relitigate settled principles. In *Klewer and NDIA*, following Federal Court remittal, both parties argued that the Federal Court was wrong and invited the ART to ignore its findings.[139] Deputy President O'Donovan's refusal was emphatic. Accepting that invitation 'would show a distinct lack of respect for the respective tasks that the Parliament has assigned to the tribunal and to the Federal Court'.[140] This assertion of institutional boundaries demonstrates the judiciary's determination to maintain coherent legal order despite legislative upheaval.

C *Surveying the New Landscape*

These forms of resistance (interpretive creativity, persistent merits review, and defence of procedural foundations) reveal an administrative law system adapting to new constraints while preserving core commitments. They demonstrate the paradox of legibility in action. Each interpretive dispute about categorical boundaries, each contest over quantum where categories do not apply, and each procedural challenge to transitional arrangements is enabled by the precision the reforms introduced. The government's attempt to create certainty may instead have multiplied the sites of legal contestation, creating new doctrinal flashpoints that could prove harder to manage than the principled discretion they replaced. This resistance preserves space for individualised, contextual decision-making that programmatic invisibility seeks to foreclose. It maintains administrative law's commitment to substantive justice within a system designed for mechanical application. Ultimately, it reveals that the foundational tension between rules and

[139] *Klewer and National Disability Insurance Agency* [2025] ARTA 155 ('*Klewer*'); *Klewer v National Disability Insurance Agency* [2023] FCA 630. The Federal Court decision in 2023 set aside an AAT decision with respect to Mr Klewer's Statement of Supports, and remitted it for rehearing. On rehearing, the parties raised an issue regarding the time from which any alteration to Mr Klewer's plan would take effect. The ART found that, even where subsequent decisions had cast some doubt on the correctness of the Federal Court's decision on that issue, 'in circumstances where a question of law which arises in these proceedings has been considered and resolved by the Federal Court, [the ART] should treat the question as settled for the purposes of these proceedings and apply the facts to the law as determined by the Court' (at [38]).

[140] *Klewer* (n 139) [37].

discretion cannot be resolved by an act of Parliament. It can only be displaced, destined to re-emerge on new doctrinal terrain.

V CONCLUSION

The transformation of the NDIS marks a decisive retreat from discretion towards prescription, revealing the inherent instability of principle-based systems when confronted with "wicked problems". While this analysis has critiqued the consequences of this shift, it acknowledges a foundational premise of the reforms; the pre-2024 scheme was, by many measures, unsustainable. The central issue this paper has explored, then, is not the need for change, but the nature of the choice made: whether the government's legislative rebuttal, in hardening soft law to achieve consistency, has sacrificed the individualised judgement essential for justice.

The original NDIS architecture, built on the 'reasonable and necessary' standard, created vast discretionary space that generated conflict. When the NDIA failed to operationalise this discretion fairly or consistently, the Federal Court and AAT forged a body of principles emphasising individualised assessment, holistic support, and collaborative process. This intervention was necessary, fulfilling the administrative continuum's promise that merits review would address defects in primary decision-making. By transforming soft law guidelines into binding legislative instruments, creating categorical exclusions, and mandating fragmented assessment through the 'accepted impairment' gateway, the reforms fracture the administrative continuum. By design, these mechanisms sever the feedback loop whereby merits review of individual cases could inform and shape administrative practice. This is not merely technical law reform but a fundamental reconceptualisation of disability support administration that prioritises actuarial certainty over individual justice.

This transformation generates two profound consequences in productive tension. First, it creates 'programmatic invisibility', a state where the system cannot see or respond to participants' holistic needs. The reformed architecture legally mandates a fragmented view of the person, forcing decision-makers to parse integrated human experiences into discrete, fundable categories, and to assess a participant's interconnected disabilities only as isolated, separate impairments. This is not an unintended consequence but the logical endpoint of a system designed to transform human complexity into governable administrative categories. Yet this attempt to achieve administrative control generates the second consequence: the 'paradox of legibility'. The transformation of discretionary policies into precise legal rules, intended to insulate

decision-making from judicial scrutiny, creates new and potentially more powerful avenues for legal challenge. Every categorical exclusion requires definition; every definition creates boundaries; every boundary becomes a site of contestation. The shift from soft to hard law triggers enhanced judicial scrutiny and opens possibilities for systemic challenges that transcend individual cases. What was meant as a shield becomes a target.

The post-reform resistance cases demonstrate this paradox in operation. Judicial creativity has not disappeared but relocated: from articulating broad principles to policing categorical boundaries, from defining 'reasonable and necessary' to interpreting 'standard recreational equipment'. The proliferation of interpretive disputes, procedural challenges, and creative 'unbundling' strategies reveals a fundamental truth of administrative law. The tension between rules and discretion cannot be resolved through legislation; it can only be displaced. The NDIS presents a different pathology of executive power than the unlawful automation of Robodebt. Where Robodebt represented illegal defiance of administrative law principles, the NDIS reforms represent their lawful circumvention. This may prove the more dangerous precedent. It offers a playbook for future governments, demonstrating how to achieve ends similar to Robodebt not through unlawful administrative action, but through the powerful, and entirely lawful, tool of legislative reform.

This is not to argue that the reforms are universally negative or that external review is extinct. Indeed, the persistence of robust merits review where rules permit shows that oversight continues in the new system's cracks. While the scheme may benefit participants whose needs align with its new categories, my core contention is that the structural logic of the administrative architecture has fundamentally transformed. The question is whether Australian public law can develop adequate doctrinal tools for this new challenge. A focus on individual errors and procedural fairness seems ill-equipped to address legislatively mandated systemic blindness. The early post-reform cases suggest judicial ingenuity persists, but within narrowing channels. The interplay between programmatic invisibility and the paradox of legibility will define the evolving character of Australian administrative justice, testing the judiciary's ability to protect the individual when the state's simplifying gaze is enshrined in law.

BOOK REVIEW

THE MAKING OF MEDICAL PRODUCTS REGULATION SCHOLARSHIP IN AUSTRALIA

PENNY GLEESON, *THE REGULATION OF MEDICAL PRODUCTS: DOPE, DRUGS AND DEVICES* (ROUTLEDGE, 2025)

MARCO RIZZI *

I INTRODUCTION

Medical products (or 'therapeutic goods' in the language of Australian law)[1] include a vast array of products. Medicines, or pharmaceutical products, range from over-the-counter products, such as paracetamol, to biologicals and vaccines. Medical devices range from simple band aids to implantable smart technologies. Combined medical products are some of the most heavily regulated goods to hit large consumer markets worldwide. Medicines for human use constitute one of

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[1] *Therapeutic Goods Act 1989* (Cth) s 3. For consistency with the title of the monograph under review, this essay will refer to 'medical products'.

the oldest fields of product-specific regulatory governance,[2] while medical devices have been playing catchup, piggybacking on the development of regulatory frameworks for the governance of general products.[3] Yet, despite its centrality to any modern society, thus far the field of medical products regulation has received scant attention in Australian legal scholarship. Rather than establishing itself as a distinct object of critical analysis, regulation of medical products has tended to feature in legal research in a functionalist and fragmented way, discussed with reference to specific sub-topics raising questions about the regulatory framework's fitness for purpose in select contexts.[4]

The monograph by Penny Gleeson, *The Regulation of Medical Products: Dope, Drugs and Devices*,[5] constitutes a first attempt to dissect the Australian regulation of medical products as a standalone corpus of norms. It does so through the analytical lens of political legitimacy and puts forward a set of normative conclusions with potentially far-reaching implications for the future of the field in Australia, and possibly beyond. The book is indubitably timely. Trust in both science and public health authorities is under significant strain,[6] while at the

[2] See, eg, Antoine Cuvillier, 'The Role of the European Medicines Evaluation Agency in the Harmonisation of Pharmaceutical Regulation' in Richard Goldberg and Julian Lonbay (eds), *Pharmaceutical Medicine, Biotechnology and European Law* (Cambridge University Press, 2000); Arthur Daemmrich, *Pharmacopolitics: Drug Regulation in the United States and Germany* (University of North Carolina Press, 2004).

[3] As discussed, in the Australian context, by Julia Symons and Marco Rizzi, 'Consumers or Patients? Medical Device Recipients under Australian Law Straddle Two Worlds' (2023) 30(3) *Journal of Law and Medicine* 572, 575, referring to the broader discussion of regulatory developments for medical devices in Paul Verbruggen and Barend Van Leeuwen, 'The Liability of Notified Bodies under the EU's New Approach: The Implications of the PIP Breast Implants Case' (2018) 43(3) *European Law Review* 394; and Marco Rizzi, 'The Court as Pontius Pilate: Reflecting on Missed Opportunities in the PIP Decision' (2017) 1(1) *European Pharmaceutical Law Review* 42.

[4] Some examples include Chris Rudge and Cameron Stewart, 'Injecting Tighter Regulation: Implications of the TGA's Clampdown on Cosmetic Injectables Advertising' (2024) 31(3) *Journal of Law and Medicine* 464; Chris Rudge et al, 'A New Priority Pathway for Biologicals in Australia: Contextualising and Evaluating the Proposed Reforms' (2022) 29(3) *Journal of Law and Medicine* 677; Eimear Reynolds, 'Machine Learning-Integrated Medical Devices in Australia: Safety Defects and Regulation' (2024) 50(3) *Monash University Law Review* 466; Marco Rizzi, Penny Gleeson and Jeannie Marie Paterson, 'Floors and Ceilings: Coordination, Coherence and Consistency in the Relationship between Therapeutic Goods Regulation and Consumer Protection' (2024) 47(2) *Melbourne University Law Review* 466; Tatiana Aranovich, Rita Matulionyte and Farah Magrabi, 'Detangling AI Transparency in the Medical Regulation Space' (2025) 32(2) *Journal of Law and Medicine* 382.

[5] Penny Gleeson, *The Regulation of Medical Products: Dope, Drugs and Devices* (Routledge, 2025).

[6] News reporting on constant slashing of funding and job cuts affecting key United States ('US') health institutions have become too many to recount. A recent summary can be found here: Peter Gwynne, 'The United States Faces and Assault on Science' (2025) 68(6) *Research-Technology Management* 95.

same time blind faith in innovation can sweep aside legitimate concerns.[7] In this context, scholarly works like Gleeson's book set the scene for researchers and policymakers alike to rethink established modes of regulatory governance and their normative underpinnings, in a quest to ensure decision-making is both technically robust and politically legitimate.

The book develops its argument across six substantive chapters. Chapter 2 outlines the substance and historical development of what Gleeson identifies as the underlying ideologies of therapeutic goods regulation: scientism and technocracy. Chapter 3 delves into the many ways political legitimacy has been conceptualised in the literature and proceeds to develop its own 'constant dialogic approach'.[8] This is then used as a lens to assess the legitimacy of the Australian regime of medical products regulation against the backdrop of three complex case studies: the regulation of medicinal cannabis in ch 4; the regulation of the abortifacient drug RU486 in ch 5; and the regulation of urogynaecological mesh devices in ch 6. In ch 7, Gleeson reflects on the learnings of these case studies and proposes a shift in the ideological architecture of medical products regulation, which she argues should be grounded in the concept of 'regulatory courage'.[9]

It bears noting from the outset that a key strength of Gleeson's work is that it does not attempt to fix practical problems at any cost. Instead, it raises crucial first-order questions interrogating the political legitimacy of medical products regulation and provides in-depth reflections whilst avoiding any pretence of conclusive solutionism. Her contribution is therefore of the greatest practical relevance, as it prompts us to rethink ideological assumptions and normative hierarchies that have long dominated the field, and thereby critically engage with its future direction.

[7] For example, the risks of blind faith in the potential of AI clinical tools are discussed in this issue by Jane Chin, Meredith Blake and Marco Rizzi, 'Civil Liability for AI Clinical Tools in Western Australia: A Critical Overview'. The issue of techno-utopianism in health has been explored for example by Deborah Lupton, 'Beyond Techno-Utopia: Critical Approaches to Digital Health Technologies' (2014) 4(4) *Societies* 706.
[8] Gleeson (n 5) 52.
[9] Ibid 217.

II THE PREMISE: SCIENTISM AND TECHNOCRACY AS THE CURRENT STATUS QUO

The modern history of therapeutic goods regulation, and particularly pharmaceutical products, is rooted in the aftermath of two significant drug disasters.[10] The first involved a compound known as Sulfanilamide, which was imported to the United States ('US') from Germany in the early 1930s for the treatment of streptococcal infections. To turn the drug into syrup form for sale in the US market, the compound was mixed with a solvent, diethylene glycol. This untested formulation was sold in a number of US states and resulted in over one hundred deaths in 1937.[11] The ensuing adoption of the *Food Drug and Cosmetic Act*[12] in 1938 constituted a critical milestone in the establishment of the modern US Food and Drug Administration ('FDA') and its regulatory powers, with a view to introducing scientifically rigorous testing ahead of marketing new products.[13] A broadly equivalent move occurred in Europe in the mid 1960s, with the adoption of the first European Directive dedicated to the harmonisation of legal, regulatory, and administrative requirements leading to the marketing of human medicines in the European common market.[14] This was primarily in response to the well-known Thalidomide tragedy, which saw tens of thousands of children born with severe birth defects across a number of countries (primarily Germany) as a result of Thalidomide being prescribed to pregnant women to treat morning sickness.[15]

What both stories have in common is that they functioned as catalysts for the development and refinement of pharmaceutical product regulation in the two regions that have been, historically at least, the primary markets and innovation hubs for these products.[16] Specifically, both events were instrumental to the

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[10] 'Drug disaster' is a common phrase to describe incidents involving large numbers of patients harmed by a particular medicine.

[11] David F Cavers, 'The Food, Drug and Cosmetic Act of 1938: Its Legislative History and its Substantive Provisions' (1939) 6 *Law and Contemporary Problems* 2, 20.

[12] *Food Drug and Cosmetic Act*, 21 USC ch 9 § 301 et seq (1938).

[13] Harry M Marks, *The Progress of Experiment: Science and Therapeutic Reform in the United States, 1900–1990* (Cambridge University Press, 1997) 73–77.

[14] *Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products* [1965] OJ 22/369.

[15] A first historical account can be found in Harvey Teff and Colin Munro, *Thalidomide: The Legal Aftermath* (Saxon House, 1976).

[16] In recent years, China has overtaken Europe, but historically the US and Europe have been the primary markets and innovation hubs for pharmaceutical products. See, eg, the report by the European Federation of Pharmaceutical Industries Association, *The Pharmaceutical Industry in Figures* (Key Data, 2025) 4.

inception of bespoke regulatory frameworks with a set of common characteristics. The nascent frameworks, though roughly 30 years apart, emphasised the centrality of technical scientific expertise as both an anchor for their legitimacy and a necessary premise for their effectiveness. This development continued steadily throughout the 20th century, progressively becoming the dominant model of governance of pharmaceutical products.[17] Gleeson succinctly addresses this historical trajectory in the US, Europe and Australia in ch 2,[18] where she lays down the conceptual premise of the entire book. She subsequently revisits this premise and further unpacks its problematic implications in ch 7 when developing her alternative normative paradigm.

Gleeson argues that the regulation of medical products is predominantly rooted in the two germane 'ideologies' of 'scientism' and 'technocracy'.[19] It is of note, from a semantic perspective, that Gleeson chooses the term 'ideology' instead of, for example, 'concept'. While the rationale for this choice is never explicitly tackled, it is coherent with the overall argument of the book, premised on the observation that both terms are inherently value laden.

Scientism stands for the proposition that 'science is the pinnacle of human thought'.[20] While initially anchored to the rationalist tradition born out of the Enlightenment in the 17th century, scientism as described by Gleeson is less a creature of rigorous rationality and more a product of ideological thinking. A quote by Richard Williams encapsulates the nature of scientism as entailing

> a zealous metaphysical commitment and a requisite orthodoxy in method and in thought regarding the nature of the world and how understanding of the world is to be approached.[21]

Crucially, Gleeson's issue with scientism is not its commitment to science and the scientific method as a primary source of evidence for decision-making in a field permeated by high levels of technical complexity such as the regulation of medical products. Rather, she laments what she terms the 'dominance of scientism in

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[17] This is discussed for example in Daemmrich (n 2) 151. The global implications are the object of several scholarly contributions including Sabrina Röttger-Wirtz, *The Interplay of Global Standards and EU Pharmaceutical Regulation: The International Council for Harmonisation* (Hart Publishing, 2021), and before that Marco Rizzi, 'Non-Measurable Negotiations: The EU between Transnational Regulation of Pharmaceuticals and Private Law' in Marise Cremona and Hans-W Micklitz (eds), *Private Law in the External Relations of the EU* (Oxford University Press, 2016) 273.

[18] Gleeson (n 5) 29–52.

[19] Ibid 27.

[20] Ibid, referencing Tom Sorell, *Scientism: Philosophy and the Infatuation with Science* (Routledge, 1991) 1.

[21] Gleeson (n 5) 27, quoting Richard N Williams, 'Introduction' in Richard N Williams and Daniel N Robinson (eds), *Scientism: The New Orthodoxy* (Bloomsbury, 2015) 1, 4.

relation to the *content* of the knowledge and expertise on which the regulatory regime relies'.[22] This dominance, she warns, can degenerate into two fallacies: first, 'epistemic arrogance'[23] — the misplaced conviction that hard sciences can solve all regulatory problems; and secondly, 'epistemic scarcity'[24] — the limitation of types of knowledge the regulatory regime is allowed to draw upon to resolve what are, ultimately, societal problems. An example may assist to illustrate the point.

It is common knowledge that, under standard atmospheric pressure, water boils when it reaches 100°C. This replicable observation is a good example of a 'pure' scientific fact.[25] While replicable observations are a critical component of the evidence base used in regulatory decision-making about the safety and efficacy of medical products, the reality is more complex. First, there is the question of how the experimental settings that generate the data are designed. In the realm of pharmaceutical products, the gold standard is represented by randomised controlled clinical trials.[26] In simple terms, these trials are clinical studies in which neither the participants nor the researchers know who is receiving the experimental treatment and who is receiving a placebo or control. The idea behind this design is to eliminate bias in treatment administration and outcome assessment, ensuring more reliable and objective results.[27] While there is no doubt that observing a randomised controlled clinical trial will provide scientists with important data as to the safety and efficacy of the experimental treatment, a plethora of decisions influences how such results are generated. These include criteria for the selection of participants in the trial, the duration of the trial, etc. It is, however, the subsequent step that really distinguishes a 'pure' scientific fact from what has become known as 'regulatory science':[28] the assessment that, based on clinical trial data available, the experimental treatment is safe and effective. This assessment involves an unavoidable measure of judgement, which is not reduceable to a scientific observation. Yet, as scientism progressively became the orthodoxy in medical products regulation, other forms of knowledge equally relevant to the formulation of this kind of judgement became effectively ostracised, as further discussed below. This is particularly well exemplified by the

[22] Gleeson (n 5) 21.
[23] Ibid 210.
[24] Ibid (n 5) 212.
[25] Though even this simple fact is subject to debate: see Hasok Chang, 'The Myth of the Boiling Point' (2008) 91(3) *Science Progress* 219, 220.
[26] Jonathan Cook, *An Introduction to Clinical Trials* (Oxford University Press, 2023) 51.
[27] Ibid.
[28] Sheila Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (Harvard University Press, 1990) 76.

case studies conducted in chs 4 and 5 of the book, focused on medicinal cannabis and the RU486 pill respectively.[29]

The second ideological premise of the regulatory framework for medical products, complementary to scientism, is that of technocracy, which stands for the proposition that governance should be in the hands of experts.[30] The legitimacy of this form of governance lies in the high levels of technical knowledge possessed by those in charge, and in the neutral or apolitical nature of that expertise.[31] While scientism affects the content of the knowledge relied upon by those in charge, technocracy defines the '*approach* to expertise'. Gleeson describes this approach as 'both directive (professing certainty and neutrality) and unilateral (excluding other voices and knowledge)'.[32] This observation echoes a broader literature on technocracy, which identifies a crucial vulnerability of this approach in its assumption that 'there is no alternative'[33] to the course of action identified by technocratic governance reliant on exclusionary forms of knowledge defined by scientism.[34]

Having identified scientism and technocracy as the problematic premises of the current regulatory framework for medical products, Gleeson spends the rest of her book corroborating her claim, and building an alternative approach grounded on an inclusive and dialogical interpretation of political legitimacy.

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[29] Gleeson (n 5) 78, 112.
[30] Ibid 28.
[31] This issue is widely discussed in regulatory theory. See for example the classic argument on technocracy developed by Giandomenico Majone, 'Regulatory Legitimacy' in Giandomenico Majone (ed), *Regulating Europe* (Routledge, 1996) 284–301. This position has long been criticised: see, eg, Sheila Jasanoff, 'Ordering Knowledge, Ordering Society' in Sheila Jasanoff (ed), *States of Knowledge: The Co-Production of Science and Social Order* (Routledge, 2006) 13; Elisabeth Fisher, 'Expert Executive Power, Administrative Constitutionalism and Co-Production: Why They Matter' in Maria Weimer and Anniek de Ruijter (eds), *Regulating Risks in the European Union: The Co-Production of Expert and Executive Power* (Hart Publishing, 2017) 37.
[32] Gleeson (n 5) 21.
[33] On the history and fallacy of this approach, see Jake A Scott, "There Is No Alternative"? The role of depoliticisation in the emergence of populism' (2022) 42(3) *Politics* 325. The issue is contentious even in scientific debates: see, eg, Richard Dawid, Stephan Hartmann and Jan Sprenger, 'The No Alternatives Argument' (2015) 66(1) *British Journal for the Philosophy of Science* 213.
[34] Further to the reference at n 33, on the broader societal consequences of a 'There Is No Alternative' approach see also Benjamin Farrand and Marco Rizzi, 'There is No (Legal) Alternative: Codifying Economic Ideology Into Law' in Eva Nanopoulos and Fotis Vergis (eds), *The Crisis behind the Eurocrisis: The Eurocrisis as a Multidimensional Systemic Crisis of the EU* (Cambridge University Press, 2019) 23.

III THE ARGUMENT: REDRAWING LEGITIMACY THROUGH CONSTANT DIALOGUE AND REGULATORY COURAGE

Building on the conceptual premise of her analysis, Gleeson develops a sophisticated evaluation of the current regulatory framework for medical products, using political legitimacy as an analytical tool, and concluding with a call for 'regulatory courage.' It is useful to unpack how the argument is built by following the structure of the book.

A *'Political Legitimacy' as an Analytical Tool*

Chapter 3 develops the analytical lens of political legitimacy through which the regulatory regime for medical product is subsequently assessed in a series of case studies. The chapter is not only a key piece of Gleeson's overall argument, but also an excellent resource for teachers of regulatory governance seeking to expose their audience to the variety of theoretical approaches to legitimacy in the regulatory context.[35] Given the level of variety in this field, Gleeson makes a clear choice, and takes as a starting point David Beetham's framework for legitimacy, which hinges on three elements: a *legality* element, requiring legitimate power to be both 'acquired and exercised in accordance with established rules');[36] a *normative* element, requiring legitimate power to be 'justified "by reference to beliefs shared by both dominant and subordinate" parties to a relationship of power';[37] and finally a *consent* element, whereby legitimate power requires 'evidence of consent by the subordinate to the particular power relation'.[38]

Having laid out Beetham's framework, Gleeson succinctly analyses a series of limitations of the model, which have to do with difficulties in its overall applicability; the inherent circularity of its normative component; its difficulties in dealing with multiple players instead of two-party settings; its insufficient attention to dominant parties' self-perception; and its excessive focus on defined points in time instead of extended timelines.[39]

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[35] In this sense, the chapter is a good companion to ch 11 of Karen Yeung and Sofia Ranchordàs, *An Introduction to Law and Regulation: Text and Materials* (Cambridge University Press, 2nd ed, 2024) 321.
[36] Gleeson (n 5) 60, citing David Beetham, *The Legitimation of Power* (MacMillan Education, 2nd ed, 2013) 64.
[37] Gleeson (n 5) 61, citing Beetham (n 36) 16.
[38] Gleeson (n 5) 62, citing Beetham (n 36) 14.
[39] Gleeson (n 5) 63–66.

The rest of the chapter builds on Beetham's model to develop an analytical understanding of political legitimacy that addresses these limitations. In essence, Gleeson proposes a framework of political legitimacy grounded on the idea of a 'constant dialogic approach'[40] — a conclusion she reaches by combining elements of Beetham's framework with Anthony Bottoms and Justice Tankebe's dialogic idea.[41] Gleeson's conclusion is that, first, '*legitimacy should be analysed as a constant dialogue*' that is not to be confined to an isolated point in time but needs to be framed as 'a *perpetual* discussion'.[42] Secondly, through this constant dialogue '*a set of shared normative beliefs and values are formulated*',[43] which moves away from Beetham's static view that beliefs need to be *shared* to begin with by parties to a power relationship, by adopting a dynamic perspective. Finally, the constant dialogue needs to take place '*between all parties to a power relationship*',[44] thereby embracing the diversity of views and beliefs held across the full spectrum of affected parties.

B *Dope, Drugs and Devices: Three Complex Case Studies*

Having developed her own concept of political legitimacy, Gleeson moves to focus on three complex case studies involving medical products to ask what each of these case studies tells us about the political legitimacy (understood as above) of medical products regulation in Australia. What all three cases have in common is that they are hard, or, as Gleeson puts it, 'characterised by public controversy and conflict'.[45] This puts them at odds with the purported neutrality of the regulatory regime that governs the relevant products, underpinned by scientism and technocracy. The choice of difficult case studies aligns with Julia Black's approach,[46] which favours hard cases over non-controversial ones as better suited to provide meaningful insights about regulatory governance. The case studies are the core of the book, where Gleeson fleshes out the legitimacy shortfalls of medical products regulatory governance in the relevant periods of time. She does so with reference to such an abundance of sources and richness of

[40] Ibid 74.
[41] Anthony Bottoms and Justice Tankebe, 'Criminology: Beyond Procedural Justice: A Dialogic Approach to Legitimacy in Criminal Justice' (2012) 102(1) *Journal of Criminal Law and Criminology* 119.
[42] Gleeson (n 5) 74 (emphasis in original).
[43] Ibid 75 (emphasis in original).
[44] Ibid (n 5) 76 (emphasis in original).
[45] Ibid (n 5) 19.
[46] Julia Black, 'Constructing and Contesting Legitimacy and Accountability in Polycentric Regulatory Regimes' (2008) 2(2) *Regulation & Governance* 137.

perspectives that the case studies cannot be adequately summarised here. Each of them is absolutely worth a full read.

In extreme synthesis, the first case study is covered in ch 4 and involves the regulation of medicinal cannabis in Australia in the period 2014 to 2018. By showcasing the diversity of views that emerged during that period of regulatory reform, the chapter shows how, in failing to engage in a constant and inclusive dialogue, the regulatory regime pushed several voices to the margins and favoured an established technocratic approach to knowledge at the expense of alternative but relevant sources.

The second case study, in ch 5, revisits the regulatory journey of the abortifacient pill RU486 between 1996 and 2012. The analysis uncovers how, by failing to embrace a dialogic approach, the regulatory regime camouflaged value laden choices as technical and neutral ones, thereby stamping out important voices and devaluing them as irrelevant — and in doing so, causing what Gleeson terms a lack of 'normative congruence'.[47]

The final case study, in ch 6, focuses on the scandal involving urogynaecological mesh devices in Australia. It follows events taking place between 2006 and 2021, which culminated with the Full Court of the Federal Court of Australia's decision in favour of the plaintiffs in the class action *Ethicon Sàrl v Gill*.[48] The chapter uncovers how failing to engage in a constant dialogic approach led to a short-circuit in the regulatory process, which was polycentric in nature, resulting in appraisals of acceptable levels of risks attached to the use of these devices by different parties that were both inadequate and ineffective.

C *The Case for a Conceptual Shift Towards a 'Science +' Approach*

Gleeson's normative argument is developed in ch 7, where the findings of the three case studies are revisited to propose an innovative way forward. The chapter begins by reassessing the book's premise in light of the case studies. This prompts Gleeson to identify two major regulatory challenges, which can be described as the natural consequences of technocracy and scientism in practice.

The first challenge is that of 'the Regulatory Regime as Expert'.[49] The section outlines how the three case studies support the claim that the regulatory regime for medical products has a track record of adopting a unilateral and directive approach to expertise. The directive approach rests on the proposition that the

[47] Gleeson (n 5) 141.
[48] (2021) 288 FCR 338, on appeal from *Gill v Ethicon Sàrl (No 5)* [2019] FCA 1905.
[49] Gleeson (n 5) 201.

knowledge underpinning the expertise has the 'ability to comprehensively and objectively solve any societal, policy or regulatory' questions,[50] no matter how complex. The premises of the directive approach to expertise are that such knowledge is both certain (if not in substance, at least in appearance), and neutral (that is, unaffected by biases of any kind). The latter has long been debunked by scholars of Science and Technology Studies, and chiefly Sheila Jasanoff,[51] whose work Gleeson builds upon. The section further explores how the case studies support the finding that the dominant approach to expertise in medical products regulation is not only directive, but also unilateral. Indeed, it operates in a primarily one-sided fashion, with technocratic decision-making allowing very little broader involvement of parties affected by regulatory decisions.

The second challenge is that of 'the Regulatory Regime as Scientist'.[52] In this section Gleeson unpacks in greater detail, and with reference to the relevant findings of her case studies, the problematic consequences of 'epistemic arrogance' and 'epistemic scarcity' that characterise a regulatory regime underpinned by scientism. For example, she refers to the exclusion of 'non-"dominant"',[53] but pertinent, sources of knowledge from the debate on medical cannabis as a form of arrogance, and to the inability of the regulatory regime to 'address the broader normative issues so obviously relevant to the regulation of abortifacients'[54] as a form of scarcity.

The outcome of the analysis in the first part of ch 7 highlights an underlying conflict between the two identified regulatory challenges and political legitimacy in the form of a constant dialogue as described above. This is not to say that the regulatory regime is irredeemably flawed. Rather, this conclusion is drawn for the purpose of making the subtler observation that complex cases require a level of nuance that cannot be catered to by rigid adherence to a purely technocratic paradigm that embraces scientism.

To break the impasse, Gleeson recommends revisiting the normative foundations of the regulatory regime for medical products by embracing 'regulatory courage'.[55] This idea, first described by Oren Perez,[56] entails the ability of regulators to value pluralism in the face of epistemic scarcity, and to provide

[50] Gleeson (n 5) 202.
[51] See, eg, Jasanoff (n 28) and (n 31).
[52] Gleeson (n 5) 210.
[53] Ibid 211.
[54] Ibid 213.
[55] Ibid 217.
[56] Oren Perez, 'Courage, Regulatory Responsibility, and the Challenge of Higher-Order Reflexivity' (2014) 8(2) *Regulation & Governance* 203.

'articulated moral justification for their choices and … take responsibility for their choices'.[57] This idea, which stands in stark contrast to technocracy and scientism, provides Gleeson with an overarching model to advocate for two regulatory evolutions in response to the two identified regulatory challenges.

The first suggested regulatory evolution, in response to the consequences of scientism, is that of 'Normative Pluralism'.[58] This stands for the proposition that the regulatory regime ought to 'recognise when dominant scientific-based norms are operating to the exclusion of other, relevant norms'.[59] In pushing back against the fallacious dichotomy between 'scientific objectivity *versus* lay irrationality',[60] Gleeson revisits Julia Black's argument for the integration of a plurality of rationalities, both scientific and non-scientific. The courage of this position lies in the recognition that scientific rationality can indeed be fallible. This may sound obvious, but it goes against deeply embedded convictions that animate regulatory frameworks governing highly technical fields. Yet, when broad societal interests are at stake, as is very much the case with medical products regulation, other forms of knowledge, ethos and rationality can (and should) play significant complementary roles. In crafting this argument, Gleeson is very conscious of exposing herself to the criticism of excessive relativism, and of 'displacing the guidance of scientific knowledge' which would make the regulatory regime 'subject to the self-interested whims of political actors'.[61] Her response is simple but authoritative. The argument put forward by the book does not aim to displace or devalue scientific expertise. Rather, the goal is to support such expertise by taking it into due consideration '*in addition* to a range of other normative perspectives and sources of knowledge'[62] — which are relevant and should not be ousted entirely, as is often currently the case.

The second evolution, very much complementary to the first and in response to the consequences of technocracy, is that of 'Facilitative Expertise'.[63] Gleeson's argument here combines Julia Black's idea of the regulator as a facilitator[64] with Sheila Jasanoff's broader contribution to the nature of scientific truth in governance. The result is a concept antithetic to directive and unilateral expertise

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[57] Ibid 212.
[58] Gleeson (n 5) 218.
[59] Ibid.
[60] Ibid 219 (emphasis in original), citing Julia Black, 'Regulation as Facilitation: Negotiating the Genetic Revolution' in Roger Brownsword, WR Cornish and Margaret Llewelyn (eds), *Law and Human Genetics: Regulating a Revolution* (Hart Publishing, 1998) 60.
[61] Gleeson (n 5) 221.
[62] Ibid (emphasis in original).
[63] Ibid.
[64] Black (n 60).

as described above. Instead, expertise is reframed as a plurality of relevant contributions that together can give rise to what Jasanoff describes as

> a serviceable truth: a state of knowledge that satisfies the test of scientific acceptability and supports reasoned decisionmaking, but also assures those exposed to risk that their interests have not been sacrificed on the altar of an impossible scientific certainty.[65]

Crucially, to meet the standards of the 'constant dialogic approach' to political legitimacy, the inclusive and facilitative model deriving from this two-fold regulatory evolution would require an ongoing practice as opposed to isolated decision-making events. And to conclude on a positive note, Gleeson recognises certain recent efforts by the Australian Therapeutic Goods Administration as indicia that the medical products regulator is attempting to embrace what she terms a 'facilitative expertise ethos'.[66] This is occurring for example via the hosting of public forums in response to safety concerns held by various interest groups, and by promoting greater inclusiveness in current regulatory reform processes.[67] While still in very early stages, the move is indeed significant.

IV CONCLUSION

The Regulation of Medical Products fills an important gap in legal scholarship. It is the first scholarly work that focuses on the Australian regulation of medical products as a standalone object of study. It does so by offering a compelling argument in support of normative developments in the political legitimacy of Australian medical products regulation. It adeptly critiques the limitations of scientism and technocracy, which have long dominated this regulatory landscape, and makes a reasoned argument for a move towards regulatory courage.

The book carefully develops this argument to emphasise the need for a constant dialogue between all parties to a regulatory relationship as a necessary anchor for the political legitimacy of the regulatory regime. This constant dialogue is premised on embracing both normative pluralism and a facilitative approach to expertise. Penny Gleeson is to be congratulated for putting forward her argument so eloquently. This is a particularly noteworthy achievement in the current global environment for medical products, dominated by both unprecedented potential for therapeutic innovation (occasionally permeated by blind faith in scientific progress) and, simultaneously, worrisome wholesale attacks on scientific

[65] Jasanoff (n 28) 250.
[66] Gleeson (n 5) 223.
[67] Ibid.

knowledge. Gleeson's sophisticated and nuanced reflection on political legitimacy is exactly the type of scholarly exercise that can function as a powerful antidote to the risks of polarisation in public health discourse. Her contribution not only enriches the academic debate, but also offers practical insights for policymakers and regulators.

This book is therefore an essential resource for anyone interested in the intersection of law, policy, and the regulation of medical products. But more generally, the arguments presented will be of great interest to anyone engaging in complex regulatory theory, whether from an academic or a practical perspective. Future research will be able to build on the foundation provided by Gleeson's powerful insights, as the political legitimacy of technical regulatory regimes will continue to raise difficult questions.

BOOK REVIEW

MICHELLE DE SOUZA, *THE REGULATION OF EMBRYO TESTING IN AUSTRALIA: A PRINCIPLES-BASED APPROACH* (SPRINGER NATURE, 2025)

STEPHAN MILLETT *

The Regulation of Embryo Testing in Australia is a scholarly, readable, relevant, timely, interesting and important book. It both lays out clearly the significant shortcomings of the current regulation of reproductive technology and provides a roadmap for regulation that could make things considerably better for those who need the assistance of technology to have a child. It is, in essence, a moral argument for a novel (national) regulatory model covering an area of complex and rapidly changing health science. De Souza's argument for a principles-based approach to assisted reproductive technology ('ART') and pre-implementation genetic testing ('PGT') legislation and regulation should be of considerable interest to all Australian health legislators and regulators as the argument is careful, nuanced and informed by insightful analyses of the ethics of ART and PGT. It is a regulatory model that might be applied more widely.

This is an important book because infertility is big business that deals with often very vulnerable people who incur significant costs in trying for a baby, and which, in Australia, operates under multiple regulatory systems. The book's focus on regulation of embryo testing is important as the embryological science and work in genetics that is fundamental to the success of ART is changing very rapidly and presenting new and often challenging choices for clinics, prospective parents, and Australian society more generally. The legislation currently governing ART and PGT in Australia is being outpaced by the science and has struggled to address adequately the multiplicity of challenges raised.

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To begin, de Souza notes that health legislation in Australia can be created by state or federal government, with federal regulation occurring only via guidelines set by the National Health and Medical Research Council (last updated in 2017) and the Fertility Society of Australia's Reproductive Technology Accreditation Committee. Regulation by the states and territories varies significantly, or in two cases is simply absent. In the face of significant change to the underlying science of, and social attitudes towards, ART and PGT, the current arrangements offer no unified response, and have resulted in gaps and inconsistencies that have denied some groups access to ART — forcing them to "shop" in jurisdictions other than their own for what they need, or to continue being denied what other Australians have access to. De Souza's proposal is a timely and deeply considered alternative.

The proposal for national regulation is timely also because industry-based governance of ART has experienced significant failures in recent years, with limited penalties, while the state-based regulatory regimes have had relatively little influence.

The core of the book and the proposed national legislative action rests on three principles:

- The Protective Principle, which seeks to ensure that future children have an 'open future' — that is, a future where they have choices as to their own wellbeing;
- The Beneficence Principle, in which prospective parents are permitted to 'act in a procreatively beneficent manner,' the main element of which is choosing an embryo that is expected to have the 'best' life; and
- The Protective Principle, applying more narrowly to Human Leukocyte Antigen ('HLA') testing. De Souza summarises this principle as follows: 'in cases where embryo testing is utilised for the purposes of creating a tissue-matched child, in order to save the life of a person who will be a family member of the future child, regard must be had for the welfare of the future child'. The Protective Principle takes priority if the principles overlap.

The Protective Principle — as proposed in the book — appears to rely on the recognition that a *future child* has a *right* to an *open future* (in which the child has choices about their own wellbeing as they grow up). However, such a right necessarily applies to something (or someone) that does not yet exist. That it needs to apply in such a way is *necessary* (with respect to PGT), de Souza argues, because not acknowledging that future children have rights will require waiting

until a child is born with a disability, and thereby suffers harms, before it is possible to take steps to address the problem. This is clearly not a simple matter, and de Souza carefully explores some of the consequences of acknowledging a 'right' to an open future for not-yet-existing children. A particularly notable example centres on whether it may be permissible to select *for* disabling conditions. For de Souza, addressing this question hinges firstly on the meaning of the term 'harm', which, following Joel Feinberg, she defines as a setback to interests; and, secondly, on whether a not-yet-existing child *can* be harmed. The interests involved are *welfare interests.* This type of interest has the effect of imposing a moral obligation on others to ensure the interests are protected, as not doing so can permit serious harms to be sustained. Answering the question of whether yet-to-exist children can be harmed (in the sense above) relies strongly on Derek Parfit's non-identity problem, in which the 'identity' of each of us depends critically on when we were conceived; if we were conceived from different gametes at a different time, we would not be the same person. That is, a child from any given embryo can only become a specific child — and not any other child. De Souza starts with this philosophical issue and explores justifications for and against parents being able to choose an embryo that will result in a child with a disabling condition. How she deals with this is exemplary of de Souza's philosophical engagement with her topic and the depth of thinking that underpins the book's arguments. Her nuanced discussion of the interests of not-yet-existing individuals concludes that it would be wrong to select deliberately an embryo which will become a child with a disabling condition if there are embryos without the condition, and that constraining the 'reproductive liberty' of people can be justified in at least some circumstances. There is more to be said on this point, and the argument is likely to be tested by informed readers. It is, however, only part of a larger argument in favour of regulating ART, and regulating it in a new way. The case for regulation does not rest on it.

The second arm of this book's principles-based approach to PGT regulation is a familiar and sturdy workhorse in health ethics, the principle of beneficence — modified to the more specific concept of 'procreative beneficence'. This is a contested concept in ART, and de Souza explains clearly some of the key points of contention before asserting that it 'is an essentially simple concept' that justifies people 'doing what they have good reason to do, and selecting an embryo that will develop into a child without a disabling condition, over an embryo that will develop into a child with a disabling condition, makes sense if it maximises that child's wellbeing'. The upshot of this for a regulatory regime is that it should permit parents to act in a procreatively beneficent manner.

The principle related to HLA testing is to respect the welfare interests of the future child. Given the preceding two principles, this may seem superfluous, but it is necessary, as choosing an embryo that is tissue-matched to a family member has the inherent risk of treating the future child only as a means to an end, rather than as an end in itself. , Specifically, there is a risk in HLA testing of selecting an embryo only to benefit an existing person. In Kantian terms, those doing so would effectively debase the "humanity" of the future child by treating the child as a "mere" means to their ends. Additionally, they would be basing their decision on a principle that it would be irrational to apply universally. Their need for a cell donor cannot be the sole justification for the creation of a child, and safeguards for the future child are warranted.

The principles-based approach outlined by de Souza is worth serious discussion, and offers an approach to regulating PGT (and ART more generally) that has sound prospects of being able to keep pace with scientific changes and social attitude changes in ways that protect the interests of future children and their families (however a family is defined).

In Australia, the state-based (and rule-based) approach to regulating PGT and ART has not been able to keep pace adequately with scientific or social change. This has resulted in some long-term inequities for those who desire or need to use ART to have a family, and in significant disparity between Australian jurisdictions.

A principles-based regulatory system is, for good reason, a worthwhile way to begin addressing inequities in Australia's governance of ART and PGT and, more generally, for addressing areas of law and ethics with "wicked" problems. Giving a statutory body with carefully chosen membership broad principles instead of a suite of rules will allow such a body to bring a (Kantian) reflecting judgment to situations for which there are no existing maxims to guide the rightness or wrongness of a decision.

The type of regulatory system argued for in this book has precedents in United Kingdom ('UK') regulation, but, for constitutional reasons, a UK model cannot be simply cut and pasted into an Australian legal environment. To resolve this, de Souza explores the usefulness of two powers in the *Australian Constitution* that might be exercised by the Commonwealth Parliament to legislate on ART and PGT: the Reference Power, and the Corporations Power. She questions whether the Reference Power would be a realistic way to bring about the relevant national

legislation and instead argues that the Corporations Power would be a better, and politically simpler option, although not straightforwardly so.

This brief review does not do justice to the clarity and depth of de Souza's clear, well-organised, and meticulous argument for an Australian national regulatory regime for ART in general and PGT in particular. The regulatory model proposed in the book deserves to be discussed, and supported, as establishing a national regulator able to respond well to wicked problems and with sufficient flexibility to engage with rapid changes in science — and social norms — is, simply, necessary.