BOOK REVIEW

THE MAKING OF MEDICAL PRODUCTS REGULATION SCHOLARSHIP IN AUSTRALIA

PENNY GLEESON, *THE REGULATION OF MEDICAL PRODUCTS: DOPE, DRUGS AND DEVICES* (ROUTLEDGE, 2025)

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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.