

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.

* Dr Millett is a moral philosopher and a former Chair of the Reproductive Technology Council of Western Australia.

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.