FLOORS AND CEILINGS: COORDINATION, COHERENCE AND CONSISTENCY IN THE RELATIONSHIP BETWEEN THERAPEUTIC GOODS REGULATION AND CONSUMER PROTECTION

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This article examines the tensions between the two Australian regimes that govern the regulation of therapeutic goods: the broad consumer protection regime of the Australian Consumer Law *and the more specific regime under the* Therapeutic Goods Act 1989 *(Cth). The authors develop three case studies of therapeutic products (hand sanitisers, vaccines and medical implants) to illustrate the challenges of consistency and coherence that may arise between the regimes. These challenges arise specifically when one regulatory regime responds to a public health crisis such as the COVID-19 pandemic. Our more general point, however, is that the regimes should act in a complementary manner, as the floor and ceiling of consumer and patient protection. This requires a coordinated and dynamic approach to regulation in order to ensure the relationship between the regimes remains coherent and consistent.*

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I Introduction

The regulation of therapeutic products[1] is at the core of any well-functioning consumer protection regime. Such products — most commonly, pharmaceuticals (including many vaccines) and medical devices — have a direct and significant impact on the health and wellbeing of consumers and patients.[2] In Australia, regulatory responsibility for these specific matters falls between two regimes: the *Therapeutic Goods Act 1989* (Cth) ('*Therapeutic Goods Act*') administered by the Commonwealth Therapeutic Goods

[1] The terms 'therapeutic products' and 'therapeutic goods' are used interchangeably in this article. The definition of a 'therapeutic good' includes goods that are, or are represented to be, for use in 'preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury'; or 'influencing, inhibiting or modifying a physiological process'; or 'testing the susceptibility of persons to a disease or ailment'; or 'the replacement or modification of parts of the anatomy in persons': *Therapeutic Goods Act 1989* (Cth) s 3 (definitions of 'therapeutic goods' para (a)(i) and 'therapeutic use' paras (a)–(d), (f)) ('*Therapeutic Goods Act*').

[2] The terms 'consumer' and 'patient' will be used in this article according to the appropriate context — for example, 'consumer' in relation to the *Competition and Consumer Act 2010* (Cth) sch 2 ('*ACL*') and 'patient' in relation to the *Therapeutic Goods Act* (n 1). There is of course extensive debate in the relevant literature about the use of the terms 'patient' and/or 'consumer': see, eg, Daniel SJ Costa et al, 'Patient, Client, Consumer, Survivor or Other Alternatives? A Scoping Review of Preferred Terms for Labelling Individuals Who Access Healthcare across Settings' (2019) 9(3) *BMJ Open* 1, 1–2.

Administration ('TGA')[3] and the *Australian Consumer Law* ('*ACL*') contained in sch 2 of the *Competition and Consumer Act 2010* (Cth) and administered by the Australian Consumer and Competition Commission ('ACCC').[4] The TGA regulatory regime aims to ensure that therapeutic products are safe and effective when they go to market according to a range of scientific standards (often described as 'pre-market' regulation).[5] The *ACL* complements this regime with a suite of general market protections that, through a liability regime, aim to ensure that consumer products are accurately represented,[6] and meet baseline standards of quality[7] and reasonable expectations of safety.[8] This article focuses on the normative tension between the pre-market regulatory regime exclusively administered by the TGA and the remedies and causes of action provided to consumers under the *ACL*.

The combined effect of these regimes is that, in most instances, consumers and patients are entitled to assume the products they buy live up to the statements made by those promoting them, and that these products will be reasonably safe and reliable. Of course, in practice, some products, and the conduct of the firms promoting them, will depart from these assumptions, and such products will be defective or their performance will have been misrepresented. In these instances, the *ACL* provides robust enforcement powers to its regulators to respond to contraventions of the *ACL*,[9] and remedial options to consumers who suffer loss or damage because of a contravention or failure to comply with the regime, including seeking damages and compensation.[10]

Consumers and patients are additionally entitled to expect that each of the pertinent regulatory regimes will work in a rigorous, consistent and coherent manner in protecting their wellbeing. This is even more the case in circumstances where there is a public health crisis and public health

[3] 'TGA Regulatory Framework', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 1 September 2020) <https://www.tga.gov.au/tga-regulatory-framework>, archived at <https://perma.cc/43NL-W7S7>.

[4] *Competition and Consumer Act 2010* (Cth) s 6A ('*Competition and Consumer Act*').

[5] *Therapeutic Goods Act* (n 1) s 4(1)(a); 'TGA Regulatory Framework' (n 3).

[6] See, eg, *ACL* (n 2) ss 18 (misleading or deceptive conduct), 29 (false or misleading representations about goods or services), 33 (misleading conduct as to the nature etc of goods).

[7] Ibid pt 3-2 div 1 sub-div A (guarantees relating to the supply of goods).

[8] Ibid pt 3-5 (liability of manufacturers for goods with safety defects).

[9] Ibid pt 5-1.

[10] Ibid pt 5-2.

imperatives demand the highest levels of confidence from consumers and patients in relation to the effectiveness and safety of therapeutic goods.[11] Coherence between the regulatory regimes in relation to therapeutic goods is therefore important to ensure that government can fulfil its role in protecting citizens' health.[12]

The core regulatory approaches to determining whether therapeutic products should go to market, whether they meet community expectations of reasonable safety, and the veracity of statements made about them, are themselves dynamic.[13] This is to be expected as community expectations and the demands of the health system change over time and in response to evolving circumstances.[14] What is unclear is whether and how the two regimes — the *ACL* and the TGA regulatory scheme — should and do interact with each other to ensure the best outcomes for patients and consumers. Thus, we see uncertainty about whether and how the two regimes ensure a consistent stance about patient and consumer protection. This was illustrated by recent class action litigation for contraventions of the *ACL* for implantable transvaginal mesh medical devices approved under the TGA regulatory regime.[15] It is equally unclear how a judicial finding of a safety defect would be considered or otherwise accommodated within the TGA's own approval processes.[16]

A mismatch between regulatory approaches introduces a risk of incoherence between the workings of the specific TGA regulatory regime and

[11] See, eg, Sheila Jasanoff and Stephen Hilgartner, 'A Stress Test for Politics: A Comparative Perspective on Policy Responses to COVID-19' in Joelle Grogan and Alice Donald (eds), *Routledge Handbook of Law and the COVID-19 Pandemic* (Routledge, 2022) 289, 289–91, 293–4.

[12] See Dorothy Porter, 'Introduction' in Dorothy Porter (ed), *The History of Public Health and the Modern State* (Clio Medica, 1994) 1, 1, citing George Rosen, *A History of Public Health* (John Hopkins University Press, 1958) 17; Dorothy Porter, *Health Citizenship: Essays in Social Medicine and Biomedical Politics* (University of California Medical Humanities Press, 2011) 204–5, 214–15.

[13] 'Product Regulation According to Risk', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page) <https://www.tga.gov.au/product-regulation-according-risk>, archived at <https://perma.cc/2HZ3-R8HD>.

[14] See, eg, Jasanoff and Hilgartner (n 11) 289–93.

[15] *Gill v Ethicon Sàrl [No 5]* [2019] FCA 1905, [1]–[15] (Katzmann J) ('*Gill*').

[16] See, eg, Therapeutic Goods Administration, Department of Health and Aged Care (Cth), 'TGA Response to Federal Court Decision on Urogynaecological Mesh Class Action' (Media Release, 26 November 2019) <https://www.tga.gov.au/news/media-releases/tga-response-federal-court-decision-urogynaecological-mesh-class-action>, archived at <https://perma.cc/G8EX-88B7>.

the standards demanded by the general consumer protection regime under the *ACL*. Moreover, there is a risk of real harm to consumers in this important field if the regulatory approaches are out of step. The purpose of this article is to draw attention to the risks of inconsistency between the regimes and the importance of regulators coordinating their approaches in regard to core overlapping responsibilities. We recognise that other sources of statutory and common law may, and do, contribute to consumer protection in relation to therapeutic goods, most notably the law of negligence.[17] However, the focus of this article is the key legislative sources of regulation of therapeutic goods, namely the TGA and *ACL* regulatory regimes, at the heart of this issue.

We recognise that, following the holding of the Full Court of the Federal Court in *Merck Sharp & Dohme (Australia) Pty Ltd v Peterson*, regulation of therapeutic goods should be understood as providing a floor, not a ceiling, when it comes to overseeing safety, quality and efficacy.[18] Relevant conduct and performance obligations under the *ACL* may well impose higher standards than required under the TGA regulatory regime leading to pre-market authorisation. Our concern, however, is that the differences between the two regimes may easily slide beyond the floor/ceiling complementary interplay and result instead in conflicting outcomes, which in turn risk compromising the overarching goal of consumer/patient protection. We additionally observe that differentiating between constructive interplay and detrimental conflict is, at its core, a normative argument and should be acknowledged as such.

We illustrate the merits of this argument as follows. Part II of this article discusses the general regulatory framework for consumer protection under the respective TGA and *ACL* regulatory regimes. Parts III, IV and V provide three in-depth case studies (hand sanitisers, COVID-19 vaccines and transvaginal mesh medical device implants) where different stances were implicit in the regulatory approaches promoted under the two regimes. Part VI discusses the merits of regulatory coherence. We then offer some concluding remarks.

[17] See, eg, *Gill* (n 15) [3608], [3624]–[3884] (Katzmann J).

[18] (2010) 184 FCR 1, 305–6 [792]–[795] (Jessup J), affd (2011) 196 FCR 145, 189–90 [161]–[163] (Keane CJ, Bennett and Gordon JJ), cited in Richard Goldberg, *Medicinal Product Liability and Regulation* (Hart Publishing, 2013) 140–2.

II Evolving Norms in Setting Reasonable Consumer Expectations

In the specific context of therapeutic goods, the general regulatory regime of consumer protection in the *ACL* operates alongside the specific approval regime administered by the TGA. However, the two regulatory regimes are driven by distinct objectives and norms. In synthesis, the TGA regulatory regime is animated by the goal of gatekeeping access to market for therapeutic goods by setting a rigorous baseline (the 'floor') for their safety and efficacy.[19] To do so, the TGA subjects the marketability of new therapeutic goods to a cost-benefit (or risk-utility) assessment epistemically grounded in 'scientism'.[20] By contrast, the *ACL* operates as a general consumer protection regime,[21] setting high standards of conduct for firms in their dealings with consumers, and with each other,[22] as well as with performance standards for the quality[23] and safety[24] of consumer products, including therapeutic ones (the 'ceiling').

A *The TGA Regulatory Regime*

The TGA forms part of Australia's overarching public health architecture. The legislative regime it oversees has two objectives relevant to this article — first, to provide for a 'national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods', and second, to provide a uniform national approach for the control and safe handling of poisons.[25]

The role of the TGA includes ensuring that therapeutic products that are supplied and marketed in Australia have been through a pre-market approval process to meet 'requisite standards of quality, safety and efficacy and/or performance'.[26] The degree of regulatory scrutiny that is applied to the

[19] *Therapeutic Goods Act* (n 1) s 4(1)(a).

[20] Penny Gleeson, 'Dope, Drugs and Devices: The Political Legitimacy of Therapeutic Goods Regulation in Australia' (PhD Thesis, The University of Melbourne, August 2020) 37.

[21] Subject to a carve out for financial services: *Competition and Consumer Act* (n 4) s 131A(1).

[22] See above n 6.

[23] See above n 7.

[24] See above n 8 and accompanying text.

[25] *Therapeutic Goods Act* (n 1) ss 4(1)(a)–(b).

[26] 'Supply a Therapeutic Good', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page) <https://www.tga.gov.au/how-we-regulate/supply-therapeutic-

evaluation of a therapeutic good generally depends on its level of risk. Where the product poses a higher level of risk, it is subject to a 'rigorous scientific evaluation of data submitted by the product sponsor' and involves the application of 'expertise from several scientific fields'.[27]

Pharmaceuticals and medical devices that meet the relevant approval requirements are included on the Australian Register of Therapeutic Goods ('ARTG').[28] The supply of a therapeutic good that has not been included in the ARTG is prohibited unless certain exceptions apply.[29] Broadly speaking, pharmaceuticals are either 'registered' on the ARTG (because they pose a higher health risk and therefore require a greater degree of regulatory control) or are 'listed' (because they pose a lower risk and therefore require less regulatory oversight).[30] All prescription medicines (as opposed to over-the-counter medicines) must therefore be registered on the ARTG before they can be supplied.[31] A similar risk-based approach applies to the regulation of medical devices,[32] which are classified as either a low to medium risk medical device (Class I and Class IIa), a medium to high risk device (Class IIb) or a high risk device (Class III).[33] The regulation of medical devices is further analysed in relation to the case study discussed below in Part V.

The TGA regulatory regime allows for provisional or temporary approval to be granted to pharmaceuticals 'where the need for early access outweighs the

good-0>, archived at <https://perma.cc/Z5HP-4XH9>. See also ibid ss 4(1)(a), (1A), 25(1)(c), 41B–41BA.

27 'Supply a Therapeutic Good' (n 26).

28 *Therapeutic Goods Act* (n 1) s 9A(1).

29 Ibid s 19B.

30 'How We Regulate Medicines', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 20 June 2019) <https://www.tga.gov.au/resources/resource/guidance/how-we-regulate-medicines>, archived at <https://perma.cc/LUA4-J5F5>. See ibid s 9A(3); *Therapeutic Goods Regulations 1990* (Cth) reg 10 ('*Therapeutic Goods Regulations*').

31 'Prescription Medicines Overview', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 18 November 2019) <https://www.tga.gov.au/resources/resource/guidance/prescription-medicines-overview>, archived at <https://perma.cc/8WXK-K77L>.

32 *Therapeutic Goods Act* (n 1) s 9A(3)(c).

33 'Medical Devices Overview', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 13 April 2022) <https://www.tga.gov.au/products/medical-devices/medical-devices-overview>, archived at <https://perma.cc/3UCY-PDR9>; ibid s 41DB; *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) div 3.1 ('*Therapeutic Goods (Medical Devices) Regulations*').

risks'.[34] A pharmaceutical product may therefore be provisionally registered on the ARTG[35] if its safety and efficacy 'for the purposes for which it is to be used have been satisfactorily established … based on preliminary clinical data'.[36] The quality of the medicine must also be established[37] and the product sponsor must have an adequate plan to 'submit comprehensive clinical data' on its safety and efficacy within six years.[38] An example of the application of the provisional approval pathway is the regulation of vaccines for COVID-19. A number of vaccines had been provisionally registered on the ARTG during the pandemic to facilitate access.[39] In comparison, the provisional approval of medical devices is not generally permitted under the TGA regulatory regime.

In addition to overseeing the 'pre-market' approval of therapeutic goods, the TGA has a vital role in monitoring the post-market performance of those goods. This is primarily achieved through the collection of information about 'adverse events' (eg side effects) that are reported by manufacturers, clinicians and the public in relation to the use of a pharmaceutical or medical device.[40]

The TGA regulatory regime also imposes controls in relation to the advertising of therapeutic products 'beyond those required for everyday consumer goods'.[41] Consequently, the regulatory regime prohibits the making

[34] 'COVID-19 Vaccine: Information for Consumers and Health Professionals', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 28 September 2021) <https://www.tga.gov.au/products/covid-19/covid-19-vaccines/covid-19-vaccine-information-consumers-and-health-professionals>, archived at <https://perma.cc/TM6F-EL2P>. See also *Therapeutic Goods Act* (n 1) pt 3-2 div 1A.

[35] *Therapeutic Goods Act* (n 1) ss 25(1)(d), (3).

[36] Ibid s 25(1)(d)(i).

[37] Ibid s 25(1)(d)(ii).

[38] Ibid s 25(1)(d)(iii).

[39] 'COVID-19 Vaccines Regulatory Status', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 14 November 2023) <https://www.tga.gov.au/products/covid-19/covid-19-vaccines/covid-19-vaccine-provisional-registrations>, archived at <https://perma.cc/J9D4-XQM3>.

[40] 'Reporting Adverse Events', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 19 August 2021) <https://www.tga.gov.au/resources/resource/guidance/reporting-adverse-events>, archived at <https://perma.cc/7ZBK-QAC7>; 'Prescription Medicines Overview' (n 31); 'Vaccines Overview', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 14 November 2023) <https://www.tga.gov.au/vaccines-overview>, archived at <https://perma.cc/P3DM-5MPP>; *Therapeutic Goods Act* (n 1) ss 29A–29C, 41FN(3)(d), 41MP–41MR; *Therapeutic Goods (Medical Devices) Regulations* (n 33) regs 5.7, 10.4–10.4AA.

[41] 'Can I Advertise This Therapeutic Good to the Public?', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page)

of certain 'false or misleading statement[s]', representations or advertisements relating to the registration or listing of a therapeutic good.[42] Therapeutic goods are subject to the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* (Cth) ('*Therapeutic Goods Advertising Code*').[43] Its purpose includes ensuring 'that advertisements are accurate, balanced and not misleading, promote the safe and proper use of the goods and are consistent with public health campaigns'.[44]

One of the key norms that guides, and is reflected by, the TGA regulatory regime is that only therapeutic goods whose benefit or utility outweighs their risk should be approved for supply to the public.[45] For example, a medical device must comply with certain 'essential principles',[46] including that '[t]he benefits to be gained from the use of a medical device … must outweigh any undesirable effects arising from its use'.[47] This 'risk-benefit' principle is also reflected in the provisional approvals granted to pharmaceuticals during periods of greater need, such as the COVID-19 pandemic.[48] In such a context, therapeutic goods may be provisionally approved because it is perceived that they offer greater benefits than the risk they pose during a particular public health crisis. The risk-benefit paradigm consistently underpins the TGA's

<https://www.tga.gov.au/resources/can-i-advertise-therapeutic-good-public>, archived at <https://perma.cc/WY2P-3M8K>. See also *Therapeutic Goods Act* (n 1) pt 5-1; *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* (Cth) s 2 ('*Therapeutic Goods Advertising Code*').

42 *Therapeutic Goods Act* (n 1) ss 21B(1), (3), 22(2)–(5).

43 *Therapeutic Goods Advertising Code* (n 41) s 5(1).

44 Ibid s 7. A significant breach of the *Therapeutic Goods Advertising Code* (n 41) may result in the cancellation of the registration or listing of a therapeutic good: *Therapeutic Goods Act* (n 1) s 30(1)(fb).

45 See, eg, 'Overview of Supplying Therapeutic Goods in Australia', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 28 August 2020) <https://www.tga.gov.au/overview-supplying-therapeutic-goods-australia>, archived at <https://perma.cc/YB3Z-V3KH>. See also *Therapeutic Goods Act* (n 1) s 25.

46 *Therapeutic Goods Act* (n 1) ss 41BA(a), 41BH; *Therapeutic Goods (Medical Devices) Regulations* (n 33) reg 2.1. The essential principles are contained in sch 1 of the *Therapeutic Goods (Medical Devices) Regulations* (n 33).

47 *Therapeutic Goods (Medical Devices) Regulations* (n 33) sch 1 cl 6; Therapeutic Goods Administration, Department of Health and Aged Care (Cth), *Clinical Evidence Guidelines for Medical Devices* (Guidelines, June 2022) 13 <https://www.tga.gov.au/sites/default/files/clinical-evidence-guidelines-medical-devices.pdf>, archived at <https://perma.cc/97NS-Q2ZE>.

48 'COVID-19 Vaccine: Information for Consumers and Health Professionals' (n 34).

regulatory regime's counterparts in other jurisdictions, such as Europe and the United States ('US').[49]

A further norm embedded in the regulatory control exercised by the TGA is that of scientism.[50] This norm dictates that 'the only reality that we can know anything about is the one science has access to' and that consequently 'what lies beyond the reach of scientists cannot count as knowledge'.[51] The scope of the TGA's regulatory field includes an exceptional number of patients' and consumers' individual and collective experiences of health and illness, and thousands of therapeutic interventions. But the TGA regulatory regime is dominated by the reduction of these persons and their experiences to objective, scientifically measurable data.[52] In this respect, commentary that the regulation of the quality and safety of the Australian healthcare system favours 'technical and professional' perspectives above those of patients and the broader public applies equally to the TGA regulatory regime.[53]

Together, these norms amount to a regulatory regime that is firmly focused on the 'scientific' attributes (or otherwise) of the therapeutic good itself and the scientific standards by which the quality, safety and efficacy of those goods are assessed.[54] The focus of the TGA regulatory regime is not the protection of the patient or consumer per se, but the analytical assessment of the risk/benefit of the therapeutic *product* to the Australian public. This, as will be seen, contrasts with the general consumer protection regime under the *ACL*. It is perhaps only in relation to the advertising of therapeutic goods that the TGA regulatory

[49] See, eg, John Johnston and Khadija Rantell, 'Clinical Efficacy and Safety: The Concept of Benefit-Risk' in Peter Feldschreiber (ed), *The Law and Regulation of Medicines and Medical Devices* (Oxford University Press, 2nd ed, 2021) 27, 50–2; 'Enhancing Benefit-Risk Assessment in Regulatory Decision-Making', *US Food and Drug Administration*, (Web Page, 15 July 2022) <https://www.fda.gov/industry/prescription-drug-user-fee-amendments/enhancing-benefit-risk-assessment-regulatory-decision-making>, archived at <https://perma.cc/PY6q-dr59>.

[50] Gleeson (n 20) 39.

[51] Mikael Stenmark, *Scientism: Science, Ethics and Religion* (Routledge, 2018) 4.

[52] Gleeson (n 20) 172–3, 184–5.

[53] See, eg, David J Carter, James Brown and Carla Saunders, 'The Patient's Voice: Australian Health Care Quality and Safety Regulation from the Perspective of the Public' (2018) 25(2) *Journal of Law and Medicine* 408, 410–13.

[54] Ibid.

regime shifts its focus from the regulated therapeutic product to the patient or consumer.[55]

B *The* ACL

In contrast to the TGA regulatory regime, the *ACL* provides a general, not sector specific, regime for consumer protection. The purposes of a consumer protection regime such as the *ACL* include promoting fair and efficient markets.[56] In furthering these purposes, the *ACL* makes extensive use of general standards (as opposed to specific rules) such as misleading conduct,[57] unconscionable conduct,[58] unfair terms,[59] acceptable quality,[60] and reasonably safe.[61] These standards are described as 'open-textured' because they are deliberately vague,[62] which requires the decision-maker to make an evaluative judgement about whether particular facts fall inside or outside the standard being set.[63] This use of open-textured standards requires 'inordinately more attention to facts than rules'[64] and a greater focus on 'situation-specific variables'.[65] The attractions of open-textured standards are in allowing courts to

[55] For example, the *Therapeutic Goods Advertising Code* (n 41) requires that an advertisement about therapeutic goods must not 'cause, or be likely to cause, undue alarm, fear or distress': at s 9(2)(a). See also at s 29.

[56] Productivity Commission (Cth), *Review of Australia's Consumer Policy Framework* (Inquiry Report No 45, 30 April 2008) vol 1, 63 <https://www.pc.gov.au/inquiries/completed/consumer-policy/report/consumer1.pdf>, archived at <https://perma.cc/C8BU-MY4A>. See also *Competition and Consumer Act* (n 4) s 2; Peter Cartwright, *Consumer Protection and the Criminal Law: Law, Theory and Policy in the UK* (Cambridge University Press, 2004) 27–8.

[57] *ACL* (n 2) s 18(1).

[58] Ibid ss 20–1.

[59] Ibid pt 2-3.

[60] Ibid s 54.

[61] Cf ibid s 9.

[62] Joachim Dietrich, 'Giving Content to General Concepts' (2005) 29(1) *Melbourne University Law Review* 218, 219.

[63] See generally Mark Leeming, 'Commercial Equity and Statutes' (Conference Paper, The Law Society of Western Australia Summer School, 20 February 2015) 11–12.

[64] Charles EF Rickett, 'Some Reflections on Open-Textured Commercial Contracting' (2001) (January) *Australian Mining and Petroleum Law Association Yearbook* 374, 379.

[65] Melvin Aron Eisenberg, 'The Emergence of Dynamic Contract Law' (2001) 2(1) *Theoretical Inquiries in Law* 1, 6.

be responsive to the justice of the individual case[66] and flexible in responding to new situations and circumstances.[67]

The evaluative judgement required to give content to open-textured standards will rely on a number of considerations. As explained by Dietrich, giving content to an open-textured legal standard 'permits, indeed requires, an appeal to common sense, social, personal (and judicial) experience, social norms and intuition'.[68] This synthesis of relevant considerations necessarily includes decisions about policy and values.[69] Policy and values are part of the determination of whether it is right or just that the standard is treated as having been met. This nuanced process of evaluative judgement contrasts with the type of cost-benefit analysis applied in Australia by the TGA at the pre-market stage,[70] or indeed the American *Restatement (Third) of Torts: Product Liability* (a key component of American consumer protection law) which also adopts the risk-utility test.[71]

The kind of evaluative judgement being discussed is apparent in deciding whether conduct is reasonably capable of being misleading under the *ACL*. Conduct is misleading, or likely to mislead, under the *ACL* if 'viewed as a whole [it] has a tendency to lead a person into error'.[72] That inquiry involves assessing the effect of the conduct having regard to the reactions of the ordinary, reasonable members of the class of persons to whom the representation was

[66] See James Allsop, 'Uncertainty as Part of Certainty: Appreciating the Limits of Definitional Clarity and Embracing the Uncertainty Inherent in Any Matter of Complexity' (Conference Paper, Australian Academy of Science and Australian Academy of Law Joint Symposium, 23 August 2018) 1–2. Eisenberg describes the nature of 'individualised' doctrines as being based on situation-specific variables: ibid.

[67] Rick Bigwood and Joachim Dietrich, 'Uncertainty in Private Law: Rhetorical Device or Substantive Legal Argument?' (2021) 45(1) *Melbourne University Law Review* 60, 69–71; Jane Stapleton, 'Good Faith in Private Law' (1999) 52(1) *Current Legal Problems* 1, 28.

[68] Dietrich (n 62) 239. See also Bigwood and Dietrich (n 67) 79.

[69] Dietrich (n 62) 239.

[70] 'The TGA's Risk Management Approach', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 24 February 2021) <https://www.tga.gov.au/resources/resource/guidance/tgas-risk-management-approach>, archived at <https://perma.cc/8HXN-RS4B>.

[71] American Law Institute, *Restatement (Third) of Torts: Products Liability* (1998) § 2 cmt (a).

[72] *Campbell v Backoffice Investments Pty Ltd* (2009) 238 CLR 304, 319 [25] (French CJ), quoted with approval in *Australian Competition and Consumer Commission v TPG Internet Pty Ltd* (2013) 250 CLR 640, 655 [49] (French CJ, Crennan, Bell and Keane JJ).

made, with reference to the medium through which the representation was made and its context.[73]

A dynamic and contextual evaluative judgement is also demanded in the assessment of the related standards of 'safe' and 'safety defect' under the *ACL* for the purposes of liability for failing to comply with the consumer guarantees and compensation for injury from a safety defect respectively. Thus, s 54(1) of the *ACL* provides a guarantee of acceptable quality for consumer goods. The *ACL* provides a list of factors relevant to assessing whether goods were of quality,[74] which includes having regard to whether the goods were 'safe'.[75] The baseline standard for making this assessment is the expectations of a reasonable consumer who is 'fully acquainted with the state and condition of the goods (including any hidden defects of the goods)'. [76] The flexibility of the reasonableness test in the guarantee of acceptable quality is intended to protect consumers while not imposing unrealistic standards on suppliers.[77] The assessment is not, however, a cost-benefit analysis undertaken from a lens of scientism; it is a multifactorial analysis informed by the circumstances of the particular case.[78]

The Australian product liability regime is set out in pt 3-5 of the *ACL*. The regime allows consumers who suffer loss or damage because of defects in a manufacturer's goods to recover the cost of that loss or damage from the manufacturer.[79] Far from being a binary question, a safety defect is again defined in s 9(1) of the *ACL* by reference to consumer expectations: 'goods have a safety defect if their safety is not such as persons generally are entitled to expect'. Courts have affirmed that the measure is based on the experience of the affected person or group,[80] and stated that it 'would be wrong to measure the

[73] *Australian Competition and Consumer Commission v Coles Supermarkets Pty Ltd* (2014) 317 ALR 73, 82 [43] (Allsop CJ). See also *Campomar SL v Nike International Ltd* (2000) 202 CLR 45, 86–7 [105] (Gleeson CJ, Gaudron, McHugh, Gummow, Kirby, Hayne and Callinan JJ).

[74] *ACL* (n 2) ss 54(2)–(3).

[75] Ibid s 54(2)(d).

[76] Ibid s 54(2).

[77] For further guidance on this test, see *Contact Energy Ltd v Jones* [2009] 2 NZLR 830, 852–3 [106]–[108] (Miller J) ('*Contact Energy*'), applying *Consumer Guarantees Act 1993* (NZ) ss 6–7 which constitute the New Zealand equivalent of s 54 of the *ACL* (n 2).

[78] *Australian Competition and Consumer Commission v Jayco Corporation Pty Ltd* [2020] FCA 1672, [27] (Wheelahan J); *Contact Energy* (n 77) 850 [94] (Miller J).

[79] *ACL* (n 2) ss 138–41.

[80] *Ethicon Sarl v Gill* (2021) 288 FCR 338, 460 [584]–[585] (Jagot, Murphy and Lee JJ) ('*Ethicon*'), citing *A v National Blood Authority* [2001] 3 All ER 289, 311 [31] (Burton J).

reasonable expectations of the hypothetical reasonable consumer against the specialist technical knowledge of [the manufacturer]'.[81] The standard is based on the expectations of the consumer, having regard to the matters set out in s 9(2) and subject to a series of defences in s 142 of the *ACL*.

As already suggested, when it comes to assessing whether a therapeutic good has a safety defect, it is well established that sectoral regulatory requirements of safety and efficacy, such as under the TGA regulatory regime, act as a floor and not a ceiling of the level of safety that consumers can reasonably expect.[82] This regime may capture therapeutic products approved by the TGA but which have not met consumer expectations of safety under the *ACL*. Where products prove not to meet consumer expectations of safety, the redress provisions in pt 3-5 provide compensation and, in principle, a mechanism that corrects and improves the general safety of products in the market by requiring manufacturers to internalise the risks of harm.[83] As will be discussed in Part V, an example is certain types of implantable transvaginal mesh medical devices approved under the TGA regulatory regime but subsequently found by the Full Court of the Federal Court to be below the standards of safety and quality set by the *ACL*.[84]

The courts' assessment of what is reasonable for consumers to expect regarding the safety of goods and services will inevitably be shaped by social, legal and regulatory norms, as well as the operation of other cognate regulatory regimes. The role of these norms may reasonably vary over time and in response to changed circumstances, as may the impact of other regimes which themselves will be responding to different regulatory objectives and pressures. A factor that has not been squarely identified to date and that, we suggest, plays an important role, is the influence of the decisions made by the TGA; specifically, those decisions that scrutinise whether, and in what way, pharmaceutical and other therapeutic products are approved to be included on the ARTG and subsequently supplied to the Australian public in the first place. A question then arises as to how, if the approach under the TGA regime changes over time, is this accommodated under the more general *ACL* regime?

[81] *Graham Barclay Oysters Pty Ltd v Ryan* (2000) 102 FCR 307, 446 [536] (Lindgren J, Lee J agreeing at 330 [69]).

[82] See above n 19 and accompanying text.

[83] See Richard Braddock, *Product Liability: Economic Impacts* (Product Liability Research Paper No 2, Australian Law Reform Commission, January 1989) 10.

[84] *Gill* (n 15) [3584]–[3607] (Katzmann J), affd *Ethicon* (n 80) 519 [811] (Jagot, Murphy and Lee JJ).

In some instances, we may consider it legitimate and indeed necessary for courts and regulators applying the *ACL* to place new emphasis and meaning on its regulatory standards in response to the changing environment. In other instances, those applying and enforcing the *ACL* may need to adapt to new processes or accommodate findings from other agencies. But how do they do that in a manner that is clear and coherent? This is explored in greater detail in relation to the specific examples of hand sanitisers in Part III, and COVID-19 vaccines in Part IV. Conversely, to the extent that the general *ACL* regime provides oversight and scrutiny of products released under the specific TGA regime, how does the TGA design an effective feedback mechanism to ensure that legitimate expectations identified by the general high standards of the *ACL* regime are embraced by the more specific 'floor' provided by the TGA? This is also a question that is raised by the exploration of the transvaginal mesh implants case in Part V.

In this article, we do not provide definitive answers to these questions, which we do not yet have. Rather, we aim to raise the significance of being alive to the questions and demands of both consistency and coherence between the *ACL* and TGA regulatory regime, in addition to the need for some degree of systematic coordination between the regulatory agencies responsible for these regimes. We examine three case studies that highlight the urgency of this inquiry and the need for further efforts to ensure that the floor and ceiling of consumer protection in regard to therapeutic products are appropriately aligned.

III Inconsistency between the Positions Taken by the Regulatory Regimes: Hand Sanitisers

The case of 'hand sanitiser' in the COVID-19 crisis illustrates the importance of acknowledging the dynamic relationship between the general (*ACL*) and specific (TGA) regulatory regimes in times of public health crisis.[85] Hand

[85] We use the phrase 'public health crisis' throughout this article to describe a broad set of circumstances in which a nation-state is faced with a 'state of affairs in which the health of a substantial portion of a community's members is either compromised or in imminent danger because of the inability of existing mechanisms for safeguarding the public's health to cope with an emergent health threat': Alex John London, 'Research in a Public Health Crisis: The Integrative Approach to Managing the Moral Tensions' in Bruce Jennings et al (eds), *Emergency Ethics: Public Health Preparedness and Response* (Oxford University Press, 2016) 220, 221. This includes public health 'emergencies' as declared by the legislature or executive, as occurred in many countries, including Australia, during the COVID-19 pandemic: see, eg,

sanitiser used to be a product conventionally associated with personal hygiene but was by no means essential. With the outbreak of the COVID-19 pandemic in 2020, hand hygiene became one of the prime methods of prevention and containment.[86] In this context, the concept of a 'sanitiser' was elevated to a new level of significance. This new significance exposed the risks of a lack of coordination between regulators and consequentially a potential gap in Australia's consumer protection regime in relation to therapeutic products.

The initial stages of the pandemic in 2020 resulted in huge demand for personal hygiene items, the importance of which was repeatedly stressed by the Australian government.[87] Although soap was endorsed as the preferable product to protect against the severe acute respiratory syndrome coronavirus-2 ('SARS-CoV-2 virus'),[88] in the absence of soap and water, hand sanitisers were promoted.[89] It can be inferred that consumers assumed hand sanitiser would assist in protecting them from the spread of the virus,[90] as evidenced by widespread 'panic buying' and 'hoarding' in the early days of the pandemic, resulting in a shortage of toilet paper and hand sanitiser across the country.[91]

Paula O'Brien and Eliza Waters, 'COVID-19: Public Health Emergency Powers and Accountability Mechanisms in Australia' (2021) 28(2) *Journal of Law and Medicine* 346, 350; 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 of Law and the COVID-19 Pandemic* (Routledge, 2022) 457, 457.

86 See, eg, 'Protecting Yourself and Others from COVID-19', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 5 July 2023) <https://www.health.gov.au/topics/covid-19/protect-yourself-and-others?language=und>, archived at <https://perma.cc/R23Y-YGQ8>.

87 See, eg, 'Good Hygiene for Coronavirus (COVID-19)', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 18 May 2020) <https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/how-to-protect-yourself-and-others-from-coronavirus-covid-19/good-hygiene-for-coronavirus-covid-19>, archived at <https://perma.cc/2K22-LV46>.

88 Ibid.

89 Ibid; 'Hand Sanitisers: Information for Consumers', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 31 August 2020) <https://www.tga.gov.au/resources/resource/guidance/hand-sanitisers-information-consumers>, archived at <https://perma.cc/8LB9-86NA>.

90 'Hand Hygiene', *Department of Health (Vic)* (Web Page, 23 November 2021) <https://www.health.vic.gov.au/quality-safety-service/hand-hygiene>, archived at <https://perma.cc/G8X8-QUYQ>.

91 Daniel Keane, 'Coronavirus Is Causing Panic Buying, but What Does that Mean for Australia's Food Security?', *ABC News* (online, 16 March 2020) <https://www.abc.net.au/news/2020-03-16/coronavirus-is-not-a-threat-to-food-supply-experts-say/12058412>, archived at <https://perma.cc/8CAL-5TY2>; Rebeka Powell, 'Coronavirus Fears Prompt Shoppers To Stock Up on

However, not all so-called sanitisers proved effective against COVID-19.[92] Federal and state government advice was that sanitiser with a high percentage of alcohol was required.[93] There was, however, no regulatory verification of the veracity of claims about the amount of alcohol found in hand sanitiser. Indeed, the Australian Consumer Association ('CHOICE') drew attention to instances where the advertised level of alcohol had not been met.[94] While this focus on sanitisers has faded with the introduction of vaccines, at the height of the pandemic it was an issue of considerable importance to consumers.[95] It is therefore worth addressing the contribution that the regulatory regimes themselves may play in confusing, if not undermining, consumer expectations in the context of public health events such as the COVID-19 pandemic.

Critically, we consider that minimal coordination between the *ACL* and the TGA regulatory regime contributed to consumer difficulties by leading to a two-tier system of content and labelling. At the base of this confusion is a significant, but poorly understood, distinction between 'cosmetic' and 'therapeutic' kinds of sanitiser for regulatory purposes. The TGA describes cosmetic hand sanitisers as 'general consumer products' that are made up of

Essential Items, Stripping Supermarket Shelves', *ABC News* (online, 2 March 2020) <https://www.abc.net.au/news/2020-03-02/coronavirus-stockpiling-supplies/12014766>, archived at <https://perma.cc/5GLB-3FDH>.

92 Grace Smith, 'Are Alcohol-Free Hand Sanitisers Effective against COVID-19?', *CHOICE* (Web Page, 29 July 2020) <https://www.choice.com.au/health-and-body/beauty-and-personal-care/skin-care-and-cosmetics/articles/alcohol-free-hand-sanitiser>, archived at <https://perma.cc/4F8Q-37ZY>.

93 See, eg, Department of Health and Human Services (Vic), *Are You and Your Home COVIDSafe?* (Report, 11 September 2020) 2. The Commonwealth government stated in regard to hand hygiene that

> [i]f you are not able to wash your hands, use an alcohol-based hand rub/sanitiser containing 60% ethanol or 70% isopropanol. Non-alcohol-based hand rubs are not recommended, as there is limited evidence available to support their effectiveness in reducing bacteria and viruses.

'Covid-19', *Australian Commission on Safety and Quality in Health Care* (Web Page) <https://webarchive.nla.gov.au/awa/20201111064127/https://www.safetyandquality.gov.au/covid-19>.

94 See, eg, Andy Kollmorgen, 'CHOICE Investigation: Mosaic Brand Sold Mislabelled, Ineffective Hand Sanitiser', *CHOICE* (Web Page, 15 July 2020) <https://www.choice.com.au/health-and-body/beauty-and-personal-care/skin-care-and-cosmetics/articles/mosaic-brands-hand-sanitiser-fails-nmi-test>, archived at <https://perma.cc/RLS5-HT3J>.

95 Department of Industry, Science, Energy and Resources (Cth), *Hand Sanitiser in Australia: Market Insights* (Report, July 2020) 3–5 <https://www.industry.gov.au/sites/default/files/2020-10/hand-sanitiser-market-insights-brochure.pdf>, archived at <https://perma.cc/74FK-BH9G>.

'only low-risk ingredients' and which make 'therapeutic claims … limited to general low level activity against bacteria'.[96] The *Consumer Goods (Cosmetics) Information Standard 2020* (Cth) ('*Cosmetics Information Standard*'), introduced by the Commonwealth government in late 2020 under the *ACL*, defines a hand sanitiser in a similar manner.[97]

Many hand sanitisers that are available in supermarkets fall within this cosmetic category.[98] Such products are regulated under the *ACL* but are not subject to the approval requirements of the TGA regulatory regime (although they must also meet certain advertising requirements under the TGA regime).[99] Cosmetic hand sanitisers must list their ingredients including, under the *Cosmetics Information Standard*, the percentage amount of alcohol they contain.[100] Further, cosmetic hand sanitisers containing imported chemicals may be regulated under the alternative National Industrial Chemicals Notification and Assessment Scheme.[101]

In contrast, therapeutic hand sanitisers are those that claim to kill viruses or other organisms and that can be used in relation to health conditions and in medical contexts.[102] Therapeutic hand sanitisers must therefore meet the

[96] 'Hand Sanitisers: Information for Manufacturers, Suppliers and Advertisers', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 7 May 2020) <https://www.tga.gov.au/hand-sanitisers-information-manufacturers-suppliers-and-advertisers>, archived at <https://perma.cc/QXU6-77AN>.

[97] *Consumer Goods (Cosmetics) Information Standard 2020* (Cth) ss 3, 6 (definition of 'hand sanitiser') ('*Cosmetics Information Standard*').

[98] See generally, 'Hand Sanitiser Labels Need a Clean Up', *CHOICE* (Web Page, 28 October 2020) <https://www.choice.com.au/health-and-body/beauty-and-personal-care/skin-care-and-cosmetics/articles/hand-sanitiser-labelling>, archived at <https://perma.cc/8T96-AFE4>.

[99] 'Hand Sanitisers: Information for Manufacturers, Suppliers and Advertisers' (n 96). See, eg, Therapeutic Goods Administration, Department of Health and Aged Care (Cth), 'Strapit Fined $37,800 for Alleged Advertising Breaches for Disinfectant and Hand Sanitiser in Relation to COVID-19' (Media Release, 24 July 2020) <https://www.tga.gov.au/media-release/strapit-fined-37800-alleged-advertising-breaches-disinfectant-and-hand-sanitiser-relation-covid-19>, archived at <https://perma.cc/4TVK-X8GY>.

[100] 'Cosmetics Ingredients Labelling', *Product Safety, Australian Competition and Consumer Commission* (Web Page) <https://www.productsafety.gov.au/standards/cosmetics-ingredients-labelling>, archived at <https://perma.cc/X5UK-JZ73>; *Cosmetics Information Standard* (n 97) s 11(2).

[101] See generally 'Who We Are and What We Do', *Australian Industrial Chemicals Introduction Scheme, Department of Health and Aged Care (Cth)* (Web Page, 27 February 2023) <https://www.industrialchemicals.gov.au/about-us/who-we-are-and-what-we-do>, archived at <https://perma.cc/VZ2H-D77R>. Details about this alternative scheme for cosmetic products go beyond the scope of this article.

[102] 'Hand Sanitisers: Information for Manufacturers, Suppliers and Advertisers' (n 96).

TGA regulatory regime's approval and other requirements (as well as the ordinary, general standards of the *ACL*).[103] As part of the TGA regulatory requirements, therapeutic goods must meet specific standards of quality, safety and effectiveness.[104]

In response to the initial, unprecedented demand for hand sanitisers in March 2020, the then federal Health Minister announced that the TGA would relax its requirements in relation to certain therapeutic hand sanitisers.[105] The amendments meant that hand sanitisers produced according to 'recipes' approved by the World Health Organisation ('WHO') would not require TGA approval.[106] The WHO approved recipes enabled sanitisers to be manufactured with food grade alcohol, rather than medical grade alcohol.[107] The changes made it easier for local businesses to manufacture hand sanitiser, both for use in healthcare settings and by general consumers.[108] Nevertheless, manufacturers of therapeutic hand sanitisers still had to maintain certain safety standards by ensuring that the products were produced according to the correct formulation, under sanitary conditions and following safety labelling requirements.[109]

By contrast, provided a cosmetic hand sanitiser did not make misleading claims about its medicinal or therapeutic effectiveness, it was not (and still is not) required to contain the requisite percentage of alcohol to be effective against COVID-19, despite being prominently labelled as a sanitiser.[110] Particularly during the pandemic, it was reasonable to expect that consumers would look to branding statements about the legitimate use that

[103] Ibid.

[104] *Therapeutics Goods Act* (n 1) s 25(1)(e).

[105] Greg Hunt, Minister for Health and Aged Care (Cth), 'Increased Flexibility for Production of Hand Sanitiser To Bolster Supplies' (Media Release, 30 March 2020) <https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/increased-flexibility-for-production-of-hand-sanitiser-to-bolster-supplies>, archived at <https://perma.cc/X4P2-L4PL> ('Increased Flexibility for Production of Hand Sanitiser').

[106] Ibid; World Health Organisation, *Guide to Local Production: WHO-Recommended Handrub Formulations* (Guidelines, April 2010) 2–4 <https://iris.who.int/bitstream/handle/10665/332005/WHO-IER-PSP-2010.5-eng.pdf?sequence=1>, archived at <https://perma.cc/V3VM-YH5A> ('*Guide to Local Production*').

[107] *Guide to Local Production* (n 106) 4. See also *Therapeutic Goods Amendment (Excluded Goods — Hand Sanitisers) Determination 2020* (Cth) sch 1 item 1(a)(i) ('*Excluded Goods Determination*').

[108] Hunt, 'Increased Flexibility for Production of Hand Sanitiser' (n 105).

[109] *Excluded Goods Determination* (n 107) sch 1 item 1.

[110] Smith (n 92).

might be made of a sanitiser, with a risk of arriving at the mistaken conclusion that all products labelled as 'hand sanitisers' would be effective against COVID-19. Significantly, a common claim on cosmetic hand sanitisers is that they are effective against 99.9% of germs (or, in some instances, bacteria).[111] As stated, government advice was that a high alcohol concentration was required for effectiveness against COVID-19, but this was not a regulatory requirement for the supply of cosmetic hand sanitisers during the critical pre-vaccine period, or now.[112]

In this context, it is arguable that to claim effectiveness against 'germs' when the product was not effective against a virus such as COVID-19 was misleading.[113] The term 'germ' does not have a fixed scientific meaning. It may commonly be understood as 'a bacterium or other microorganism, esp[ecially] when considered to be a cause of disease'.[114] This means any supposed distinction between germs and viruses might well be dismissed as spurious. Some sanitisers state that they are effective against 'bacteria',[115] which is similarly problematic. The headline message is that the product 'sanitises', which should be given the meaning consumers would reasonably expect in the environment they are immersed in. So, it is not far-fetched to suggest that, in the COVID-19 era, consumers would reasonably expect that a 'sanitiser' would be a product that combats certain viruses, and that, in doing so, it meets certain scientific standards.

Similarly, a cosmetic hand sanitiser product is arguably not of acceptable quality under the *ACL* consumer guarantee regime,[116] at least at the time of the heightened concerns raised by the COVID-19 pandemic. As discussed earlier, the criteria for assessing acceptable quality include whether the product is fit for the purposes for which such products are used, as judged by the expectations of a reasonable consumer.[117] This baseline measure must, to some

[111] See, eg, 'Dettol Instant Sanitizer Original', *Dettol* (Web Page) <https://www.dettol.com.au/personal-hygiene/instant-hand-sanitiser/dettol-instant-hand-sanitizer-original-200ml/>, archived at <https://perma.cc/XRY5-VW6R>; 'Dettol Instant Hand Sanitizer Chamomile', *Dettol* (Web Page) <https://www.dettol.com.au/personal-hygiene/instant-hand-sanitiser/dettol-instant-hand-sanitizer-chamomile-50ml/>, archived at <https://perma.cc/6T22-PF4R>.

[112] Smith (n 92).

[113] See *ACL* (n 2) s 18(1).

[114] *Oxford English Dictionary* (online at 20 March 2023) 'germ' (def 4).

[115] See generally 'Hand Sanitisers: Information for Manufacturers, Suppliers and Advertisers' (n 96).

[116] *ACL* (n 2) pt 3-2 div 1.

[117] Ibid s 54(2)(a).

degree, be shaped by consumers' legitimate expectation of a well-regulated consumer market, whereby traders' conduct and the products sold are held to high standards of probity. During the pandemic, consumer expectations justifiably rose to embrace effectiveness against the COVID-19 virus.[118] From the perspective of consumers' reasonable expectations a hand sanitiser should be a product that sanitises effectively. In this environment, claims about 'sanitising' and effectiveness against bacteria or germs, for a product ineffective against COVID-19, would appear misleading as well as fail to meet the standards required by the *ACL* consumer guarantee regime.

Both the TGA and the ACCC imposed fines on manufacturers of sanitiser that purported to reach the therapeutic or WHO standard but did not.[119] Yet the trend of manufacturers of cosmetic sanitisers promoting effectiveness against bacteria was neither sanctioned nor clarified in a way that would have been salient for consumers by either the TGA or the ACCC.[120] Claims of effectiveness against germs and even bacteria can be considered problematic from a consumer protection perspective. However, the TGA considered these statements to be outside its regulatory purview.[121]

The regulators could, and arguably should, have promoted a more dynamic approach to consumer protection.[122] Consumers could have been helped, for example, to appreciate the important distinction between 'cosmetic' and 'therapeutic' sanitisers by requiring retailers to physically separate and label therapeutic from cosmetic products at the point of sale.[123] This simple step may

118 Ibid ss 54(3)(c)–(e).

119 Therapeutic Goods Administration, Department of Health and Aged Care (Cth), 'Australian Chemical Research Fined $25,200 for Alleged Breaches in Relation to Hand Sanitiser' (Media Release, 29 June 2020) <https://www.tga.gov.au/news/media-releases/australian-chemical-research-fined-25200-alleged-breaches-relation-hand-sanitiser>, archived at <https://perma.cc/V4EU-VTZ3>; Therapeutic Goods Administration, Department of Health and Aged Care (Cth), 'Mosaic Brands Pays $630,000 in Penalties over COVID-Related "Health Essentials"' (Media Release, 27 May 2021) <https://www.accc.gov.au/media-release/mosaic-brands-pays-630000-in-penalties-over-covid-related-health-essentials>, archived at <https://perma.cc/W9AQ-UHXQ>.

120 Cf 'Hand Sanitisers: Information for Manufacturers, Suppliers and Advertisers' (n 96).

121 Alex Jane et al, 'Coming Clean on Hand Sanitisers', *Pursuit* (Web Page, 21 April 2020) <https://pursuit.unimelb.edu.au/articles/coming-clean-on-hand-sanitisers>, archived at <https://perma.cc/2TAH-XJCD>.

122 Ibid.

123 This could be achieved, for example, through amendments to the 'supply' of 'therapeutic' hand sanitisers that are not required to be included on the ARTG under the *Excluded Goods Determination* (n 107) (as enabled by s 7AA of the *Therapeutic Goods Act* (n 1)). Further, and

have alerted consumers to the distinction and empowered them to make further enquiries. Another intervention could have been to impose more demanding standards for labelling, to require the products to specify against what types of viruses (if any) the product sanitises. A more definitive step could have even been to ban cosmetic products from being labelled as 'hand sanitisers' where they did not meet WHO standards or other government recommended levels of alcohol — on the basis that the label 'sanitiser' developed a new significance in this time of COVID-19 concern — so that only therapeutic hand sanitiser products were permitted to be called 'hand sanitisers'.

The more general lesson from this experience is the way in which the salience of the terminology used to promote consumer products changes over time, in this case the significance of 'sanitise'. While at one time it might be acceptable that commonly sold 'sanitisers' fail to meet therapeutic standards for sanitising, post-pandemic consumers might reasonably expect *all* hand sanitisers to meet scientific standards equivalent to those applied under the TGA regulatory regime in relation to 'therapeutic' hand sanitisers. In other words, there is an argument that the regulatory 'floor' should rise in step with consumer expectations. This question leads back to the overarching point: how do complementary regulatory regimes respond to changed circumstances in a way that is consistent and coherent in order to promote optimal consumer outcomes?

IV Changing Approaches to Approvals and Resetting the Standard for Safety Defects: COVID-19 Vaccines

The case of COVID-19 vaccines provides another timely example of how there can be discord between the *ACL* and TGA regulatory regimes, made worse by there being no mechanism for adjusting the application of the general protections in the *ACL* in response to changes in regulatory stance under the more specific TGA regime. These frictions risk, in turn, undermining the courts' assessment of a 'safety defect' under the *ACL* and the reasonable consumer expectations that inform this concept. Indeed, the Australian approval process and roll out of COVID-19 vaccines uncovered the existence of a measure of conflict between, first, factual evidence and value-based

more broadly, the responsible Minister may determine conditions for the supply (which includes 'sale') of any therapeutic goods listed or registered on the ARTG: *Therapeutic Goods Act* (n 1) ss 3 (definition of 'supply'), 28(1), (2)(b).

judgements and, second, between diverging value judgements predicated upon the same factual evidence by different competent regulatory authorities. This creates an intricate entanglement of inconsistent evaluative positions that, in the face of potential claims for injuries, would have to be rationalised into a coherent synthesis by adjudicating courts of what degree of safety, in the circumstances, consumers are generally 'entitled to expect'.[124]

Here we examine the different approval processes that are in place for vaccines under 'normal' circumstances as opposed to public health crises, and what this entails for the construction of reasonable consumer expectations. We subsequently contrast how the risk assessments underpinning approval for use and roll out recommendations can conflict, thereby further muddying the normative waters of safety expectations.

A *What Is a Vaccine and How Is It Made Available to the Public?*

Technically, a 'vaccine' is a pharmaceutical product that protects against a specific disease by stimulating the immune system.[125] Common vaccines include childhood vaccines against measles, mumps and rubella, or whooping cough, as well as the seasonal vaccine against influenza.[126]

The key process leading to the deployment of a new vaccine is a rigorous pre-market assessment performed by the TGA with the assistance of the Advisory Committee on Vaccines ('ACV').[127] The assessment is based on international guidelines provided by the European Medicines Agency ('EMA'),[128] which in turn refer to the standards and procedures negotiated

[124] *ACL* (n 2) s 9(1).

[125] *Black's Medical Dictionary* (43rd ed, 2017) 'vaccine'.

[126] Ibid. See also 'Immunisation for Children', *Department of Health and Aged Care (Cth)* (Web Page, 22 March 2023) <https://www.health.gov.au/topics/immunisation/when-to-get-vaccinated/immunisation-for-infants-and-children>, archived at <https://perma.cc/KHH6-64HU>.

[127] 'Advisory Committee on Vaccines (ACV)', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 2 March 2023) <https://www.tga.gov.au/committee/advisory-committee-vaccines-acv>, archived at <https://perma.cc/GT6T-HQLH>.

[128] Committee for Medicinal Products for Human Use, European Medicines Agency, *Guideline on Clinical Evaluation of New Vaccines* (Doc No EMEA/CHMP/VWP/164653/2005, 18 October 2006) <https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-clinical-evaluation-new-vaccines_en.pdf>, archived at <https://perma.cc/FK2W-BW2C> ('*2006 EMA Vaccine Guideline*'). See also 'International Scientific Guideline: Guideline on Clinical Evaluation of New Vaccines', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 6 January 2009)

internationally at the International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ('ICH').[129] Once the safety and efficacy of a new vaccine have been successfully assessed, it is included in the ARTG and becomes marketable.[130]

Under 'normal' circumstances, the pre-market assessment of a new vaccine can take up to 15 years.[131] The International Federation of Pharmaceutical Manufacturers and Associations ('IFPMA') explains that developing a new vaccine is more onerous compared to most other medicines, because the final product is targeted to a very wide and healthy population, across all age ranges.[132] This demands particularly 'large safety and efficacy datasets', making clinical development a lengthy and burdensome process.[133]

Special provisions are in place in most countries, including Australia, for the speedy approval of new annual influenza vaccines.[134] However, this is a very

<https://www.tga.gov.au/resources/resource/international-scientific-guidelines/international-scientific-guideline-guideline-clinical-evaluation-new-vaccines>, archived at <https://perma.cc/7PFM-8XFH>. The relevant EMA guideline has recently been updated (although there is no indication that the TGA and ACV have adopted this revised guideline): Committee for Medicinal Products for Human Use, European Medical Agency, *Guideline on Clinical Evaluation of Vaccines* (Doc No EMEA/CHMP/VWP/164653/05 Rev 1, 16 January 2023) <https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-clinical-evaluation-vaccines-revision-1_en.pdf>, archived at <https://perma.cc/XGQ3-3L6P>.

129 *2006 EMA Vaccine Guideline* (n 128) 19. The ICH is a transnational regulatory network for the negotiation and adoption of standards and guidelines between regulatory authorities and industry representatives: 'Mission: Harmonisation for Better Health', *ICH* (Web Page) <https://www.ich.org/page/mission>, archived at <https://perma.cc/P9ZT-QE4A>. For the full set of international scientific guidelines adopted in Australia, see 'Resources', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page) <https://www.tga.gov.au/resources/resource?f[0]=type:333316>, archived at <https://perma.cc/U8RU-X7MC>.

130 'Vaccines Overview' (n 40).

131 International Federation of Pharmaceutical Manufacturers and Associations, *The Complex Journey of a Vaccine — Part III: The Steps behind Developing a New Vaccine* (Report, 29 July 2019) 3 <https://www.ifpma.org/publications/the-complex-journey-of-a-vaccine-the-steps-behind-developing-a-new-vaccine/>, archived at <https://perma.cc/XX9S-3XJY>.

132 Ibid.

133 Marco Rizzi, 'The Road to a Vaccine for COVID-19: Regulatory and Policy Infrastructure, Incentives and Obstacles' (2020) 4(2) *European Pharmaceutical Law Review* 98, 99.

134 See, eg, Jerry P Weir and Marion F Gruber, 'An Overview of the Regulation of Influenza Vaccines in the United States' (2018) 14(3) *Influenza and Other Respiratory Viruses* 354, 355; 'Vaccines for Pandemic Influenza', *European Medicines Agency* (Web Page) <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/pandemic-influenza/vaccines-pandemic-influenza>, archived at <https://perma.cc/G6C5-GNGD>. The TGA approves annual changes to the influenza vaccine on the basis of the Australian

different process to that leading to a 'new' vaccine because including new strains of influenza viruses does not require clinical trials. As explained by the TGA:

> We take this approach because there have been many years of safe and effective use of seasonal flu vaccines in several million people. This registration process only applies for seasonal flu vaccines where the manufacturing process is the same as a previously registered vaccine and the only change is to the strains of virus.[135]

Ultimately, registration in the ARTG is the consequence of a *judgement* that the product is safe and effective, which is based on data; the quantity and depth of which is context-dependent. So, the seasonal flu vaccines receive a lighter 'regulatory touch' than newly developed ones.[136] Vaccines are regularly cited as some of the safest and most effective pharmaceutical products available,[137] and many governments around the world (including the Australian Commonwealth government and most subnational governments) have adopted various forms of mandatory childhood immunisation programs.[138] It stands to reason that the presence and operation of a lengthy

Influenza Vaccine Committee's review of epidemiological data and WHO recommendations: '2022 Seasonal Influenza Vaccines: Information for Consumers and Health Professionals', *Therapeutic Goods Administration*, *Department of Health and Aged Care (Cth)* (Web Page, 25 March 2022) <https://www.tga.gov.au/news/media-releases/2022-seasonal-influenza-vaccines>, archived at <https://perma.cc/JLP2-T6HA>.

135 'Vaccines Overview' (n 40).

136 Ibid.

137 The literature is immense: see, eg, Frank Destefano, Paul A Offit and Allison Fisher, 'Vaccine Safety' in Stanley A Plotkin et al (eds), *Plotkin's Vaccines* (Elsevier, 7th ed, 2018) 1584, 1600; H Cody Meissner, 'Understanding Vaccine Safety and the Roles of the FDA and the CDC' (2022) 386(17) *New England Journal of Medicine* 1638, 1638. See also 'Vaccine Safety', *Department of Health of Aged Care (Cth)* (Web Page, 7 August 2023) <https://www.health.gov.au/health-topics/immunisation/about-immunisation/are-vaccines-safe>, archived at <https://perma.cc/64FQ-GHTY>.

138 See, eg, Katie Attwell et al, 'Recent Vaccine Mandates in the United States, Europe and Australia: A Comparative Study' (2018) 36(48) *Vaccine* 7377, 7378–82. For an overview of the 'No Jab No Pay' national policy and the 'No Jab No Play' state policies, see 'No Jab No Play, No Jab No Pay', *National Centre for Immunisation Research and Surveillance* (Web Page, August 2023) <http://www.ncirs.org.au/public/no-jab-no-play-no-jab-no-pay>, archived at <https://perma.cc/7E2P-DB69>. See also Katie Attwell and Shevaun Drislane, 'Australia's "No Jab No Play" Policies: History, Design and Rationales' (2022) 46(5) *Australian and New Zealand Journal of Public Health* 640, 641–4.

and thorough regulatory review process would form an integral part of the normative evaluation of what consumers are generally entitled to expect.

B *The Special Nature of Public Health Crises and Their Impact on the Evaluative Basis for Consumer Expectations*

The challenges posed by the outbreak of a pandemic or epidemic disease ('PED') put the risk assessment process for therapeutic countermeasures under enormous pressure. Other challenges include the need to ensure quick, large-scale manufacturing and access to product supplies.[139] In the first instance, public health crises prompt regulators to fast track product review and approval. The search for a vaccine against the SARS-CoV-2 virus saw an unprecedented race, with first marketing approvals coming only weeks after the first anniversary of the Wuhan outbreak.[140]

This is astonishing when one looks at recent PED outbreaks that have prompted swift vaccine development. The Ebola outbreak that has affected West Africa since 2014[141] saw the first vaccine receive conditional approval by the EMA at the end of 2019, a full five years after the start of the outbreak[142] —

[139] See, eg, Nicole Lurie et al, 'Developing Covid-19 Vaccines at Pandemic Speed' (2020) 382(21) *New England Journal of Medicine* 1969, 1973.

[140] The Food and Drug Administration ('FDA') issued an 'emergency use authorization' ('EUA') for emergency use of the Pfizer-BioNTech COVID-19 vaccine on 11 December 2020: US Food and Drug Administration, 'FDA Takes Key Action in Fight against COVID-19 by Issuing Emergency Use Authorization for First COVID-19 Vaccine' (Media Release, 11 December 2020) <https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19>, archived at <https://perma.cc/SW7J-XBJS>. This was followed by a similar EUA for the Moderna COVID-19 vaccine on 18 December 2020: US Food and Drug Administration, 'FDA Takes Additional Action in Fight against COVID-19 by Issuing Emergency Use Authorization for Second COVID-19 Vaccine' (Media Release, 18 December 2020) <https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid>, archived at <https://perma.cc/L257-KJ72>.

[141] '2014–2016 Ebola Outbreak in West Africa', *Centers for Disease Control and Prevention* (Web Page, 8 March 2019) <https://www.cdc.gov/vhf/ebola/history/2014-2016-outbreak/index.html>, archived at <https://perma.cc/7UJE-P3Q4>.

[142] European Medicines Agency, 'New Vaccine for Prevention of Ebola Virus Disease Recommended for Approval in the European Union' (Press Release EMA/CHMP/282251/2020, 29 May 2020) <https://www.ema.europa.eu/en/documents/press-release/new-vaccine-prevention-ebola-virus-disease-recommended-approval-european-union_en.pdf>, archived at <https://perma.cc/PF4J-TS7K>. See also Talha Burki, 'Ebola Virus Vaccine Receives Prequalification' (2019) 394(10212) *Lancet* 1893, 1893; Ewen Callaway,

but note that the virus had been known for decades.[143] Looking further back, in the course of the A-H1N1 'swine flu' pandemic of 2009, a vaccine was conditionally approved within months.[144] This was largely because influenza vaccines are based on decades of research and development. Further, vaccine developers can rely on well-established influenza vaccine technology and new strains are relatively easy to integrate into existing vaccines.[145]

How does a process that typically takes up to 15 years get reduced so substantially? Many in the scientific community have underlined how the time lag characterising vaccine development under normal circumstances tends to be due to a combination of bureaucratic delays, lack of funding[146] and difficulties in gathering volunteers for trials.[147] In contrast, every regulatory authority involved in the global effort to secure safe and effective COVID-19 vaccines streamlined administrative processes, and had virtually limitless funding and no shortage of trial volunteers.[148] Nevertheless, the unprecedented speed at which these vaccines are being developed mandates a measure of caution. An unavoidable quantum of uncertainty accompanies such speedy development of products that, in many cases, are based on the vaccines' new

'"Make Ebola a Thing of the Past": First Vaccine against Deadly Virus Approved' (2019) 575(7783) *Nature* 425, 425.

143 'What Is Ebola Disease?', *Centers for Disease Control and Prevention* (Web Page, 17 May 2023) <https://www.cdc.gov/vhf/ebola/about.html>, archived at <https://perma.cc/M4ZN-YNE9>; Aurelie Ploquin, Kendra Leigh and Nancy J Sullivan, 'Ebola Vaccines' in Stanley A Plotkin et al (eds), *Plotkin's Vaccines* (Elsevier, 7th ed, 2018) 276, 276.

144 Jeffrey Partridge et al, 'Global Production of Seasonal and Pandemic (H1N1) Influenza Vaccines in 2009–2010 and Comparison with Previous Estimates and Global Action Plan Targets' (2010) 28(30) *Vaccine* 4709, 4711.

145 Lurie et al (n 139) 1969.

146 This has traditionally been a major obstacle to successful vaccine research and development: Marco Rizzi, 'Rethinking Vaccine Development as an Integral Part of Preparedness in the European Health Union' (2020) 11(4) *European Journal of Risk Regulation* 821, 826.

147 Rashmi Ashish Kadam et al, 'Challenges in Recruitment and Retention of Clinical Trial Subjects' (2016) 7(3) *Perspectives in Clinical Research* 137, 137–8; Richard M Jacques et al, 'Recruitment, Consent and Retention of Participants in Randomised Controlled Trials: A Review of Trials Published in the National Institute for Health Research (NIHR) Journals Library (1997–2020)' (2022) 12(2) *BMJ Open* 1, 1–2.

148 Ibid. See also Philip Ball, 'The Lightning-Fast Quest for COVID Vaccines: And What It Means for Other Diseases' (2020) 589 *Nature* 16, 16, 18; Jocelyn Solis-Moreira, 'How Did We Develop a COVID-19 Vaccine So Quickly?', *Medical News Today* (online, 13 November 2021) <https://www.medicalnewstoday.com/articles/how-did-we-develop-a-covid-19-vaccine-so-quickly>, archived at <https://perma.cc/GDB2-2K6Z>.

mRNA technological platform.[149] Moreover, the urgency and significant societal pressure on developers increase the risk of human mistakes, as exemplified by the dosing errors in the trials of the Oxford/AstraZeneca vaccine ('AstraZeneca') candidate.[150]

In addition to streamlining bureaucracy, most regulatory regimes, including that of the Australian TGA, include special provisions for provisional approval of medicines for serious or life-threatening diseases.[151] In Australia, as outlined earlier, this type of approval allows the provisional market authorisation of a product that has undergone more limited clinical review, on the condition that safety and efficacy data will be collected on a rolling basis as the product is deployed, with a final review at the end of the provisional approval period.[152] This is the pathway the TGA has adopted for COVID-19 vaccines.[153]

Crucially, despite a measure of trade-offs warranted by the seriousness and imminence of public health threats caused by a PED like COVID-19, vaccines receiving provisional approval undergo rigorous testing and must satisfy the TGA that they offer benefits far outweighing possible risks.[154] Nevertheless, rolling out vaccines subject to provisional approval carries the risk of rare, serious adverse events that remain undetected in trial phases and manifest themselves only in the general population. For example, the fast rollout of the A-H1N1 vaccine revealed several unexpected side effects, which proved particularly problematic in countries that had deployed aggressive

[149] Ball (n 148) 18. See generally Elie Dolgin, 'The Tangled History of mRNA Vaccines' (2021) 597(7876) *Nature* 318.

[150] On the incident, see Michelle Roberts, 'Oxford/AstraZeneca Covid Vaccine "Dose Error" Explained', *BBC News* (online, 27 November 2020) <https://www.bbc.com/news/health-55086927>, archived at <https://perma.cc/T63T-BYBT>; Jacqui Wise, 'Covid-19: How AstraZeneca Lost the Vaccine PR War' (2021) 373(921) *British Medical Journal* 1, 2. For a peer reviewed analysis of trial data, see Merryn Voysey et al, 'Safety and Efficacy of the ChAdOx1 nCoV-19 Vaccine (AZD1222) against SARS-CoV-2: An Interim Analysis of Four Randomised Controlled Trials in Brazil, South Africa, and the UK' (2021) 397(10269) *Lancet* 99.

[151] See, eg, 'Fast Track Approval Pathways', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 16 March 2023) <https://www.tga.gov.au/fast-track-approval-pathways>, archived at <https://perma.cc/N6VA-57H5>.

[152] 'Provisional Registration Process', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 2 August 2018) <https://www.tga.gov.au/publication/provisional-registration-process>, archived at <https://perma.cc/V8MW-7V5K>.

[153] 'COVID-19 Vaccine: Information for Consumers and Health Professionals' (n 34); 'COVID-19 Vaccines Regulatory Status' (n 39).

[154] 'Provisional Registration Process' (n 152). See also *Therapeutic Goods Act* (n 1) ss 22C–22F, 23AA; *Therapeutic Goods Regulations* (n 30) regs 10K–10L, sch 3.

immunisation campaigns, such as France.[155] Similarly, the link between the AstraZeneca COVID-19 vaccine and the rare occurrence of a blood-clotting disorder (thrombosis with thrombocytopenia syndrome ('TTS')) emerged only a few months after the vaccine had been heavily rolled out in Europe.[156]

C *Separating the Factual from the Normative*

What transpires from the analysis above is that a positive regulatory outcome for new vaccines (ie some form of registration on the ARTG on the basis of safety and efficacy assessments) can occur as a result of different processes involving different levels and amounts of evidence. However, the concluding normative judgement, that a product is sufficiently 'safe and effective' to be deployed,[157] remains similar in nature. This is despite it being based on different factual or evidentiary bases, depending on whether approval occurred following normal or provisional procedures. Public health crises are bound to call for courses of action that accept higher trade-offs between safety and speediness. This much is accepted in regulatory frameworks, such as the TGA, and at general common law.[158]

In contrast, this is not fully reflected in processes for assessing relative safety under the *ACL* product safety regime and its concept of 'safety defect'.[159] This constitutes a first layer of tension between the two regulatory regimes. It is

[155] Jeremy K Ward, 'Rethinking the Antivaccine Movement Concept: A Case Study of Public Criticism of the Swine Flu Vaccine's Safety in France' (2016) 159 (June) *Social Science and Medicine* 48, 50, 52.

[156] 'AstraZeneca's COVID-19 Vaccine: EMA Finds Possible Link to Very Rare Cases of Unusual Blood Clots with Low Blood Platelets', *European Medicines Agency* (Web Page, 7 April 2021) <https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood>, archived at <https://perma.cc/WS8R-83CD>. See also Chandini Raina MacIntyre et al, 'Thrombosis with Thrombocytopenia Syndrome (TTS) following AstraZeneca ChAdOx1 nCoV-19 (AZD1222) COVID-19 Vaccination: A Risk-Benefit Analysis for People <60 years in Australia' (2021) 39(34) *Vaccine* 4784, 4784.

[157] *Therapeutic Goods Act* (n 1) s 4.

[158] Where forms of conduct that would normally be characterised as breaches of duty of care can be acceptable in the circumstances, see the classic decision of *Watt v Hertfordshire County Council* [1954] 1 WLR 835, 836–7 (Singleton J, Morris LJ agreeing at 838–9), 838 (Denning LJ, Morris LJ agreeing at 838–9). States and territories that have adopted civil liability legislation post 2002 include provisions requiring special consideration for the 'social utility' of the activity causing harm: see, eg, *Civil Law (Wrongs) Act 2002* (ACT) s 43(2)(d); *Civil Liability Act 2003* (Qld) s 9(2)(d); *Civil Liability Act 2002* (WA) s 5B(2)(d).

[159] *ACL* (n 2) s 9.

unclear whether the level of safety that 'persons generally are entitled to expect' under the *ACL*[160] varies alongside the TGA's different evidentiary basis for granting provisional, as opposed to normal, approval for the inclusion of therapeutic goods, such as COVID-19 vaccines, on the ARTG.

A second layer of regulatory tension derives from divergent interpretations given to the same evidential basis by different regulatory authorities in relation to vaccines. The obvious example here is the approval and supply of the AstraZeneca COVID-19 vaccine. It was approved under the TGA regulatory regime on 16 February 2021 for individuals aged 18 years and older.[161] It was initially rolled out in the general population following the priority order established under the Australian government's 'COVID-19 Vaccine and Treatment Strategy'.[162] On 8 April 2021, however, in response to concerns about TTS,[163] the Australian Technical Advisory Group on Immunisation ('ATAGI') issued a recommendation that the alternative Pfizer vaccine was to be 'preferred over AstraZeneca COVID-19 vaccine in adults aged under 50 years' (later pushed to under 60 years).[164] While it is certainly within the remit of ATAGI to 'provide technical advice to the Minister for Health on the medical

[160] Ibid s 9(1).

[161] Therapeutic Goods Administration, Department of Health and Aged Care (Cth), 'TGA Provisionally Approves AstraZeneca's COVID-19 Vaccine' (Media Release, 16 February 2021) <https://www.tga.gov.au/media-release/tga-provisionally-approves-astrazenecas-covid-19-vaccine>, archived at <https://perma.cc/7M7J-WTQY>.

[162] See generally Department of Health and Aged Care (Cth), 'Australia's COVID-19 Vaccine and Treatment Strategy' (Policy Document, 23 April 2021) <https://www.health.gov.au/sites/default/files/documents/2020/08/australia-s-covid-19-vaccine-and-treatment-strategy.pdf>, archived at <https://perma.cc/96RD-UN8G>.

[163] TTS is blood clotting, including in the brain and abdomen, in conjunction with low levels of blood platelets. It is a rare but potentially very serious condition: MacIntyre et al (n 156) 4784; Australian Technical Advisory Group on Immunisation, Department of Health and Aged Care (Cth), 'ATAGI Statement on AstraZeneca Vaccine in Response to New Vaccine Safety Concerns' (Media Release, 8 April 2021) <https://www.health.gov.au/news/atagi-statement-on-astrazeneca-vaccine-in-response-to-new-vaccine-safety-concerns>, archived at <https://perma.cc/8B8B-KC6P>.

[164] 'ATAGI Statement on AstraZeneca Vaccine in Response to New Vaccine Safety Concerns' (n 163); Australian Technical Advisory Group on Immunisation, Department of Health and Aged Care (Cth), 'ATAGI Statement on Revised Recommendations on the Use of COVID-19 Vaccine AstraZeneca, 17 June 2021' (Media Release, 17 June 2021) <https://www.health.gov.au/news/atagi-statement-on-revised-recommendations-on-the-use-of-covid-19-vaccine-astrazeneca-17-june-2021>, archived at <https://perma.cc/32TK-QQUR>.

administration of vaccines available in Australia',[165] the primary regulatory responsibility to establish the safety and efficacy of vaccines remains with the TGA. The TGA did not modify its approval of the AstraZeneca COVID-19 vaccine for individuals aged 18 years and older.[166]

In addition to these divergent interpretations of safety and efficacy data, the general public has been exposed to further interpretive inconsistencies. These include the Chief Health Officer of Queensland stating: 'I don't want an 18-year-old in Queensland dying from a clotting illness who, if they got COVID, probably wouldn't die.'[167] This was in response to pressures by the federal government to ramp up the use of the AstraZeneca vaccine to revitalise a lingering rollout.[168] The skirmish was swiftly followed by the then Commonwealth Minister for Health announcing the establishment of a special COVID-19 indemnity scheme for significant adverse reactions to COVID-19 vaccines.[169] Finally, as the COVID-19 Delta variant outbreak grew worse in New South Wales, ATAGI revised their advice to underline the overall benefits of the AstraZeneca vaccine in the context of a large outbreak.[170] All of this

165 Australian Technical Advisory Group on Immunisation, Department of Health and Aged Care (Cth), *Terms of Reference* (2 September 2019) <https://www.health.gov.au/sites/default/files/atagi-terms-of-reference.pdf>, archived at <https://perma.cc/557Y-8F36>.

166 'COVID-19 Vaccines Regulatory Status' (n 39).

167 Stephanie Zillman, 'Queensland's Chief Health Officer Rejects Prime Minister's Comments on AstraZeneca's COVID-19 Vaccine for under-40s', *ABC News* (online, 30 June 2021) <https://www.abc.net.au/news/2021-06-30/qld-cho-rejects-morrisons-astrazeneca-comments-covid-vaccine/100256022>, archived at <https://perma.cc/UDW6-YCL2>, quoting Jeanette Young (Press Conference, Queensland, 30 June 2021).

168 Zillman (n 167).

169 Greg Hunt, Minister for Health and Aged Care (Cth), 'COVID-19 Indemnity Scheme To Protect Health Professionals and Patients' (Media Release, 2 July 2021) <https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/covid-19-indemnity-scheme-to-protect-health-professionals-and-patients>, archived at <https://perma.cc/9MRX-DB2W>, subsequently confirmed in Greg Hunt, Minister for Health and Aged Care (Cth), 'No Fault COVID-19 Indemnity Scheme' (Media Release, 28 August 2021) <https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/no-fault-covid-19-indemnity-scheme>, archived at <https://perma.cc/966N-FVYR>. For an initial discussion of this indemnity scheme, see Marco Rizzi et al, 'No-Fault Compensation for COVID-19 Vaccine Injuries in Australia' [2021] (36) *InSight+* <https://insightplus.mja.com.au/2021/36/no-fault-compensation-for-covid-19-vaccine-injuries-in-australia/>, archived at <https://perma.cc/4QQW-C3SC>.

170 Australian Technical Advisory Group on Immunisation, 'ATAGI Statement: Response to NSW COVID-19 Outbreak', *Department of Health and Aged Care (Cth)* (Web Page, 24 July 2021) <https://www.health.gov.au/news/atagi-statement-response-to-nsw-covid-19-outbreak-24th-july-2021>, archived at <https://perma.cc/U6YD-DTQK>.

occurred in the absence of variations to the terms of approval of the AstraZeneca vaccine by the TGA.[171]

In the Australian context, where the 'consumer expectation test' is the *ACL* benchmark for product safety,[172] assessing the AstraZeneca vaccine represents a truly wicked task. Indeed, should the matter come to litigation, courts would have to navigate a cross-current of evaluative tensions to establish what can legitimately constitute a reasonable expectation by consumers in the context of the pandemic. In part, this problem is inherent to therapeutic goods, which has prompted commentators to argue that the alternative 'risk-utility' (or risk-benefit) paradigm may be more appropriate and would align the *ACL* with the TGA regulatory regime.[173] However, this problem is also the result of the dual tension discussed in this Part. First, the application of different procedures and evidentiary bases under the TGA regulatory regime may form the basis for reasonable consumer expectations and, by implication, the identification of a safety defect under the broader consumer protection regime. Second, the existence of a complex web of considerations, particularly during a public health crisis, may lead to different regulators and other authorities (eg ATAGI) promoting different and not necessarily consistent recommendations. While the focus of this article is not the outcomes associated with these recommendations, it is valuable to highlight, as we have above, that a range of tests and standards, and their underpinning operative criteria, carry the potential to produce conflicting regulatory outcomes.

V Inadequate Scrutiny of Approval Standards: Pelvic Mesh

Recent case law from the Federal Court of Australia involving contraventions of the *ACL* in relation to implantable medical devices has raised significant questions about how such products came to be approved by the TGA — and consequently about that regulatory regime's safety and quality-assurance practices.[174] As outlined earlier, registration of a therapeutic good (such as a

[171] 'COVID-19 Vaccines Regulatory Status' (n 39).

[172] *ACL* (n 2) s 9(1); *Ethicon* (n 80) 460 [582]–[585] (Jagot, Murphy and Lee JJ).

[173] See, eg, Mabel Tsui, 'Pharmaceutical Product Liability and the Australian Consumer Law: Towards a Principled Approach' (2015) 23(2) *Competition and Consumer Law Journal* 157, 190–1. The test was famously adopted in the US: American Law Institute (n 71) § 2 cmt (a).

[174] See Therapeutic Goods Administration, Department of Health and Aged Care (Cth), 'Action Plan for Medical Devices: Progress Report Card: June 2021' (Report,

medical device) in the ARTG is, generally speaking, the culmination of a complex process of product review and approval for which the TGA adopts a risk-based approach. This allows for reduced scrutiny of products that are deemed low risk, and increased precautionary steps for products that present a higher, harmful potential.[175] Including therapeutic goods in the ARTG thus serves the twofold purpose of maintaining a high degree of control over the marketability of products that fall within the scope of the *Therapeutic Goods Act* and ensuring that the products that are included conform with set standards of safety, quality and efficacy. While the goal is obviously not to provide an unachievable no-risk guarantee, the TGA regulates to ensure that 'therapeutic goods in the marketplace … [are] of high quality and of a standard at least equal to that of comparable countries'.[176] Unfortunately, dependence by the TGA regulatory regime on schemes in 'comparable countries'[177] led to the indefensible registration of certain implantable medical devices by the TGA in

16 September 2021) <https://www.tga.gov.au/sites/default/files/2022-08/action-plan-for-medical-devices-progress-report-card-june-2021.pdf>, archived at <https://perma.cc/4Z6L-5669>, where the TGA completed extensive consultations by June 2021 to implement *An Action Plan for Medical Devices: Improving Australia's Regulatory Framework* (Report, April 2019) <https://www.tga.gov.au/sites/default/files/2022-08/action-plan-medical-devices.pdf>, archived at <https://perma.cc/N8P8-YX7K> ('*Action Plan*'). The *Action Plan* (n 174) implements three strategies for the strengthening of the regulatory framework governing the approval and monitoring of medical devices in Australia: at 4; 'Action Plan for Medical Devices', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 9 February 2023) <https://www.tga.gov.au/resources/publication/publications/medical-devices-reforms-action-plan-medical-devices>, archived at <https://perma.cc/4GYA-SY98>. See also Penny Gleeson and Marco Rizzi, 'Response No 1006016444 to Therapeutic Goods Administration', *Consultation Proposed Enhancements to Adverse Event Reporting for Medical Devices* (30 November 2020) 3–11 <https://consultations.tga.gov.au/tga/copy-of-copy-of-test-2-adverse-events-reporting-fo/consultation/view_respondent?fbclid=IwAR3SLQLiHSBU aeydltmAsnVccTjIQcpA5d5I7Mf6r-4LoJ7ILa41HTc_6iQ&uuId=1006016444>, archived at <https://perma.cc/3MKQ-ZFA8>.

175 'Product Regulation According to Risk' (n 13); Rohan Hammett and Leonie Hunt, 'The Australian Medicines Regulatory System: A Risk-Based Approach to Regulation' (2009) 43(1) *Drug Information Journal* 17, 18.

176 'How the TGA Regulates: Overview of How Therapeutic Goods Are Regulated in Australia', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page) <https://www.tga.gov.au/how-we-regulate/advertising/legal-framework/act-regulations-and-code-offences/how-tga-regulates>, archived at <https://perma.cc/KGE3-ZSRD>.

177 'List of Countries and Jurisdictions Determined To Be Comparable Overseas Regulators (CORs)', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 24 October 2019) <https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good-0/supply-prescription-medicine/application-process/comparable-overseas-regulators/list-countries-and-jurisdictions-determined-be-comparable-overseas-regulators-cors>, archived at <https://perma.cc/8PGD-2AYM>.

the ARTG. This is particularly problematic for a country like Australia where most implants are imported and not locally produced.[178] There are two aspects related to this issue that warrant further examination.

A *Blind Reliance on International Regulatory Decisions*

The first aspect can be described as one of blind reliance on the risk assessments adopted by foreign regulatory frameworks, without supplementing these with adequate independent reviews under the TGA's own regulatory arrangements.[179] A recent, painful, example of this problem is the class action brought by Kathryn Gill, Diane Dawson and Ann Sanders against subsidiaries of the Johnson & Johnson group for damages caused by two types of transvaginal mesh implants manufactured and supplied by the group.[180] The case is particularly distressing because it involves relatively healthy women who decided to undergo procedures to resolve urogynaecological problems[181] and subsequently found themselves battling unexpectedly widespread and debilitating injuries.[182]

The case was decided at first instance by Katzmann J in the Federal Court of Australia in November 2019 and the substantive findings were upheld by the Full Court of the Federal Court in March 2021.[183] The High Court of Australia subsequently refused Johnson & Johnson's application for special

[178] See Senate Community Affairs References Committee, Parliament of Australia, *Number of Women in Australia Who Have Had Transvaginal Mesh Implants and Related Matters* (Report, March 2018) 9; Gleeson and Rizzi (n 174) 4.

[179] See, eg, *Ethicon* (n 80) 371–2 [169]–[170], 523–4 [833] (Jagot, Murphy and Lee JJ).

[180] *Gill* (n 15) [1]–[16] (Katzmann J).

[181] See, eg, ibid [3890], [4092]. The mesh implants considered in the case were indicated for use as surgical implants for women with stress urinary incontinence or pelvic organ prolapse: at [1]. Stress urinary incontinence and pelvic organ prolapse are relatively common conditions amongst Australian women, and it is estimated that mesh medical devices are implanted in 25% of pelvic floor reconstructions undertaken to address these conditions: J Oliver Daly et al, 'The Australasian Pelvic Floor Procedure Registry: Not Before Time' (2019) 59(4) *Australian and New Zealand Journal of Obstetrics and Gynaecology* 473, 473.

[182] See, eg, *Gill* (n 15) [3921]–[4069] (Katzmann J). See also at [4100]–[4227], [4237]–[4356].

[183] Ibid [3458], [3496], [3515]–[3517], [3581]–[3607], [3879]–[3884], affd *Ethicon* (n 80) 352 [26] (Jagot, Murphy and Lee JJ). See also Moira Saville, Suzy Madar and Sarah-Jane Frydman, 'Appeal in Ethicon Pelvic Mesh Class Action: What Risks Need To Be Disclosed?' (2021) 29(3) *Australian Health Law Bulletin* 49, 49.

leave to appeal.[184] When the trial started in 2017, 700 women had registered as members of the class.[185] The trial judge estimated, however, that the membership of the class was much larger in light of the fact that over 90,000 of the incriminated devices were supplied in Australia.[186] In early September 2022, a settlement was agreed between the parties for $300 million, which the applicants' lawyers assert is 'the largest settlement in a product liability class action in Australian history'.[187] The settlement was subsequently approved by the Federal Court.[188]

The findings in *Gill v Ethicon Sàrl [No 5]* (and its appellate affirmation)[189] were particularly damning for the subsidiaries of the Johnson & Johnson group. Justice Katzmann found the respondents liable on several bases, spanning a number of consumer protection provisions under the *Trade Practices Act 1974* (Cth) (now the *ACL*), including supplying goods with a safety defect, supplying goods not of merchantable (now acceptable) quality and engaging in misleading conduct.[190] The respondents were further found liable under the law of negligence.[191] However, aside from the misconduct of the respondents, more relevant for the purposes of this article is the severe indictment of the

[184] Transcript of Proceedings, *Ethicon Sarl v Gill* [2021] HCATrans 187, 630 (Keane J). See also Sonali Paul, 'J&J Fails in Final Bid To Appeal Australian Pelvic Mesh Class Action Ruling', *Reuters* (Web Page, 6 November 2021) <https://www.reuters.com/business/healthcare-pharmaceuticals/jj-fails-final-bid-appeal-australian-pelvic-mesh-class-action-ruling-2021-11-05/>, archived at <https://perma.cc/Y488-6ALL>.

[185] *Gill* (n 15) [13] (Katzmann J).

[186] Ibid.

[187] Shine Lawyers, 'Settlement Reached in Mesh Class Actions' (Media Release, 11 September 2022) <https://www.shine.com.au/media-centre/media-releases/settlement-reached-in-mesh-class-actions>, archived at <https://perma.cc/Q8B4-P6YN>.

[188] *Gill v Ethicon Sàrl [No 10]* [2023] FCA 228, [2] (Lee J). On the subsequent mechanism to distribute the settlement between class members, see *Gill v Ethicon Sàrl [No 11]* [2023] FCA 229.

[189] *Ethicon* (n 80).

[190] *Gill* (n 15) [3515]–[3517], [3544], [3581]–[3607], affd ibid 488 [696], [698], 519 [811] (Jagot, Murphy and Lee JJ).

[191] *Gill* (n 15) [3879]–[3884] (Katzmann J). These findings were restated by the Full Court in *Ethicon* (n 80) 389 [291] (Jagot, Murphy and Lee JJ). For an overview, see the official summary by the Federal Court of Australia: Anna Katzmann, 'Gill v Ethicon Sàrl & Ors (No 5) [2019] FCA 1905: Summary', *Federal Court of Australia* (Web Page, 21 November 2019) <https://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2019/2019fca1905/summary/2019fca1905-summary>, archived at <https://perma.cc/6P8L-GKLN>. See also Bill Madden, 'Pelvic Mesh Litigation: Outcome of the Federal Court of Australia Trial in Gill v Ethicon Sàrl (No 5)' (2020) 28(3) *Australian Health Law Bulletin* 53, 55.

TGA regulatory regime, which led to the market authorisation of the defective implantable devices. The devices and their marketing were found by the Federal Court to fall well below the normative yardstick represented by the level of safety a consumer can reasonably expect, as reflected in the *ACL*.[192] This example therefore illustrates how the conflict between the respective TGA and *ACL* regulatory regimes can play out with devastating consequences for those involved.[193]

There are two ways in which a medical device can be registered in the ARTG. To demonstrate that the product meets the essential principles set out in sch 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth),[194] manufacturers must undertake a conformity assessment leading to a certification that can be issued either by the TGA itself (typically for domestic products) or by other recognised authorities, such as a 'European notified body' (typically for imported products).[195] 'Notified bodies' are entities notified to the European Commission (hence the name) by European Union member states, and this designation empowers them, among other things, to issue quality and conformity assessment certifications, including the CE mark (a universally-

[192] *Gill* (n 15) [3458], [3496], [3515]–[3517] (Katzmann J).

[193] Justice Katzmann also discusses alerts (relating to serious complications associated with the implants under review in *Gill* (n 15)) issued in the US by the US Food and Drug Administration as early as 2008: at [2449], quoting 'FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence', *US Food and Drug Administration* (Web Page, 20 October 2008) <https://www.govinfo.gov/content/pkg/USCOURTS-ca4-15-01454/pdf/USCOURTS-ca4-15-01454-1.pdf>, archived at <https://perma.cc/4UNZ-NKB4>.

[194] *Therapeutic Goods (Medical Devices) Regulations* (n 33) sch 1 pts 1–2. Part 1 identifies six general principles:

1 Use of medical devices not to compromise health and safety …
2 Design and construction of medical devices to conform with safety principles …
3 Medical devices to be suitable for intended purpose …
4 Long-term safety …
5 Medical devices not to be adversely affected by transport or storage …
6 Benefits of medical devices to outweigh any undesirable effects…

Part 2 identifies a number of more specific principles about design and construction.

[195] 'Australian Regulatory Guidelines for Medical Devices (ARGMD)', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 2 November 2023) <https://www.tga.gov.au/resources/resource/guidance/australian-regulatory-guidelines-medical-devices-argmd>, archived at <https://perma.cc/9L4V-5GMH>.

accepted mark of quality assurance).[196] As noted by Katzmann J, and restated by the Full Federal Court, the pelvic mesh implants involved in the class action (except for one) were added to the ARTG without independent TGA scrutiny on the basis that they all carried the CE mark.[197] This was per se problematic given the controversial nature of notified bodies and their contested status even in the European market.[198] Indeed, notified bodies are often private entities offering quality assurance certifications as professional services.[199] In addition to this, processes of research and development of new devices are mostly self-regulated by the industry.[200] This is a significant point of difference from the development of pharmaceutical products, which is highly regulated from drug discovery to pre-clinical testing, clinical trials and pre-market approval.[201] The

196 'Notified Bodies', *European Commission* (Web Page) <https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/notified-bodies_en>, archived at <https://perma.cc/V5HS-KD9A>. This is an example of what is commonly referred to as the European 'new approach' to goods, under which general goals are mandated by legislation (European Union directives or regulations), but standard setting and conformity assessment are outsourced to private or hybrid entities. The regime applicable to medical devices is explained in *Gill* (n 15) [1389]–[1397] (Katzmann J) and *Ethicon* (n 80) 371–2 [168]–[170], [174] (Jagot, Murphy and Lee JJ).

197 *Gill* (n 15) [1391], [1398]; *Ethicon* (n 80) 372–3 [173]–[178] (Jagot, Murphy and Lee JJ). Only one of the devices under scrutiny was classified as 'class III', that is, a 'high' risk device: *Gill* (n 15) [1391], [1400] (Katzmann J). See also 'Medical Devices Overview' (n 33) for an explanation of the classes. Note, however, that in order to have the high risk device registered, the manufacturer had to provide the TGA with further information including an audit file, but no independent review was conducted nor was specific clinical data required prior to marketing: *Gill* (n 15) [1672], [1700] (Katzmann J). The Full Federal Court used very strong wording for its damning findings about the inadequacies of the regulatory mechanisms underpinning attribution of the CE mark for medical devices: *Ethicon* (n 80) 371–3 [168]–[178] (Jagot, Murphy and Lee JJ).

198 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, 398–9, 404–5.

199 Ibid 397.

200 *Gill* (n 15) [1408] (Katzmann J). In *Ethicon* (n 80), the Full Federal Court analyses how certain products could be marketed notwithstanding the absence of any clinical evidence: at 376 [200]–[202] (Jagot, Murphy and Lee JJ).

201 This point of difference is not exclusive to Australia. The US and European regulatory regimes for pharmaceuticals developed on the back of two drug disasters: sulfanilamide in the US in the early 1900s and thalidomide half a century later in Europe: Arthur A Daemmrich, *Pharmacopolitics: Drug Regulation in the United States and Germany* (University of North Carolina Press, 2004) 22–3, 25–7, 69. Medicines have benefitted from ad hoc regulatory infrastructures for decades. The same level of attention has been lacking for medical devices, as exemplified by the European Union regulatory regime: see, eg, Verbruggen and van Leeuwen (n 198) 397–9, 404–5.

net result is that, in Australia, it is entirely possible to have an implantable medical device, classified as 'medium to high' risk,[202] developed in accordance with industry standards alone, and registered in the ARTG after a conformity assessment performed by a private entity as a professional service — rather than by an independent regulator. As Katzmann J stated, '[a]ll that CE marking proves is that the manufacturer *asserts* that a device meets those requirements'[203] and that, based on the evidence provided to the Court, the TGA regulatory regime in relation to medical devices was therefore 'largely self-regulating'.[204]

The controversial role of notified bodies has prompted the European Union to reform its regulatory framework for medical devices and put these entities under much greater scrutiny.[205] This is certainly a positive development for countries like Australia that heavily rely on the European supply of implants.[206] The harrowing experience of Kathryn Gill, Diane Dawson and Ann Sanders remains, however, a stark cautionary tale against exclusive reliance on outsourced assessments.

B *Distinctions (or Their Absence)*

Reliance on foreign approvals raises a second type of problem for the practice of ARTG registration and its significance for consumer expectations. Foreign regulatory frameworks, such as the European model discussed above, or the US's regulations administered by the Food and Drug Administration ('FDA'), may articulate distinctions in the levels of pre-market approval that are not catered for by the *Therapeutic Goods Act*. In late 2018, the International Consortium of Investigative Journalists ('ICIJ') released the results of a global investigation into the regulatory regimes for implantable medical devices in 36

[202] All but one of the devices automatically registered for bearing the CE mark were 'class IIb' devices, which are considered 'medium to high' risk: *Gill* (n 15) [398], [1400] (Katzmann J). See generally 'Medical Devices Overview' (n 33).

[203] *Gill* (n 15) [3270] (emphasis added).

[204] Ibid [3687].

[205] *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 117/1, Preamble para 4, arts 35–6, 43–5, 47, annex VII.

[206] Senate Community Affairs References Committee (n 178) 9.

countries titled, 'Implant Files'.[207] Case studies involving Australian injured parties revealed that the TGA had registered in the ARTG several devices that had not received final approval in their countries of origin.[208] Provisional approval is not equivalent to general pre-market approval and is only meant to allow limited distribution of the relevant product.[209] Provisional approval of medical devices is generally also not permitted under the Australian TGA regulatory regime. The inclusion of such devices in the ARTG has led to the distribution of implants or other devices essentially unfit for purpose, on the basis of what appears to be an inadequate regulatory appreciation of the level of safety and efficacy guaranteed by foreign risk assessments.

C *Lessons Learned — and Yet To Be Learned*

The *mea culpa* of the TGA in response to the transvaginal mesh controversy was extensive. It cancelled the approval of 43 vaginal mesh devices and

[207] 'An ICIJ Investigation: Implant Files', *International Consortium of Investigative Journalists* (Web Page) <https://www.icij.org/investigations/implant-files/>, archived at <https://perma.cc/VD3X-QU7S>; Fergus Shiel, 'About the Implant Files Investigation', *International Consortium of Investigative Journalists* (Web Page, 25 November 2018) <https://www.icij.org/investigations/implant-files/about-the-implant-files-investigation/>, archived at <https://perma.cc/VF5D-MVAL>. In Australia, the case was followed by the ABC: see, eg, Mario Christodoulou et al, 'The Implant Files: Deadly Devices', *ABC News* (online, 26 November 2018) <https://www.abc.net.au/news/2018-11-26/implant-files-shine-light-on-medical-device-industry/10521480?nw=0>, archived at <https://perma.cc/BY85-GJHM>.

[208] See, eg, Alison Branley et al, 'The Implant Files Reveal TGA Failures in Medical Device Trial', *ABC News* (online, 26 November 2018) <https://www.abc.net.au/news/2018-11-26/implant-files-reveal-tga-failures-in-medical-device-trial/10547486>, archived at <https://perma.cc/5HGT-6QFF>; Andrew W Lehren and Emily R Siegel, 'Exporting Pain: US-Made Medical Devices Cause Serious Injuries, Pain Overseas', *NBC News* (online, 26 November 2018) <https://www.nbcnews.com/health/health-care/exporting-pain-u-s-made-medical-devices-cause-serious-injuries-n939121>, archived at <https://perma.cc/2LWL-L4UK>.

[209] See, eg, the different pre-market approval methods available to the FDA: 'PMA Application Methods', *US Food and Drug Administration* (Web Page, 27 September 2018) <https://www.fda.gov/medical-devices/premarket-approval-pma/pma-application-methods>, archived at <https://perma.cc/55WK-F48U>. Commonly used methods include the 21 CFR § 814.19 (2024) for the purpose of which 'clinical evaluation of a device and the development of necessary information for marketing approval are merged into one regulatory mechanism': 'PMA Application Methods' (n 209). An example of a device that never received final approval by the FDA but was nonetheless registered in Australia is the PyroTITAN shoulder replacement device, which benefitted from mutual recognition of less stringent approval by EU notified bodies: see Alison Branley et al (n 208).

prohibited the use of others.[210] Additional conditions and requirements were imposed on mesh devices that remained on the ARTG and their classification was upgraded to reflect the higher degree of risk posed by the devices, and therefore the regulatory oversight required.[211] The political fallout from the regulatory failings was also evident. A Senate inquiry was established to investigate transvaginal mesh implants, resulting in 13 recommendations, including in relation to the regulation of medical devices more broadly, and other regulators such as the Australian Commission on Safety and Quality in Health Care.[212] Soon after, the then Commonwealth Minister for Health and Aged Care apologised '[o]n behalf of the Australian government … to all of those women with the historic agony and pain that has come from mesh implantation, which have led to horrific outcomes'.[213]

Other reforms were introduced to the TGA regulatory regime in the wake of the transvaginal mesh scandal. They covered a comprehensive range of implantable devices and required manufacturers to provide 'patient information leaflets' and 'implant cards'.[214] The purpose of the reforms was to improve patient consent procedures and the capacity for implanted devices to be 'traced' following implantation.[215]

Despite these reforms, the general point raised in the preceding discussion has not been acted on. Regulators and regulatory schemes — most obviously that of the TGA — need to maintain elevated levels of care in the performance of processes designed to achieve the goals of consumer and patient safety.

[210] 'About Transvaginal Surgical Mesh Devices', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 19 December 2023) <https://www.tga.gov.au/products/medical-devices/urogynaecological-transvaginal-surgical-mesh-hub/background>, archived at <https://perma.cc/4JXQ-9DZY>; Mike O'Connor and Bill Madden, 'Vaginal Dialogues: The Trials and Tribulations of Mesh in the Repair of Prolapse' (2020) 27(3) *Journal of Law and Medicine* 618, 624.

[211] See above n 210.

[212] Senate Community Affairs References Committee (n 178) ix–xii, 3.

[213] Melissa Davey, 'Greg Hunt Apologises to Women Affected by "Horrific" Transvaginal Mesh Scandal', *The Guardian* (online, 10 October 2018) <https://www.theguardian.com/society/2018/oct/10/greg-hunt-apologises-to-women-affected-by-horrific-transvaginal-mesh-scandal>, archived at <https://perma.cc/8GDX-EGQU>, quoting Greg Hunt (Press Conference, 10 October 2018).

[214] 'Australian Regulatory Actions: About Transvaginal Surgical Mesh', *Therapeutic Goods Administration, Department of Health and Aged Care (Cth)* (Web Page, 13 April 2023) <https://www.tga.gov.au/products/medical-devices/urogynaecological-transvaginal-surgical-mesh-hub/australian-government-actions>, archived at <https://perma.cc/XNF5-EWKM>.

[215] Ibid.

Specifically, if the purpose of TGA approval of a medical device is to signal compliance with elevated safety and quality standards, the processes leading to registration must be 'fit for purpose'. By virtue of its relatively small size, Australia is bound to prevalently be an importer of advanced technological devices (medical or otherwise).[216] As such, it is critical that regulators remain alive to the characteristics of foreign regulatory models, to preserve the integrity of Australian consumer protection regimes, which exist to govern the market for consumer goods, not to be subordinate to its necessities. The example of implantable devices, with reference to the pelvic mesh class action and the Australian 'Implant Files',[217] is admittedly egregious. Yet, it is symptomatic of broader structural weaknesses that Australian patient and consumer safety regulations need to confront openly and independently. Or, in other words, it suggests a significant misalignment between the floor and ceiling of consumer protection in an area where expectations of safety and quality are inherently high.

VI The Need for Regulatory Coherence and Coordination

A strong consumer protection regime must be clear and coherent in relation to therapeutic goods for Australian consumers and patients. This is particularly the case during public health crises such as the COVID-19 pandemic. The preceding case studies, however, highlight a lack of regulatory coherence in the control of therapeutic goods and possible insufficient coordination between regulators. This is, at least in part, explained by the distinct and divergent norms, outlined earlier, which inform the TGA regulatory regime, on the one hand, and those of the *ACL*, on the other. The resulting operational inconsistencies create a range of challenges for Australian consumers and patients which must be addressed.

In the case of hand sanitisers, the inconsistencies between the respective regulatory regimes concerned the degree of safety and efficacy that consumers could expect from that product. During a pandemic, it was reasonable for consumers to expect that a 'sanitiser' would achieve a protective purpose relevant to that public health crisis. The TGA and *ACL* regulatory regimes supported, however, a distinction that arguably created, at best, public

[216] See Senate Community Affairs References Committee (n 178) 9.

[217] See above nn 207–8 and accompanying text.

confusion and, at worst, harmful individual and public health outcomes. Broad claims of sanitisers' effectiveness against 'germs' or 'bacteria' can lead ordinary consumers into error. They are unlikely to appreciate a distinction which, in the midst of a public health event, is likely to appear artificial. While the TGA regulatory regime adapted to accommodate the supply and demand challenges of the public health crisis (by substituting TGA approvals for WHO-approved formulations), [218] it did not evolve to adequately consider the reasonable expectations of consumers. This reflects the norms inherent in the therapeutic goods regulatory regime discussed earlier: that it is the scientific standards and the goods to which they apply (and, in turn, their manufacturers) that are at the centre of that regulatory regime. Unlike the *ACL*, neither the patient nor the consumer appeared central to the TGA regulatory regime's control of this therapeutic good. Importantly, the ACCC did not pick up the slack by pushing back on the arguably misleading claims of mere cosmetic sanitisers which, although previously innocuous, assumed new salience during, and in the aftermath of, the pandemic.

The provisional approval of COVID-19 vaccines under the TGA regulatory regime is a further example of how that scheme adapted to the demands of a particular health event. What remains unclear, however, is how such an adaptation might (or should) impact a subsequent judicial assessment of 'reasonable consumer expectations' in relation to that therapeutic good, and therefore the existence, or otherwise, of a safety defect under the *ACL*. In relation to COVID-19 vaccines, the situation is further complicated by a prominent divergence in normative assessments of who should receive those vaccines based on the available evidence. Such an intricate overlay of regulatory and policy assessments reveals additional challenges to the complex interaction between TGA and *ACL* standards in fast-moving emergency scenarios.

The final case study discussed — implantable transvaginal mesh devices — highlighted the normative 'distance' between the TGA regulatory regime's focus on the product of regulation (and their associated assessments by third parties) and patients' focus on their own expectations of safety, quality and efficacy. In contrast, it is the latter which constitutes the normative foundation for the broader *ACL* regulatory regime. And it is that regime which ultimately provided legal redress for the survivors of transvaginal mesh implants. The *ACL* regime proved effective in prompting a revised approach to regulation by the TGA of the product in question. But more general questions of the standards

[218] Hunt, 'Increased Flexibility for Production of Hand Sanitisers' (n 105).

applied by the TGA in assessing the safety of medical devices more generally remain. In relation to implantable medical devices therefore, it appears that at a bare minimum, some level of independent review by the TGA remains necessary for imported therapeutic goods. This may support a degree of normative consistency with Australian patients' expectations of safety and efficacy — and of regulatory coherence between the TGA and *ACL* regulatory regimes. The alternative is to permit a hollowing out of the TGA regulatory regime in relation to the many therapeutic goods imported into Australia which have undergone conformity assessments in their countries of origin.

Collectively, these case studies indicate that the TGA regulatory regime should be cognisant of the flexible and dynamic consumer protection goals underpinning the *ACL*. Similarly, the ACCC and Commonwealth government should contemplate how the *ACL* might best engage with the scientific norms inherent in the TGA regulatory regime and their impact on patient and consumer expectations. At its core, this requires regulators to engage in a positive dialogue to bridge the inevitable gap that exists between the consumer expectation logic underpinning the *ACL* and the risk-utility one that informs the TGA. Patients and consumers expect that the TGA and *ACL* regulatory regimes should and will operate in a normatively coherent manner. That is, for example, a product not captured by the TGA should not be marketed with claims that invoke in consumers an expectation of medical efficacy. Conversely, that a medical device approved under the TGA regime would not contravene the *ACL* and likewise, that a product that contravenes the *ACL* would not be approved by the TGA.

In relation to therapeutic goods, coherence between the applicable regulatory regimes is fundamental to the state's ability, and perceived ability, to protect the health of its citizens.[219] Incoherence between the relevant regulatory schemes can unwittingly sow the seeds of distrust about the regulation of these important products and in government, particularly at times when trust is vital to sound public health outcomes.[220] A government which via one regulatory regime (ie the *ACL*) provides redress for the sale of therapeutic goods which do not meet reasonable expectations of safety, may not be perceived as supporting public health if it also approves the original supply of the same goods via another regulatory regime (ie the TGA regulatory regime) and fails to ensure a positive dialogue between the two. Enhanced coherence between the TGA

[219] See above n 12 and accompanying text.

[220] Jasanoff and Hilgartner (n 11) 289, 293–4.

and *ACL* regulatory regimes may also lead to greater certainty about the legal treatment of therapeutic goods and result in improvements in regulatory compliance.[221]

VII Conclusion

This article has sought to illustrate that reasonable expectations of consumers and patients are not simply exogenous elements that relevant laws, regulations and governing actors refer to as set parameters of safety or quality. They are constructs to which these laws, regulations and governing actors actively contribute, and in doing so, they shape the 'edifice' of consumer and patient protection. The risk we have identified is one of misalignment between the floor and ceiling of this 'edifice', something that goes beyond the physiological variations in focus and degrees of protection offered by different regimes. We developed this argument through the exploration of three case studies, which highlighted how circumstances that put regulatory frameworks to the test can sharpen or alter patient and consumer focus, and in turn exacerbate pressure back on the regulatory frameworks to respond promptly, appropriately and in a coordinated way. The analysis points to the conclusion that where constructive interplays between different levels of the broad regulatory architecture that protects patients and consumers are ignored, harm can ensue for consumer and patient protection and the integrity of the TGA and *ACL* regulatory schemes respectively. While the COVID-19 pandemic has made these issues more apparent, they are not exclusive to public health crises, and the analysis has much broader and ongoing ramifications for effective, just and safe regulation of commerce and the protection of consumers and patients.

[221] See, eg, Ida Mae de Waal, 'Coherence in Law: A Way To Stimulate the Transition towards a Circular Economy?' (2021) 28(6) *Maastricht Journal of European and Comparative Law* 760, 763–9.