A Critical Review of Australia's Regulatory Oversight for New Generation Personalised Medical Devices

By

Amandeep Singh Grewal

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Preface

In 2018, an international investigation into faulty medical implants, including the related industry practices and regulatory inadequacies resulting in the deaths of thousands of patients, forced many governments around the world to re-examine their regulatory practices.[1] In 2019, the Australian therapeutic goods regulatory authority, the Therapeutic Goods Administration (TGA), proposed a regulatory scheme for personalised medical devices. However, the implementation of Australian proposed regulatory reforms was postponed until 2021 due to the COVID-19 epidemic.

This book examines regulatory control of personalised medical devices in Australia with a primary focus on the *Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019* intended to amend the *Therapeutic Goods (Medical Devices) Regulations 2002.* The interaction of medical and legal fields in this legal project topic involves extensive use of existing knowledge to address actual pre-existing and anticipated future problems and to answer specific questions related to these problems.

The book aims to highlight regulatory inadequacies and explore solutions to address these inadequacies to improve and, where possible, assist in future-proofing of the personalised medicine regulatory framework in Australia in view of advances in this field on the international level. It also attempts to assist the evolution of a safe, optimal, balanced and almost future-proof regulatory system. In assessing the nature of the regulations, it identifies areas lacking or deficient of adequate standards before outlining general suggestions towards rectifying those shortcomings without participating in legislative drafting. The book's aims or goals are achieved through a basic understanding of the field of personalised medicine, including exploration of pre-existing regula-

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[1] Hilary Osborne and Hannah Devlin, 'Uncovering the implants scandal: 'the lack of transparency is shocking', The Guardian (online), 15 December 2018 <https://www.theguardian.com/membership/2018/dec/15/medical-implants-scandal-project-lack-transparency-shocking>.

tory practices at the state, national and international levels, exploration of upcoming technological advancements and relevant regulatory practices, followed by a critical review of the regulatory frameworks and suggestions to optimise regulatory mechanisms.

The research aspects of this book involve the interaction of legal and technically complex medical areas. A basic understanding of the field of personalised medicine, including 3D-printed medical devices and other relevant concepts, is included in the initial parts of the book. Identification of existing systems and concepts in relation to personalised medicine, developments including innovations in personalised medicine, possible futuristic applications and the basic risk profile of this field in view of regulatory frameworks with examples to facilitate a better understanding of the concepts is explored.

Information about the pre-existing regulatory framework is included to facilitate an understanding of the regulatory framework prior to the introduction of the 2019 regulatory amendments, how rapidly evolving technological advancements in the medical field were regulated and how the pre-existing system may or may not benefit the consumers and the innovators. A brief outline of different applicable or likely applicable legislative, including regulatory and other provisions in the area of personalised medicine, is included prior to the discussion about 2019 regulatory amendments.

Detailed information about 2019 regulatory proposals for personalised medical devices, including 3D-printed medical devices, includes six regulatory proposals, stakeholder feedback, the regulator's ability and willingness to incorporate feedback, corporate and the patients' interests and effectiveness of the regulatory development process.

Information about the 2019 regulatory proposals precedes the critical analysis of the 2019 Australian regulatory scheme for personalised medical devices, including 3D-printed devices. The exploratory analytical approach assists in identifying the book's research outcomes. A review of the fundamentals acting as the driving force behind specific regulatory changes, examination of the elements of change, anticipated

effects of the change including short- and long-term effectiveness, change management mechanisms including transitional provisions, advantages or strengths and disadvantages or weaknesses of this overall exercise including specific regulatory changes are also included in the critical analysis.

The above-identified elements, including major factors influencing regulatory effectiveness, assist in understanding how various aspects of medical devices are changing and are likely to behave in the future. The regulator's ability to effectively respond to modern challenges through a balanced approach in a timely manner, the structure of the proposed regulatory changes and other influencing factors also govern the structure and flow of this critical analysis. Detailed findings of the critical analysis are summed up in conjunction with the recommendations.

Ongoing efforts to align Australian medical device regulatory practices with international regulatory practices are primarily influenced by the International Medical Device Regulators Forum (IMDRF). The other participating members of the IMDRF, the United States and South Korea, are also participating in the IMDRF initiatives. Elements of the Australian medical device regulatory framework updated in 2019 are also compared with the similar elements of the United States and South Korean medical device regulatory frameworks. Comparative analysis of the Australian regulatory system with these two systems is selected because the diverse nature of the US and South Korean regulatory systems provides insight into different ways of addressing modern regulatory challenges while attempting to align closely with international regulatory practices.

Core findings of the comparative analysis of the updated Australian medical device regulatory framework with the relevant regulatory frameworks of the United States and South Korea are also included in the final part of the book. The book concludes with observations about the overall project and recommendations aimed at improving the Australian regulatory framework for new-generation personalised medical devices.

Chapter 1

Introduction and Context

1.1 Introduction

We live in a connected world where humans also act as valuable data sources for corporations and governments. The evolution of medicine and technology has presented enormous opportunities for various stakeholders directly or indirectly involved with the healthcare, technology and financial industries. As the current medical treatment approach of one size fits all is slowly becoming outdated, the emerging approach of individually tailored solutions to a person's medical problems seems to be a way of the future.

However, one major issue with technology is its rapid pace of development. The United Nations 2018 Technology and Innovation report estimated the average life cycle of technological platforms to be around five to seven years and the average regulatory response time to develop relevant regulatory mechanisms to be around 'ten to fifteen years'.[1] It seems the regulatory authorities are always playing catch up to regulate new innovations.[2]

The field of medicine has a long history of embracing technology from a simple magnifying glass to modern-day complex personalised medical devices.[3] Australia recorded faster health expenditure growth than population growth between 2006 and 2016.[4] The Australian govern-

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1 United Nations Conference on Trade and Development, Technology and Innovation Report 2018, UNCTAD/TIR/2018 (2018) 22 <https://unctad.org/system/files/official-document/tir2018_en.pdf>.

2 Gary Marchant, Braden R Allenby and Joseph R Herkert (eds), The Growing Gap Between Emerging Technologies and the Law (Springer Netherlands, 2011) ch 2, 19-32.

3 Nicholas Bakalar, Karen Barrow, Jon Huang and Diantha Parker, 'Milestones in Medical Technology', The New York Times (online) 10 October 2012 <https://archive.nytimes.com/www.nytimes.com/interactive/2012/10/05/health/digital-doctor.html#/#time15_375>.

4 Australian Institute of Health and Welfare, Australia's health 2018 Australia's health series no, 16 <https://www.aihw.gov.au/getmedia/941d2d8b-68e0-4883-a0c0-138d43dba1b0/aihw-aus-221-chapter-2-2.pdf.aspx#>.

ment has committed about $65 million in research funding to 'unlock the potential of personalised medicine through genomics'.[5] In 2018, an international investigation into faulty medical implants including the related industry practices and regulatory inadequacies resulting in the deaths of thousands of patients forced many governments around the world to re-examine their regulatory practices.[6] It seems the regulatory framework worldwide is struggling to keep up with the pace of technological advancements.[7] In 2018, the International Medical Device Regulators Forum (IMDRF) established a personalised medical device working group to assist in addressing regulatory challenges related to personalised medical devices in multiple global medical device regulatory jurisdictions.[8] In 2019, the Australian therapeutic goods regulatory authority, the Therapeutic Goods Administration (TGA) proposed a regulatory scheme for personalised medical devices.[9] However, the implementation of Australian proposed regulatory reforms was postponed until 2021 due to the COVID-19 epidemic.[10] It is noteworthy that the TGA's own timeframe for developing and implementing 2019 regulatory reforms from 2017 to 2024 keeps the regulator at least one generation behind emerging technological platforms.

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5 Commonwealth Department of Health, '$65 million to unlock the potential of personalised medicine through genomics' (Media Release, 26 March 2019) <https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/65-million-to-unlock-the-potential-of-personalised-medicine-through-genomics#>.

6 Hilary Osborne and Hannah Devlin, 'Uncovering the implants scandal: 'the lack of transparency is shocking', The Guardian (online), 15 December 2018 <https://www.theguardian.com/membership/2018/dec/15/medical-implants-scandal-project-lack-transparency-shocking>.

7 Marchant et al (n 1).

8 Therapeutic Goods Administration, Regulation impact statement: Proposed regulatory scheme for personalised medical devices, including 3D-printed devices (Version 1.0, December 2019 - OBPR reference: 24680, 21 February 2020) <https://www.tga.gov.au/publication/regulation-impact-statement-proposed-regulatory-scheme-personalised-medical-devices-including-3d-printed-devices#fn8>.

9 Therapeutic Goods Administration, Consultation: Proposed regulatory scheme for personalised medical devices, including 3D-printed devices (13 February 2019). <https://www.tga.gov.au/consultation/consultation-proposed-regulatory-scheme-personalised-medical-devices-including-3d-printed-devices>.

10 Therapeutic Goods Administration, Proposed delayed commencement of certain medical device regulatory changes (16 June 2020) <https://www.tga.gov.au/proposed-delayed-commencement-certain-medical-device-regulatory-changes>.

This book examines regulatory control of personalised medical devices in Australia with a primary focus on the *Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019* (Cth) ("2019 Amendment Regulations").[11] These regulatory measures were scheduled to be fully implemented prior to the end of 2024. The book examines three specific aspects of personalised medical devices from a legal perspective. These three aspects include the manufacturing process, the materials and the applicable regulations.

The specified tasks are addressed by exploring the Australian medical device regulatory framework before and after the introduction of amendments included in the 2019 Amendment Regulations, and the specific regulatory provisions applicable to the two identified elements of the personalised medical devices; the manufacturing processes and the specific materials, including technology used or likely to be used for manufacturing medical devices. The scope of the associated research includes an examination of the nature of existing regulations on the usage of existing and very recent innovations or even experimental personalised medical devices within the medical profession. The research considers examples that represent new technologies as well as new uses for established technologies transferring from other industries or professions. In examining the emerging and significant potential for 3-D printed devices, the book also explores the additional issues that may arise due to complexities associated with associated interactions of multiple technologies, such as issues associated with 3D printed human body parts involving biological information.

The book incorporates a comparative analysis of the Australian medical device regulatory framework with similar regulatory controls in other comparable jurisdictions where similar issues are arising, namely, the United States and the Republic of South Korea. In assessing the nature of current regulation, the book identifies those areas where adequate standards are likely deficient or entirely absent and offers general suggestions towards rectifying those shortcomings. This book concludes

[11] Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019 (Cth) ("2019 Amendment Regulations").

by giving reform recommendations, but legislative drafting of provisions is beyond the scope of this book.

1.2 Some Background Information

Regulation is a way of governing various aspects of the governed cohort with the aim of achieving specific results. Traditionally, the regulation has been deemed a necessity to control certain behaviours and safeguard the interests of all parties, especially the vulnerable parties likely to be affected by the behaviours or actions of the other involved parties. Medical devices and pharmaceuticals come under therapeutic goods, and these items can significantly interfere with human health to improve it, or worse, or to result in a fatal outcome for an individual and/or humanity. Therefore, governments globally have been regulating therapeutic goods for a long time. In Australia, the importance of the regulation of therapeutic goods is demonstrated by the relevant regulation history dating back to the pre-1900s.[12]

Therapeutic goods regulatory frameworks are generally polycentric to some extent[13] and include direct government regulatory controls and self-regulation. Julia Black proposes three key elements of legitimacy and accountability relationships that are central to understanding their dynamics, namely the role of the institutional environment in the construction of legitimacy; the dialectical nature of accountability relationships; and the communicative structures through which accountability occurs and legitimacy is constructed.[14] The polycentric regulatory strategies are necessary, and the accountability in polycentric regulatory setups is shared at multiple points. A regulator's legitimacy can be affected in a polycentric regulatory framework in accordance with the

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[12] John McEwen, A History of Therapeutic Goods Regulation in Australia (Therapeutic Goods Administration, 2007) 1.

[13] Julia Black, 'Constructing and contesting legitimacy and accountability in polycentric regulatory regimes' (2008) 2(2) Regulation & Governance 157 <https://doi.org/10.1111/j.1748-5991.2008.00034.x>.

[14] Ibid.

legitimacy of the other regulatory point or actor.[15]

Self-regulation of the therapeutic goods is generally preferred by some stakeholders although experts, such as Braithwaite, continue to highlight the drawbacks of this approach.[16] Braithwaite also argues that adequately strengthened self-regulation and regulatory setup can perform better than any standalone regulatory point.[17]

The TGA in Australia regulates therapeutic goods since its establishment in 1989 under the Therapeutic Goods Act 1989. The TGA is also responsible for the administration of the *Therapeutic Goods (Charges) Act 1989* (Cth). The TGA carries out its regulatory activities with authority from these two main legislations and through various regulations, including legislative instruments. The TGA's regulatory activities include the regulation of medicines, medical devices and other therapeutic goods such as in vitro diagnostic medical devices (IVDs), blood, sterilants and disinfectants.[18]

Medical devices in Australia are defined under section 41BD of the Therapeutic Goods Act 1989. A medical device needs to be included in the Australian Register of Therapeutic Goods (ARTG) prior to its Australian market launch 'unless an exemption applies'.[19]

The TGA generally identifies an item as a medical device if it is; 'used for humans; intended to diagnose, prevent, monitor, treat or alleviate a disease or injury, or modify or monitor anatomical or physiological functions of the body; generally achieves its purpose by a physical, mechanical or chemical action'.[20] The term personalised medical device

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15 Ibid.

16 John Braithwaite, 'Submission on Consultation Paper: Improving Advertising Arrangements for Therapeutic Goods in Australia', Therapeutic Goods Administration (26 August 2010) <https://www.tga.gov.au/sites/default/files/consult-advertising-arrangements-101028-submission-braithwaite.pdf>.

17 Ibid.

18 Therapeutic Goods Administration, What the TGA regulates <https://www.tga.gov.au/what-tga-regulates>.

19 Therapeutic Goods Administration, Regulation impact statement: Proposed regulatory scheme for personalised medical devices, including 3D-printed devices (n 7).

20 Therapeutic Goods Administration, Overview of medical devices and IVD regulation (1 October 2020) <https://www.tga.gov.au/sme-assist/medical-devices-regulation-introduction>.

is generally used to describe medical devices made available to address specific individual requirements.[21]

Before 2019 regulatory reforms, personalised medical devices were regulated under the 'definition of custom-made medical device, and its corresponding exemption; already supplied medical devices referred to in the definition of manufacturer under section 41BG of the Therapeutic Goods Act 1989 but intended to be assembled or adapted to suit an individual and medical devices incorporating human original materials are regulated as biologicals'.[22] The TGA uses the 'Conformity assessment' process to assess the 'safety, quality and performance' of the medical devices.[23] The regulatory process for custom-made medical devices is different compared to other medical devices. A personalised medical device can be produced in a commercial manufacturing unit complying with relevant manufacturer assessment certifications and it can be 3D printed. Many types and forms of available personalised medical devices include various types of prosthetics, artificial organs such as kidneys made from stem cells, and combination medical device incorporating biological, chemical, structural physical and information technology components. An example includes 'ReCell 1920 Autologous Cell Harvesting Device - Autologous skin cell grafting kit' also known as 'ReCell Spray-On Skin'[24], which is classified as a high-risk class III medical device in the Australian Register of Therapeutic Goods (ARTG).[25]

ReCell Spray-On Skin is used to spray a patient's own harvested skin cells in thermal burns patients to facilitate overall wound healing.[26] While the ReCell Spray-On Skin system kit is classified as a high-risk

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[21] Therapeutic Goods Administration, Regulation impact statement: Proposed regulatory scheme for personalised medical devices, including 3D-printed devices (n 7).

[22] Therapeutic Goods Administration, Regulation impact statement: Proposed regulatory scheme for personalised medical devices, including 3D-printed devices (n 7)7.

[23] Ibid.

[24] AVITA Medical, AVITA Medical Corporate Fact Sheet <https://avitamedical.com/wp-content/uploads/2020/11/IFU030-RECELL-1920-US-Rev_5.pdf>.

[25] Therapeutic Goods Administration (Cth), ARTG search: ARTG ID 338864 <http://search.tga.gov.au/s/search.html?collection=tga-artgandprofile=recordandmeta_i=338864>.

[26] AVITA Medical (n 17).

class III medical device, the product or the spray on skin produced by these devices in each patient lacks any specific ongoing relevant regulatory oversight despite the use of a human biological product and animal origin enzyme used in the process which involves cell growth or multiplication process during the wound healing.[27]

The TGA's performance and transparency related issues have been repeatedly raised by the experts over the years.[28] A general overview of the Australian medical device regulatory framework gives the impression that the pre and post-2019 regulatory frameworks have insufficient consideration of complexities involved in these elements of personalised medical devices due to various reasons such as lack of sufficient scientific evidence in the relevant fields and financial considerations, especially in view strong pharmaceutical industry lobbying in some countries. The complexities related to personalised medical devices go far beyond the physical elements-related issues and these extend to the socio-religious areas[29]. For example, the ReCell Spray-On Skin system uses animal origin enzyme without identifying specific animal in the important safety information[30] included with the product. The use of specific animal-origin products such as non-halal and Swine products is prohibited in Islam[31]. Lack of animal-specific information in the ReCell Spray-On Skin system important safety information can cause serious issues including in relation to informed consent in patients from the Islamic community[32].

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27 Ibid.

28 Wendy Bonython and Bruce Baer Arnold, 'Consumers lose out as TGA reform turns into a hot potato', The Conversation (16 April 2013) <https://theconversation.com/consumers-lose-out-as-tga-reform-turns-into-a-hot-potato-13383>. See also Jill Margo, 'The Implant Files: How the Therapeutic Goods Administration regulates medical devices', Financial Review (27 November 2018) <https://www.afr.com/companies/healthcare-and-fitness/the-implant-files-welcome-to-fortress-symonston-home-of-the-tga-20181126-h18c3y>.

29 Eriksson, Axelina, Jakob Burcharth and Jacob Rosenberg, 'Animal derived products may conflict with religious patients' beliefs' (2013) 14 (48) BMC medical ethics <https://doi.org/10.1186/1472-6939-14-48>.

30 AVITA Medical, Product: Overview <https://avitamedical.com/product/>.

31 Islamic Council of Western Australia, ICWA Halal Guidelines <https://www.islamiccouncilwa.com.au/halal-certification/halal-guidelines/>.

32 Ibid.

The TGA's delayed implementation of significant medical device regulatory reforms as per the 2019 Amendment Regulations is primarily aimed at improving 'the safety, performance and quality of medical devices'.[33] The TGA also intends to achieve Australian regulatory control harmonisation with other international jurisdictions which, will also 'facilitate global supply'.[34] These regulatory reforms include pre-2019 amendments to custom-made medical device definition scope limitation, the introduction of new definitions regarding personalised medical devices, changes to 'the exemption requirements for custom-made medical devices', the introduction of 'Medical Device Production System (MDPS)' concept and relevant regulatory framework to enable 'healthcare providers to produce personalised devices' for their patients without manufacturing certification requirement and classification rule 5.4[35] update 'for medical devices that record diagnostic images'.[36]

In order to explore existing and proposed regulatory frameworks applicable to the two identified elements of personalised medical devices, it is important to understand the two identified elements of personalised medical devices. The first element is the nature of the device, and the second element is the nature of the elements from which the device is constructed.

The first element incorporates the printing action or the manufacturing process of personalised medical devices. The second element includes components, or the materials, which could be biological or non-biological or a combination of both, used to make the device and the likely reaction of these materials with the body.

Manufacturing of medical devices is a complex and specialised field

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[33] Therapeutic Goods Administration, Medical devices reforms (2 December 2020) <https://www.tga.gov.au/medical-devices-reforms>.

[34] Therapeutic Goods Administration Regulation impact statement: Proposed regulatory scheme for personalised medical devices, including 3D-printed devices (n 7).

[35] Therapeutic Goods (Medical Devices) Regulations 2002 (Cth) ("2002 Therapeutic Goods Regulations') reg 5.4.

[36] 2019 Amendment Regulations.

requiring the collaboration of skills from various specialities, including biomedical engineering, designing and technical skills.[37] Medical device manufacturers need to comply with various regulatory provisions including 'assessment certifications to produce devices'.[38] A 3D printer with software capable of producing various types of medical devices without sufficient regulatory oversight is likely to produce undesirable outcomes. Healthcare settings capable of 3D printing medical devices may not produce industry-standard high-grade finished products usually produced by a collaboration of expertise from various fields. A 3D printer will produce a patient-specific device as per entered data and/or a patient's relevant imaging inputs and it will be difficult to establish each device's compliance with the regulatory and a patient's individual requirements in the healthcare settings. Design and manufacturing issues resulting in end-product failure will lead to litigation resulting in higher-end-product costs with high production risks.

Medical devices will have some kind of foreign material, usually not part of a human body which may be of biological, non-biological or hybrid origin. This foreign material will eventually be implanted inside the human body, just like pharmaceutical products. The human body is expected to react to a foreign substance in one way or the other. It is important to understand how elements of a device are going to interact with the human body once they are part of or inside the human body. Above mentioned example of the regulatory control of the ReCell Spray-On Skin system kit and its product produced with the assistance of an animal-origin enzyme clearly highlights multiple complex regulatory problems in relation to the nature of the elements of personalised medical devices. Pharmaceutical products go through rigorous regulatory assessment or evaluation process before their official market launch, including authorisation for human use. These regulatory controls ensure the safety of the pharmaceutical product for human use or consumption. Pharmaceuticals and personalised medical devices have one common

[37] Griffith University, Submission to Therapeutic Goods Administration, Consultation: Proposed regulatory scheme for personalised medical devices, including 3D-printed devices, 2019, <https://www.tga.gov.au/sites/default/files/submission-consultation-proposed-regulatory-scheme-personalised-medical-devices-gu.pdf>.

[38] Ibid.

aspect, they both affect the human body. The manufacturing and use of manufactured personal medical devices, particularly those utilising the latest technologies, such as 3D printing capability, should require a similar or comparable degree of regulatory control on efficacy and usage that exists with pharmaceuticals. However, gaps in the regulatory oversight, overall management, and control of such devices, including the materials used to produce these devices, have the potential for dire consequences for the vulnerable users of these devices.

1.3 Contemporary Systematic Regulatory Problems

The importance of robust regulatory mechanisms becomes even more relevant when technological innovations offer an opportunity to almost everyone in society to produce important and risky medical devices with limited effort and investment.[39] There exists the misuse of scientific resources by rogue state and non-state actors[40] and it is important to have mechanisms in place to deal with any undesirable outcomes rather than have a reactive approach to dealing with issues as they come up. The 2018 International Consortium of Investigative Journalists' investigation into the faulty implants discovered that the medical products were allowed to be marketed after minimal or without human testing, sale of the medical devices in some countries continued despite the market recall of the same devices in other countries, medical device industry and the regulators faced difficulties in timely identification of the medical devices' problems[41] and the regulatory framework transparency and loopholes continued threatening the patient safety.[42] The

[39] Jay Peters, 'Volunteers produce 3D-printed valves for life-saving coronavirus treatments', The Verge (online) 17 March 2020 <https://www.theverge.com/2020/3/17/21184308/coronavirus-italy-medical-3d-print-valves-treatments>.

[40] Jon Cohen, 'The untold story of the 'circle of trust' behind the world's first gene-edited babies', Science (online) 1 August 2019 <https://www.sciencemag.org/news/2019/08/untold-story-circle-trust-behind-world-s-first-gene-edited-babies>.

[41] International Consortium of Investigative Journalists, Implant Files: Key Findings <https://www.icij.org/investigations/implant-files/>.

[42] Dean Starkman and Delphine Reuter, 'The Implant Files: Dangerous medical devices let through by loopholes and lax regulation', (26 November 2018) Financial Review (online) <https://www.afr.com/policy/health-and-education/the-implant-files-dangerous-medical-devices-let-through-by-loopholes-and-lax-regulation-20181125-h18bep>.

TGA responded to the concerns raised by the stakeholders by announcing an action plan including the medical device regulatory reforms. However, concerns were raised about the effectiveness of the TGA's proposed regulatory reforms and the TGA's action plan was also criticised for being 'all plan, no action'.[43]

This specific topic is selected because of the identified regulatory gaps, some of which have been outlined by examples included in this chapter so far. These regulatory insufficiencies existed prior to the implementation of the 2019 proposed regulatory updates, and in the 2019 proposed regulatory updates. The author's background in clinical medical practice, and legal practice experience in personal injury, including the medical negligence field, certainly assisted in completing the identified research and other tasks competently. The author's experiences of handling diverse groups of patients in clinical environments and handling medical issues in the plaintiff personal injury litigations also assisted the author in handling various associated tasks such as ramifications of the regulatory inadequacies in view of clinical practice complexities, issues with valid consent in critical situations and liability issues.

1.4 Specific Topics Targeted

It is important to have a robust regulatory framework in place that promotes innovation while safeguarding the interests of vulnerable patients. Patients are in a vulnerable position when they are asked to make choices to proceed with or not to proceed with technology-driven solutions to their health problems. These vulnerable patients may or may not fully understand the benefits and potential harms related to proposed technologically driven solutions to their health problems.

This book endeavours to draw attention to the problems related to person-

[43] Will Fitzgibbon, 'Australia's regulator has pledged to fast-track safety reforms and improve transparency, but critics have said their plan lacks substance and detail', (8 April 2019) International Consortium of Investigative Journalists <https://www.icij.org/investigations/implant-files/australia-announces-medical-device-action-plan-to-address-patient-concerns/>.

alised medicine, including its regulatory aspects in Australian and other comparable international jurisdictions, explore complexities involved in addressing these problems and attempt to address raised problems, including specific questions related to the identified problems.

It seeks to highlight regulatory inadequacies and explore solutions to address these inadequacies to improve and, where possible, assist in future-proofing of the personalised medicine regulatory framework in Australia in view of advancements in this field on an international level. It attempts to assist the evolution of a safe, optimal, balanced and almost future-proof regulatory system. In assessing the nature of the regulations, it also identifies areas lacking or deficient of adequate standards before outlining general suggestions towards rectifying those shortcomings. The primary topic aims or goals are achieved through a basic understanding of the field of personalised medicine, including exploration of pre-existing regulatory practices at the state, national and international levels, exploration of upcoming technological advancements and relevant regulatory practices followed by a critical review of the regulatory frameworks and suggestions to optimise regulatory mechanisms.

The book explains:

I. **A basic understanding of the field of personalised medicine, including 3D-printed medical devices and other relevant concepts**. The book initially identifies existing systems and concepts in relation to personalised medicine, developments including innovations in personalised medicine, possible futuristic applications and the basic risk profile of this field in view of regulatory frameworks with examples to facilitate a better understanding of the concepts discussed.

II. **Identification of existing Australian regulatory framework**. The book outlines different applicable or likely applicable legislative, including regulatory and other provisions to the area of personalised medicine, with an overview of the relevant regulatory system. The primary intention of this is to provide an understanding of the existing regulatory framework, how rapidly evolving technological advance-

ments in the medical field are currently regulated and how the existing system may or may not benefit the consumers and the innovators.

III. **Identify and outline 2019 Australian regulatory amendments and relevant provisions of similar regulatory frameworks in the United States and South Korea**. The intention of this aspect is to provide a good understanding of the Australian medical device regulatory scheme implemented in 2019, how similar regulatory practices are carried out in comparable international jurisdictions of the United States and South Korea as members of the IMDRF, and to provide a baseline understanding for comparative reviews of these systems.[44] The TGA has been incorporating some of the US regulatory practices over the years and South Korea has been Australia's major pharmaceutical trade market for some time.[45] Comparative analysis of the Australian regulatory system with these two systems is selected because the diverse nature of the US and the South Korean regulatory systems is expected to provide insight into different ways of addressing modern regulatory challenges while attempting to align closely with international regulatory practices.

IV. **Critically review the 2019 Australian regulatory scheme for personalised medical devices, including 3D-printed devices**. The book explores the potential strengths and drawbacks of the proposed regulatory scheme. The exploratory analytical approach used in this chapter assists in identifying the associated research outcomes. Detailed findings of this chapter are summed up in a conclusion in conjunction with the recommendations.

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[44] International Medical Device Regulators Forum, About IMDRF <https://www.imdrf.org/about#:~:text=IMDRF%20was%20established%20in%20October,operation%20of%20this%20new%20Forum>.

[45] Australian Trade and Investment Commission, 'Life science and healthcare to Korea' <https://www.austrade.gov.au/australian/export/export-markets/countries/republic-of-korea/industries/life-science-and-healthcare-to-korea>.

1.5 New Regulatory Environment

Media reports continue to highlight the benefits of personalised medicine in the coming years.[46] Australian Bureau of Statistics data suggests that the population of people aged 65 years and above is expected to increase by 139% between 2020 and 2030.[47] The resources are finite, and it is the responsibility of the governing system to develop, implement and achieve the right balance between fostering innovation and developing optimal regulatory practices to safeguard the interests of the people who are expecting substantial benefits from these technological advances.

A therapeutic device in the Therapeutic Goods Act 1989 'means therapeutic goods (other than biologicals) consisting of an instrument, apparatus, appliance, material or other article (whether for use alone or in combination), together with any accessories or software required for its proper functioning, which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means though it may be assisted in its function by such means, but the expression does not include therapeutic goods declared by the Secretary, by order published in the Gazette or on the Department's website, not to be therapeutic devices'.[48]

Regulation 1.3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) ("2002 Therapeutic Goods Regulations") defines a custom-made medical device as:

a medical device that:

- is made specifically in accordance with a request by a health professional specifying the design characteristics or construction of the medical device; and

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[46] Alessandro R Marcon, Mark Bieber and Timothy Caulfield, 'Representing a "revolution": how the popular press has portrayed personalized medicine' (2018) 20 Genetics In Medicine, 950–956.

[47] Commonwealth Department of Health, Report on the Audit of Health Workforce in Rural and Regional Australia: 2.5.2 Trends in population ageing (2008) <https://www1.health.gov.au/internet/publications/publishing.nsf/Content/work-res-ruraud-toc~work-res-ruraud-2~work-res-ruraud-2-5~work-res-ruraud-2-5-2>.

[48] Therapeutic Goods Act 1989 s 3(1).

- is intended:
- to be used only in relation to a particular individual; or
- to be used by the health professional to meet special needs arising in the course of his or her practice.[49]

Under the regulatory framework prior to the introduction of 2019 amendments, regulatory requirements such as 'the conformity assessment procedure for custom-made medical devices, compliance with the essential principles, exemption from inclusion in the ARTG, and record keeping and reporting' were different for the regulation of custom-made medical devices when compared with the regulation of other medical devices.[50] Combination medical devices with human origin complements were regulated under the Therapeutic Goods Act's Biologicals regulatory framework and the *Therapeutic Goods Regulations 1990* (Cth). These pre-existing Australian regulatory practices differed from the regulatory practices in comparable overseas jurisdictions.[51] Rapid technological advancements in personalised medicine including medical imaging and 3D printing technology combined with non-alignment of existing Australian regulatory practices with comparable overseas regulatory practices initiated 2019 proposed regulatory amendments for personalised medical devices in Australia.

The TGA's protracted regulatory amendments process followed by the delayed commencement of the 2019 Amendment Regulations still seems to leave many questions unanswered in relation to custom-made medical devices. A custom-made medical device is produced using information and sometimes specific biological materials collected from a recipient. Custom-made medical device exemption from inclusion into the ARTG means the obligations and responsibilities associated with inclusion into the ARTG such as third-party assessment and approval

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[49] 2002 Therapeutic Goods Regulations reg 1.3.

[50] Therapeutic Goods Administration, Regulation impact statement: Proposed regulatory scheme for personalised medical devices, including 3D-printed devices (n 7).

[51] Therapeutic Goods Administration Regulation impact statement: Proposed regulatory scheme for personalised medical devices, including 3D-printed devices (n 7).

prior to supply are not applicable to such devices.[52] Precision medicine, just like any other field of medicine is not fault free[53] and Griffith University's submission in response to the TGA's consultation regarding the 2019 proposed regulatory scheme for personalised medical devices highlights such risks including the risk of undesirable behaviour of human origin materials inside a custom-made medical device recipient's body.[54]

Any inadequate regulatory oversight including the conformity assessment process can result in significant repercussions in the human healthcare industry especially when multinational corporations are competing in a global market for higher profit margins. For example, financial considerations and other factors[55] can overtake adverse health risk concerns in a corporate environment when decision-makers are considering launching a new product as likely happened in the matter of Theranos in the United States.[56] There are many examples of unethical and illegal corporate conduct in the medical device industry.[57] Corporations can still launch a new product after a financial assessment of sales profit and litigation losses if something goes wrong with the product. Such entities can then choose to launch their new product in a country with a weak accountability system and use people as guinea pigs. Companies can also use such products in manufacturing, which may cause or accelerate certain medical conditions commonly found in certain age groups, making it difficult or impossible for the victims or

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52 Ibid.

53 Cynthia Graber, 'The Problem with Precision Medicine' (5 February 2015) The New Yorker <https://www.newyorker.com/tech/annals-of-technology/problem-precision-medicine>.

54 Griffith University (n 30).

55 Kari Paul, 'https://www.theguardian.com/technology/2022/dec/29/tech-grifter-sbf-elizabeth-holmes-therano-ftx' The Guardian (online, 29 December 2022) <https://www.theguardian.com/technology/2022/dec/29/tech-grifter-sbf-elizabeth-holmes-therano-ftx>.

56 Benjamin Mazer, 'Theranos exploited black box medicine', (2022) 379 British Medical Journal <British medical journal>.

57 Associated Press, Medical devices for pain, other conditions have caused more than 80,000 deaths since 2008 (25 November 2018) Stat <https://www.statnews.com/2018/11/25/medical-devices-pain-other-conditions-more-than-80000-deaths-since-2008/>.

their families to link faulty products with adverse outcomes.[58] Cobalt cardiomyopathy in many patients has been linked to some specific type of metal implants[59] and is an example and reminder of the risks associated with medical devices.[60]

It may not be possible to have an ideal or flawless system, especially when an unknown or untested territory involving interference with the human body is being explored. However, it is important to identify and address possible social, ethical, legal and other implications of the new technological advancements developed by using significant resources and which may become an integral part of the human bodies in coming years.

The jurisdictional specific and international information included in this book is expected to assist the readers from various backgrounds in better understanding the topics included in the book from different prospectives. For example, overview of personalised medicine, including personalised medical devices, pre-existing regulatory scenario, 2019 proposed regulatory scheme, some aspects of the European Union together with the South Korean and the USA regulatory frameworks and specifics regarding research questions attempt to address practical legal issues identified in this book.

The explanatory approach used in this book also provides the information about:

- Understanding of personalised medicine including 3D printed human body parts and potential future possibilities as a result of technological advancements;

- Identification and understanding of applicable legislative pro-

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[58] World Health Organisation, Substandard and falsified medical products (31 January 2018) <https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products>.

[59] Quentin McDermott and Karen Michelmore, Patients reveal agony of toxic hip implants (16 May 2011) ABC <https://www.abc.net.au/news/2011-05-16/patients-reveal-agony-of-toxic-hip-implants/2694656>.

[60] Milton Packer, 'Cobalt Cardiomyopathy: A Critical Reappraisal in Light of a Recent Resurgence' (2016) 9(12) eLaw Journal: American Heart Association Journals <https://www.ahajournals.org/doi/10.1161/CIRCHEARTFAILURE.116.003604>.

visions including proposed regulatory measures and mapping the potential of pre-existing regulatory measures for potential future advancements; and

- Raises further questions about effective regulation of upcoming technologically driven solutions to medical problems, effectiveness and longevity of the current models of regulatory systems and the need to achieve a balance between promoting innovation and safeguarding consumer interests.

Information about the South Korean, the United States and sometimes about the European Union regulatory frameworks discussed in this book is also because of the Australian attempts to closely align with international practices.[61] These regulatory systems provide a comparable framework for proposed Australian regulatory practices and Australian regulators are intending to provide regulatory approvals for personalised medical devices based on their approval in any of these regulatory jurisdictions.[62] Situations like the COVID-19 pandemic with cross-jurisdictional implications and lack of specific regulatory status for the parts and components of medical devices[63] under the EU Medical Devices Directive 93/42/EEC[64] provide an opportunity to consider operational aspects of regulatory frameworks under future unforeseen scenarios, especially in case of technologically driven solutions to the healthcare problems. Additionally, the regulatory aspects of these systems also assist in:

- Exploring improvement opportunities in the 2019 proposed Australian medical device regulatory scheme;

- Understanding regulatory loopholes or drawbacks, implica-

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[61] Therapeutic Goods Administration, Regulation impact statement: Proposed regulatory scheme for personalised medical devices, including 3D-printed devices (n 7) 26.

[62] Ibid.

[63] European Commission, Conformity assessment procedures for 3D printing and 3D printed products to be used in a medical context for COVID-19 <https://webcache.googleusercontent.com/search?q=cache:VQSsBUaAIfIJ:https://ec.europa.eu/docsroom/documents/40522/attachments/1/translations/en/renditions/native+andcd=4andhl=enandct=clnkandgl=au>.

[64] European Union, Council Directive 93/42/EEC of 14 June 1993 Concerning Medical Devices [1993] OJ L 169, 1

tions of reliance on work carried out in overseas jurisdictions and interactions with other jurisdictional specific concepts such as pre-existing laws;

- Answering research questions including from the international perspective; and
- Formulating well-informed conclusions and recommendations.

1.6 This Book Intends to Do the Following

This book comprises six chapters, including the current chapter. A brief introduction of the next five chapters is provided below.

Chapter 2 provides detailed information about the Australian regulatory framework for the regulation of personalised medicine, including personalised medical devices such as 3D printed medical devices prior to the introduction of 2019 medical device regulatory updates.

The first part of this chapter provides general information about the contents and structure of the chapter.

The second part includes information about therapeutic goods, including medicines, biologicals, medical devices and other therapeutic goods. It also includes information about the historical development of various legislative and regulatory provisions.

Information about the regulatory framework prior to the introduction of 2019 medical device regulatory updates, including pre-existing personalised medicine regulatory framework in view of rapidly evolving technological innovations, is outlined.

The chapter then provides details about the specifics of the regulatory provisions listed in the previous chapter in view of the interdisciplinary nature of the regulatory framework. Interactions of the TGA's regulatory activities with legislative provisions outside the TGA's jurisdiction are discussed.

In general, this chapter provides detailed information about regulatory provisions for personalised medical devices and assists in understanding the complexities of the overall regulatory framework. The information included in this chapter will also assist in understanding the application of the pre-existing and 2019 proposed regulatory provisions for futuristic personalised medical devices in view of ongoing technological innovations.

Chapter 3 outlines specifics of the TGA's proposed regulatory scheme for personalised medical devices, including 3D printer devices. The application and likely effects of the TGA's proposals on manufacturing and materials of personalised medical devices are examined in view of technological advancements in the medical field. The TGA's public consultations and feedback by various stakeholders through submissions are discussed with the regulatory impact statement released by the regulator. Some unaffected personalised medicine regulatory provisions and their possible interactions with the newly proposed regulatory scheme are also discussed in this chapter.

The first part of the chapter includes chapter content and structure-related information, including information about the 2019 proposed regulatory scheme in Australia. It then provides background information and input from various stakeholders, including information about the forces behind proposed regulatory amendments, the regulator's ability to work with the stakeholders and respond to ongoing challenges.

Detailed information about the specific regulatory proposals is discussed. The discussion includes pre-existing or old regulatory provisions, 2019 proposed regulatory amendments and their implementation timeframes, proposed transitional arrangements and the TGA's future plans including evaluation timeframes to assess the regulatory impact of newly introduced regulatory provisions. In essence, this part of the chapter contributes towards understanding the specifics of the proposed provisions, including an understanding of how specific regulatory aspects used to work in the past and what would change in the future.

Chapter 4 incorporates a critical review of the 2019 Australian regulatory scheme amendments in view of the information discussed so far. The 2019 Amendment Regulations commenced on 25 February 2021 and this regulatory reform transition is expected to complete on 31 October 2024.

A general introduction, including information about the structure of the chapter, forms the first part of the chapter. The second part, which forms the central part of the book, includes a critical analysis of the medical device regulatory amendments introduced into the Australian regulatory framework in 2019. This part incorporates a detailed analytical review of the different aspects of the 2019 amendments in conjunction with possible issues or complexities as a result of the ongoing technological developments and developments in the regulatory framework. These complexities generally arise because of the development of complex combination medical products and devices while the proposed regulatory changes are being introduced. This part also details how various components of the personalised medical devices will probably interact with other existing laws and may interfere with the proposed regulatory changes.

Chapter 5 provides a comparative analysis of the Australian medical device regulatory system with the US and South Korean medical device regulatory systems. The TGA has been consistently engaged in the international alignment of Australian regulatory practices and the influence of overseas regulatory practices is also evident in the TGA's 2019 regulatory amendments. The IMDRF is spearheading medical device international regulatory alignment and the United States and South Korea as IMDRF members are participating in this exercise.

The second part of the chapter examines the US Food and Drug Authority (USFDA) medical device regulatory system. Information about the FDA's regulatory framework, its development and identification of the relevant regulatory provisions is followed by a comparative analysis of the identified regulatory provisions.

The third part addresses the South Korean medical device regulatory

mechanisms, including identification of the relevant South Korean provisions, and a comparison with the Australian medical device regulatory provisions.

The chapter includes a brief synopsis of the key findings of the comparative analysis of the Australian regulatory practices with the US and South Korean regulatory systems.

Chapter 6 incorporates the book's research queries' synopsis together with findings of the critical analysis of 2019 medical device regulatory amendments. The concluding information in this part of the chapter highlights the findings of the central theme of this project.

The chapter concludes with the overall findings of the discussion, including research conclusions. It also includes recommendations aimed at improving the Australian regulatory framework for new-generation personalised medical devices based on a systematic review of the information provided in the previous chapters.