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# Modifiable Futures: A Right to Repair for Medical Devices and Assistive Technologies?

**Wanda Kuai, Kevin Witzenberger, Kayleen Manwaring, Iain Brown, Jackie Leach Scully & Matthew Kearnes**

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# Modifiable Futures:

## A Right to Repair for Medical Devices and Assistive Technologies?

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**Document Context**

This White Paper, which considers issues pertaining to a right to repair for Medical Devices and Assistive Technologies, has been prepared through a collaborative research effort, engaging researchers based at:

1. School of Private & Commercial Law, Faculty of Law and Justice (UNSW);
2. School of Humanities and Languages, Faculty of Arts, Design and Architecture (UNSW);
3. Faculty of Creative Industries (QUT);
4. Disability Innovation Institute (UNSW); and
5. The National Committee for Rehabilitation Engineering (EA)

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***Author Biographies***


- Wanda Kuai is a Research Assistant based in the School of Private and Commercial Law, Faculty of Law and Justice (UNSW);
- Kevin Witzenberger is a research fellow at QUT's GenAI lab and affiliate investigator at the ARC Centre of Excellence for Automated Decision-Making and Society. His research background is grounded in science and technology studies and media theory.
- Kayleen Manwaring is an Associate Professor in the School of Private and Commercial Law, Faculty of Law and Justice (UNSW). Her research focuses on the intersection of sociotechnical change and private and commercial law, with a particular focus on challenges arising out of cyber-physical technologies.
- Iain Brown is the current Chair of the National Committee for Rehabilitation Engineering of the Biomedical College of Engineers Australia. His primary work involves working with end-user to identify their equipment needs and meet these through the selection and setup of appropriate assistive technologies.
- Jackie Leach Scully is a Research Professor and Director of the UNSW Disability Innovation Institute. Professor Scully is an internationally recognised bioethicist specialising in disability and feminist bioethics.
- Matthew Kearnes is a Professor based in the Environment and Society Group, School of Humanities and Languages, UNSW. His work explores the societal dimensions of processes of scientific and technological change.


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# EXECUTIVE SUMMARY

In recent years debate concerning the right to repair has emerged as a critical issue at the interface between law, technology, and society. Current debates concerning the right to repair have largely focused on improving the repairability and interoperability of consumer electronic devices, agricultural machinery, and renewable energy systems.[1] Issues of planned obsolescence, the high costs of maintenance and proprietary strategies that function to constrain the repairability of technological devices have particular and profound implications for medical devices and assistive technologies ('**AT**').

While initially gaining momentum in the context of consumer electronics, the last few years have shown an uptick in the advocacy work for a right to repair of medical devices. Most of the arguments for a right to repair in the realm of medical devices are not unique but rather draw on the same arguments as in other spaces. These mainly advocate for the ability of consumers and third-party repairers to have access to the necessary tools, parts, and information to repair and maintain devices. However, the sensibilities of working with medical devices – such as patient safety, healthcare costs, and technological innovation – carry unique reasons for the implementation of a right to repair, as well as barriers to its implementation.

Inspired by the Right to Repair Inquiry Report by the Australian Productivity Commission ('**Productivity Commission**'), this white paper explores the challenges and implications surrounding maintenance and a right to repair in the context of medical devices and AT. These concerns should be brought to light in the discourse on consumer protection as we see an increasing integration of digital technologies into such devices. Not only does this multiply technological interdependency across the spectrum of medical devices, but digitisation thereby increases possible points of failure in these systems. Our white paper seeks to shift the right to repair movement beyond consumer electronics and shed light on the fact that the repair and maintenance of medical devices and AT are not just matters of convenience but of life, death, and 'normality'. As only 10% of countries have adequate training to repair and maintain AT, this white paper advocates for greater access to functioning AT because they improve a user's quality of life and encourage community inclusion.[2]

Our key takeaways include:

- The disability community has a social reliance on reliable repair and maintenance of the AT used by people with disability.
- Regulators need to strike a balance between the transition to a circular economy through repairs, and upholding patient safety, which is regulated by the *Therapeutic Goods Act 1989* and *Therapeutic Goods (Medical Devices) Regulations 2002* (the '**Australian Therapeutic Goods regulatory framework**').

[1] Bronson, "Smart Farming," 7–14; Hernandez, "Empowering Sustainable Consumption by Giving Back to Consumers the 'Right to Repair,'" 850; Lepawsky, "Planet of Fixers?".
[2] World Health Organization, Global Report, 10, 39.

- The Australian therapeutic goods regulatory framework was drafted with the key objective of minimising risks to patient safety – this has restricted the law's ability to regulate the post-market repair and maintenance of medical devices and AT.
- As AT is not legally defined, this has led to confusion about how different types of AT should be regulated – some are regulated by the therapeutic goods laws and others are not.
- If the existing therapeutic goods laws are not equipped to protect a right to repair, consumers may rely on other types of law.

# 1 Introduction

The term 'right to repair' does not have an internationally agreed definition nor a unitary policy. The Productivity Commission defines the 'right to repair' as 'the ability of consumers to have their products repaired at a competitive price by the repairer of their choice' and that 'enabling a right to repair may involve various policies, such as a requirement for manufacturers to make repair information and tools available to third-party repairers, or to produce spare parts for a certain period'.[3] Indeed, recent government policy regarding Australia's transition to a circular economy has echoed the importance of empowering consumers to make informed decisions. For example, the Victorian Government's circular economy policy, launched in 2020, was committed to funding repair cafes and product sharing schemes, such as toy libraries.[4]

While significant regulatory reform around product life cycles, waste management and stewardship has focused on **recycling and reuse** (together with the regulation of hazardous waste streams), repair by contrast focuses attention on the **often-informal practices** through which products are maintained, refurbished and restored; and on the **unevenly regulated third-party repair market**. With the advent of repair cafés or public 'fixit clinics' over the last decade, makerspaces are increasingly tuned toward practices of restoration, reuse and rebuilding – alongside the dissemination of online knowhow and tutorials in repair practices. Relocating these ad hoc repair practices to public spaces contributes to a broad social movement engaged in collaborative and cooperative repair practices. Rosner suggests that 'the practices of plaster spackling and hardware tinkering that once occupied back porches and home workshops inhabit new territory in the public attention'.[5] In this light, repair 'becomes an analytic tool with which to produce and sustain multiple political projects and with which to socially and structurally refigure society'.[6]

At the same time, there is an increasingly ubiquitous integration of information and digital technologies within consumer devices and industrial and agricultural machinery. This technological sophistication of products tends to limit the scope for informal and unauthorised repair, that is, repair not authorised by either the original equipment manufacturer ('**OEM**'), a subsidiary of the OEM, or public funding body, such as EnableNSW. For example, OEMs may use contractual warranties to void unauthorised repair, limit the supply of spare parts and sharing of repair information, use Technological Protection Measures to prevent copyright infringement, and use End User Licence Agreements to limit access to the digital infrastructure of products.

As such, right to repair functions to challenge current views on our relationship with technology and urges us to consider how much more we should value technologies that work, and the skills to keep them working, than technologies with more 'up to date' features. This shift in value orientation could combine with a

[3] Productivity Commission, Right to Repair, 1.
[4] State of Victoria Department of Environment, Land, Water and Planning, Recycling Victoria.
[5] Rosner, "Making Citizens, Reassembling Devices," 55.
[6] Rosner, "Making Citizens, Reassembling Devices," 55.

more holistic legal and policy approach to the right to repair, to help re-design market infrastructures to complement current circular economy initiatives.[7]

In this context, it is notable that repair and maintenance of medical devices and AT are increasingly recognised as critical issues, whilst also being shaped by specific regulatory and socio-political dynamics. For example, although Botelho notes 'the potential of electronic technologies to offer new opportunities for persons with disabilities', often digital devices 'are not designed in a way that allows for easy replacement of parts'.[8] Rather, manufacturers intentionally force users to replace hardware before its natural end-of-life (planned obsolescence), which may have an especially harsh impact on individuals with disabilities.[9]

What we see in this space are the ways in which issues of planned obsolescence, high costs of maintenance and proprietary strategies, that function to constrain the repairability of technological devices in general, have particular and profound implications for AT and medical devices. Further, the increased digitisation of medical devices and AT leads to more failure points in software or data collecting sensors. For instance, if the hardware in a connected pacemaker or insulin pump malfunctions, the user is at risk of suffering serious illness or death. Where monitoring, diagnostic, or therapeutic equipment in a hospital is rendered unusable for long periods of time because there are barriers to repair, this delay can cause detrimental effects to many patients, as well as additional costs for both hospitals and patients. And these problems are not merely hypothetical: during the early stages of the COVID-19 pandemic, repairs to much-needed ventilators in a hospital in Colorado Springs were delayed because of restrictions imposed by the supplier.[10]

In recent years we have seen some initial policy developments that seek to address this regulatory challenge of providing timely, yet safe repairs. In May 2022, the Colorado state legislature passed legislation requiring powered wheelchair manufacturers to offer 'fair and reasonable terms and costs' to owners, and to independent repairers 'any documentation, parts, embedded software, firmware, or tools that are intended for use with the equipment', as well as anything required to unlock an electronic security lock.[11] This legislation was passed in response to lobbying by disability groups who faced long delays in fixing wheelchairs – meaning that users might be immobile for months at a time – through authorised repairers.[12]

In the context of the economy-wide review of right to repair the Productivity Commission found the existing regulation of medical devices and AT does not adequately 'account for the potential harm from reduced access to repair services (such as delays in medical treatment and additional costs), particularly for time-sensitive procedures, or users that are highly dependent on their devices'. This is despite the low risks of repairing some devices, especially when performed by

[7] Manwaring, "What Does a Right to Repair Tell Us about Our Relationship with Technology?"; Munro, "Towards a Repair Research Agenda for Off-Grid Solar E-Waste in the Global South."
[8] Botelho, "Accessibility to Digital Technology," 31.
[9] Botelho, "Accessibility to Digital Technology," 31.
[10] Manwaring, "Repairing the Third Wave of Computing."
[11] Colo. Rev. Stat. § 6-1-15 (1973).
[12] Hawryluk, "No Easy Fix for Wheelchair Users."

highly skilled repairers in hospitals.[13] The Productivity Commission therefore rightly recommended 'an independent public review of existing medical device regulations, to ensure they strike a balance between repair access and device safety that maximises community wellbeing'.[14]

More broadly, what we see across advocacy and activism for a right to repair, and especially those made by disability advocates, is the insistence on connecting accepted norms of co-design with the inclusion of product users in design processes, and a recognition of the creative ways in which AT are tinkered with, modified, maintained and repaired. Blanchard notes that 'by necessity, many crips are also makers, and learn to modify their environment to suit their needs'. For example, users may paint their prostheses to serve both an aesthetic and a functional role by improving their mental health.[15]

Addressing issues of repairability in medical devices and AT therefore entails engaging simultaneously with the complex web of legal and regulatory issues that characterise this space and the practical ways in which devices users are already engaged in creative and innovative practices of repair, modification and maintenance.

The objective of this white paper is to provide an overview of the issues around repair and maintenance across the fields of medical devices and AT. Accordingly, while this white paper suggests an ordering of these into separate categories, it is important to note how many of these issues remain related.

The white paper is structured into the following parts. Section 2 presents the backdrop of our right to repair discussion. Sections 2.1 and 3.1 introduce two hypothetical vignettes (the '**Vignettes**'), which we use in this white paper to illustrate the legal and social challenges of upholding a right to repair in the context of medical devices and AT. Section 2.2 introduces the need to achieve accessible repair services in healthcare, despite the barriers. This is emphasised in Section 2.3 because many people with disability are highly dependent on affordable repair and reliable maintenance of the AT they use. Section 2.4 discusses the issue of repair from a 'circular economy' perspective and recognises barriers to implementing sustainable practices in medical technology management. Section 2.5 to 2.10 examines the *Therapeutic Goods Act 1989* (Cth) ('***TG Act***') and the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) ('***TG Regulations***') to determine whether the legislation secures a right to repair for users of medical devices. Section 3 then pivots attention towards the regulation of AT. It discusses the complexities of classifying AT in the existing legislative framework and welcomes TGA's recent efforts to improve the clarity of the legislation. Drawing upon our discussion in sections 2 and 3, section 4 evaluates the effectiveness of the Australian Therapeutic Goods regulatory framework in protecting an individual's right to repair. The final section 5 of the white paper provides a closer examination of the other legal issues that may be put forward against the effort to improve access to repair services, including tort law, intellectual property laws, contractual warranties, and the product liability and

[13] Productivity Commission, Right to Repair, 16.
[14] Productivity Commission, Right to Repair, 16.
[15] Blanchard, "Cripping Assistive Tech Design," 7-8.

consumer guarantees regimes under the *Australian Consumer Law 2001* (Cth) (‘***ACL***’).

# 2 Medical devices and the right to repair

## 2.1 A hypothetical vignette illustrating repair issues for medical devices

***RespireFix***

The situation in northern Italy was dire in early 2020. Struggling to keep a record number of COVID-19 patients alive in its intensive care, the hospital (‘**Hospital**’) proved unable to obtain valves needed to operate their ventilators. Due to the high demand in a time with strict lockdown policies, the manufacturer RespireFix Inc (‘**RespireFix**’)[16] was unable to fill any orders for the valve, officially listed at a price of 10,000 euro. A repair technician offered his help to 3D print the missing valve parts. Headquartered in the United States, RespireFix was unwilling to provide the 3D files, citing medical manufacturing regulations. Word soon reached Fracassi, head of a pharmaceutical company in possession of the coveted machine. Without RespireFix’s authorisation, Fracassi reproduced the dimensions of the valve and produce the missing pieces in a few hours at a production cost of just €1. However, despite helping the Hospital, he was too afraid to share his 3D file with other hospitals due to possible legal consequences.[17]

## 2.2 The need for a right to repair for medical devices

Given experiences highlighted during responses to COVID-19, we have identified four key factors informing our considerations of a right to repair regarding medical devices:

a) the supply shortage of medical devices, such as ventilators, haemodialysis machines, personal protective equipment, and decontamination equipment, during the COVID-19 pandemic highlighted the need for stronger repair mechanisms in the healthcare system.[18] Indeed, Street and Kelly had already cautioned about the uneven distribution of supply in public health emergencies after the Ebola outbreak.[19]

b) these shortages, arising in a global supply chain, take place beyond a nation’s border and therefore cannot be solely addressed on local or national level. This is illustrated by Abbas, who argues that 3D printed technologies could alleviate shortages if consumers had the rights to reproduce them.[20]

c) a right to repair improves the efficiency, affordability, and sustainability of healthcare systems. Some scholars have even proposed a right to repair suitability for different forms of medical devices.[21]

[16] We would like to note that all manufacturer names used in the vignettes are fictional.
[17] This account is drawn from Moody, “3D-Print.”
[18] Ranney, “Critical Supply Shortages”; He, “The Medical Right to Repair,” 1260.
[19] Street, “Tolerable Tests,” 6.
[20] Abbas, “Patent Law and 3D Printing Applications in Response to COVID-19.”
[21] He, “SAFER Framework for Moving Forward,” 97.

d) a right to repair ensures a patient has access to functional critical medical equipment. For example, a DIY platform iFixit is targeting manufacturers of ventilators or EKG/ECG monitors to demand fewer restrictions on their repairs and more cooperation from their manufacturers.[22] As part of the call, the platform has already released hundreds of repair manuals for medical equipment.[23]

### 2.3 Barriers to a right to repair for medical devices

Implementing a right to repair for medical devices is necessary. However, in addition to any technical issues, barriers exist in the device market itself and how it is regulated.[24]

Barriers include:

a) ensuring patient safety and the reliability of repaired devices.

   Medical devices are complex and often require specialised knowledge and tools for proper maintenance and repair. As a result, limited skills and lack of knowledge and spare parts makes it difficult to evaluate the effectiveness of repair and its implications for a device's safety. Many medical devices are also quite small, which can lead to practical difficulties with repair.

b) inadequate investment in developing needed expertise to assess the appropriateness of repair or replacement.

c) insufficient availability of spare parts, due to supply and delivery deficiencies, especially within geographically remote communities.[25]

   During the Ebola outbreak from 2014 to 2016, medical devices, including diagnostic tools, were unevenly distributed or unavailable in regions of West Africa.[26] Five years later, during COVID-19, it was reported that many hospitals in Tanzania had several unused and unusable incubators 'all just shoved in corners, broken, dismantled – some rather expensive – because they don't have the right piece for it, and no one knows how to repair it'.[27] Additional concerns may arise when using non-OEM parts, such as 3D-printed valves, as opposed to using authorised parts.

d) manufacturers of medical devices must also comply with stringent regulatory standards. There is an expectation that repairs comply with these standards, and this can be challenging, especially when performed by third-party entities.

These barriers are exacerbated by the fact that it is not clear how legislation, such as the *TG Act*, applies to repair or modification.

[22] Goode, "Right-to-Repair Groups."
[23] iFixit, "Medical Device Repair."
[24] Wiseman, "Restoring Human Dignity."
[25] World Health Organization, Global Report, 46-47.
[26] Street, "Tolerable Tests," 6, 18.
[27] Schwartz, "Tanzania."

## 2.4 Circular economy of medical technology

While treating medical devices as a separate category to consumer items, the approach to a right to repair still follows one that is anchored in notions of repair that are tied to market power and ownership. Taking a broader stance on repair allows us to re-think a right to repair in the context of circular economies of the medical device industry that is particularly encouraged to design disposable items out of concern for patients. However, the concept of a circular economy, which emphasises the reuse and recycling of products, presents both challenges and opportunities in the healthcare sector, particularly in the management of medical technology.

### *2.4.1 What is a circular economy?*

A circular economy is centred around sustainable management and reducing waste and pollution. In the medical industry, it is important to uphold sustainable practices in the lifecycle of medical equipment, from preacquisition to disposal.[28] Currently, most of the medical device industry is set up as a linear supply chain, where manufactured products are used once and discarded. However, circular economy principles can ensure healthcare systems significantly reduce medical waste and pollution, contributing to environmental sustainability.[29]

### *2.4.2 Barriers to transitioning to a circular economy*

For manufacturers, their commercially valuable information is often kept secret, which hinders hospitals from evaluating the environmental impact of acquired devices.[30] Manufacturers, and even hospitals, have developed a 'productionist bias'. In order to maintain workplace and organisational order, production is prioritised at the expense of valuing repair and maintenance work.[31] Distinctive to the healthcare industry, supply of service agreements between OEMs and healthcare providers may expressly require healthcare providers to implement infection control practices, such as using single-use equipment, to prevent health and safety risks for patients and avoid financial liability. These infection control practices pose a significant barrier to the adoption of reusable and recyclable medical technologies in the shift to a circular economy.

Similarly, consumers have entrenched behaviours and preferences towards disposable devices. An additional barrier is the unreliable replacement timelines of medical equipment, especially for AT users. National Disability Insurance Scheme ('**NDIS**') participants may expect to receive a replacement AT periodically. This replacement, or repair, of AT is, arguably, a NDIS-funded 'reasonable and necessary' support.[32] As obtaining such support requires approval from the CEO of the National Disability Insurance Agency, AT users may experience further delays, on top of the manufacturer's initial timeline.[33] Therefore, NDIS participants may pre-emptively apply for a replacement of their *functional* AT to receive the same funding under their new plan.

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[28] Hyman, "The UK Medicines and Healthcare," 188.
[29] MacNeill, "Transforming the Medical Device Industry."
[30] Lyndon, "Secrecy and Access in an Innovation Intensive Economy."
[31] Henke, "The Mechanics of Workplace Order," 55.
[32] *National Disability Insurance Scheme Act 2013* (Cth) s 34 ('*NDIS Act*').
[33] *NDIS Act* s 34.

## 2.5 The TGA's efforts to date

The Secretary of the Department of Health and Aged Care ('**Secretary**') has delegated powers under the *TG Act* and *TG Regulations* to the Therapeutic Goods Administration ('**TGA**'). As a result, the TGA is the responsible regulatory body for the pre-market assessment and post-market monitoring of medical devices.[34] This section will apply the Australian Therapeutic Goods regulatory framework to the Vignette introduced in section 2.1 to understand the scope of regulation by the TGA and its relation to repairs to medical devices that are not authorised by the manufacturer ('**unauthorised repair**').

## 2.6 Market authorisation

Under the *TG Act*, a 'medical device' is 'any instrument, apparatus, appliance, software, implant, reagent, material or other article', including accessories, that is intended for human use to diagnose, prevent, monitor, predict, treat or alleviate a disease, injury, or disability or to replace or modify anatomy or physiological functions of the body.[35] For example, a ventilator is a 'medical device' because it is an apparatus intended to be used to 'modify' a patient's physiological breathing.[36]

Before any medical device can be supplied in, imported into or exported from Australia it must be registered on the Australian Register of Therapeutic Goods ('**Register**').[37] Two key parties are involved in the market authorisation process: the manufacturer and the 'sponsor' (although depending on the circumstances, both parties may be the same legal person). The TGA states that a sponsor must be an Australian resident or Australian-registered corporation conducting business in Australia who imports into, manufactures in, or exports the relevant device from Australia.[38] This connection to Australia is not immediately clear in the existing definition of 'sponsor'.[39]

Registration must be made by a 'person' under s 41FC of the *TG Act*. Further, s 41FD requires the applicant to certify specified information when making the application to the Secretary. Neither the *TG Act* nor *TG Regulations* clarify if the 'applicant' is the sponsor or manufacturer. However, the TGA has indicated that it expects the sponsor to make the application.[40] Import, export, supply and manufacture of medical devices not included on the Register are subject to criminal and civil penalties for the sponsor.[41] Therefore, in the Vignettes, the international manufacturers must have an Australian sponsor to import their equipment into Australia. For example, the US-based RespireFix may establish an Australian subsidiary solely for the purpose of being its sponsor.[42] Alternatively, if RespireFix chose to establish a separate entity to design, produce, package, and

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[34] *Therapeutic Goods Act 1989* (Cth) s 57 ('*TG Act*'); *Therapeutic Goods Regulations 1990* (Cth) s 47.
[35] *TG Act* s 41BD; Therapeutic Goods Administration, "Overview of Medical Devices and IVD Regulation."
[36] *TG Act* ss 41FD(a)-(b).
[37] *TG Act* ss 41FC, 9A.
[38] Therapeutic Goods Administration, "Supply a Therapeutic Good"; Therapeutic Goods Administration, "Role of the Sponsor."
[39] *TG Act* s 3.
[40] Therapeutic Goods Administration, "Supply a Therapeutic Good"; Therapeutic Goods Administration, "Role of the Sponsor."
[41] *TG Act* Part 4-11.
[42] *TG Act* s 3.

label its equipment in Australia, this entity could constitute both an Australian manufacturer and sponsor.[43]

### 2.7 Classification

Having established that it is a medical device, RespireFix and PowerWheels have the legal obligation to appropriately classify the device according to its public health and personal risks.[44] As concluded above, both companies will need to have an overseas manufacturer and Australian sponsor. The *TG Act* provides that correct classification of a medical device is made by the applicant, which the TGA interprets to be the sponsor.[45] Consistently, the TGA publicly states that the sponsor is to '[d]etermine the class and category' of the medical device.[46] Yet, on recently updated TGA websites, it states '[m]anufacturers are responsible for classifying their medical devices'.[47] Operationally, this classification should not be done without the concurrence of both the sponsor and manufacturer to err on the side of caution, as the type of classification has implications for the conformity assessment process.

In RespireFix's circumstances, its sponsor should certify that ventilators are a Class IIb medical device because they are active medical devices that administer oxygen or remove carbon dioxide from a patient and the administration and removal is potentially hazardous.[48] We will now elaborate on a manufacturer's and sponsor's regulatory obligations under the *TG Act* and *TG Regulations* below.[49]

### 2.8 Essential principles

Essential principles regulate a medical device's safety and performance by ensuring the design of a device is suitable for its intended use.[50] A manufacturer must demonstrate compliance with the essential principles[51] because a failure to do so may be a criminal or civil offence.[52] Out of a total of 15, nine essential principles apply to all medical devices regardless of classification.[53] They are:

1. 'Use of medical devices not to compromise health and safety' (principle 1);
2. 'Design and construction of medical devices to conform with safety principles' (principle 2);
3. 'Medical devices to be suitable for intended purpose' (principle 3);
4. 'Long-term safety' (principle 4);
5. 'Medical devices not to be adversely affected by transport or storage' (principle 5);

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[43] *TG Act* s 41BG(1), 3.
[44] *TG Act* s 41DB; *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) reg 3.3 ('*TG Regulations*').
[45] *TG Act* s 41FD(c).
[46] Therapeutic Goods Administration, "Steps to Supply for Device Sponsors."
[47] Therapeutic Goods Administration, "Classification of Medical Devices."
[48] *TG Act* s 41FD(c); *TG Regulations* sch 2 r 4.4(2); Therapeutic Goods Administration, Classification of Active Medical Devices, 19.
[49] *TG Act* s 41DA(3)(b); *TG Regulations* pt 3 div 3.2.
[50] *TG Act* s 41C.
[51] *TG Act* ss 41CA, 41BH; Therapeutic Goods Administration, "Compliance with the Essential Principles.".
[52] *TG Act* ss 41MA, 41MAA.
[53] *TG Act* s 41CA; *TG Regulations* reg 2.1, sch 1.

6. ‘Benefits of medical devices to outweigh any undesirable effects’ (principle 6);
7. ‘Construction and environmental properties’ (principle 9);
8. ‘Information to be provided with medical devices’ (principle 13); and
9. ‘Clinical evidence’ (principle 14).[54]

In Vignette 1, RespireFix must additionally comply with the following essential principles:

1. ‘Infection and microbial contamination’ (principle 8) because the ventilators are intended to be supplied in a sterile state; and
2. ‘Medical devices connected to or equipped with an energy source’ (principle 12).[55]

### 2.9 Conformity assessment procedures

Conformity assessment procedures require manufacturers to implement quality management systems to ensure compliance with essential principles.[56] Unless liability exceptions apply,[57] a manufacturer will otherwise incur a civil penalty and criminal offence, and a sponsor will incur a criminal offence.[58]

The conformity assessment procedures apply quality management systems and monitor the design and performance of medical devices.[59] As stated above, this means different conformity assessment procedures apply depending on a medical device’s classification.[60] As ventilators are a Class IIb medical device supplied in a sterile state, RespireFix must adopt either a full quality assurance procedure, or type examination procedures and production quality assurance procedures.[61] Further, manufacturers have clear obligations relating to each procedure. For instance, if RespireFix chose to implement type examination procedures, the Secretary may request diagrams and descriptions of the type of medical device, description of sterilising methods, risk analyses, technical tests, clinical evidence and samples.[62] RespireFix should also apply for a conformity assessment certificate as evidence to demonstrate compliance with the above essential principles and conformity assessment procedures.[63]

### 2.10 Are there post-market repair obligations?

The *TG Act* and *TG Regulations* impose limited post-market repair obligations. The Australian Therapeutic Goods regulatory framework’s overarching purpose is maintaining medical device safety, which has been reflected in the legislation’s drafting history. For example, the *TG Regulations* were introduced to establish a ‘comprehensive risk management’ system for the ‘development of safer and more

[54] *TG Regulations* sch 1; Therapeutic Goods Administration, “Quality, Safety, and Performance Requirements.”
[55] *TG Regulations* sch 1.
[56] *TG Act* ss 41D, 41DA(1); Therapeutic Goods Administration, “Conformity Assessment Overview.”
[57] *TG Act* s 41MG.
[58] *TG Act* ss 41ME, 41MEA, 41MF.
[59] *TG Act* s 41DA(4).
[60] *TG Regulations* div 3.2, sch 3.
[61] *TG Regulations* div 3.2 reg 3.7(2).
[62] *TG Regulations* sch 3 pt 2 r 2.3(3).
[63] *TG Act* pt 4-4; *TG Regulations* pt 4 div 4.1.

effective technologies'.[64] However, the drafting of the Australian Therapeutic Goods regulatory framework focuses on *pre-market safety* (e.g. manufacturing and design of new devices). As a consequence of this more limited focus, there are minimal repair or modification protections for a patient once ownership of the good has been transferred from manufacturers (such as RespireFix) to the hospital or patient.

Although limited, post-market obligations nevertheless exist. This white paper focuses on two post-market obligations as the ones most relevant to repair:

(1) reporting of; and

(2) responding to (i.e. recalls);

adverse events.

While the legislation imposes obligations to report adverse events, the conformity assessment procedures and essential principles are silent on any requirement for a timely repair or maintenance required during use, despite its importance in the post-market lifecycle of a medical device.[65] Even if making adverse reports is adequate to monitor a medical device's safety, sponsors merely have a passive obligation to report because they are not legally required to actively seek information. In the words of the Productivity Commission, the *TG Act* inadvertently 'fails to account for the potential harm from reduced access to repair services' caused by the manufacturer's inaction or delay in repairs.[66]

*2.10.1 Adverse reporting*

An adverse event occurs when a medical device's safety may be compromised due to one or more of the following:

a) a lack of compliance with the essential principles; or

b) results in, or potentially resulting in, a patient's death, or the serious deterioration of patient's health due to any of the following:

   i. malfunctions or deteriorations in the device's performance or function; or

   ii. inadequacies in the design, production, labelling or instructions of use; or

   iii. use that is contrary to the manufacturer's intention; or

c) malfunctions or deteriorations have led the manufacturer to recall the device.[67]

Once an adverse event is known, the sponsor must report it to the Secretary.[68] In addition to civil penalties and criminal offences, the Secretary may cancel the medical device's registration to prevent its supply into, out of, or within Australia.[69]

Fracassi, in our RespireFix vignette, and other unauthorised repairers may allege their repairs do not contravene the essential principles. For instance, RespireFix and its sponsor may claim Fracassi's unauthorised repairs are non-compliant with

[64] See, eg, House of Representatives, Parliamentary Debates, 191.
[65] *TG Regulations* sch 1, 3.
[66] Productivity Commission, Right to Repair, 16.
[67] *TG Act* ss 41MP(2), 41MPA(2).
[68] *TG Act* ss 41FN(3)(d), 41MP, 41MPA; Therapeutic Goods Administration, Potential for Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities in Australia, 7.
[69] *TG Act* ss 41GN(1)(b), 41MN(1)-(4A).

the essential principles. In particular, manufacturers must eliminate or reduce risks 'as far as possible by adopting a policy of inherently safe design and construction' under essential principle 2 and ensure the long-term safety of a medical device under essential principle 4.[70]

While these essential principles have not been interpreted by Australian courts, a United Kingdom court concluded that medical device safety is a 'relative concept'[71] because, as the Australian Department of Health and Aged Care similarly asserts, a 'medical device is never entirely without risk'.[72]

Moreover, essential principles serve to guarantee that all medical devices **entering** the market have a 'positive risk-benefit ratio'[73] and are 'safe and fit for their intended purpose'.[74] The 'risk', which refers to the chance of an adverse event occurring, may be extended to include the potential harm caused from using a defective medical device in the **existing** market. Even if unauthorised, Fracassi's repair may improve the risk-benefit ratio by reducing the repair turnaround time.

On its face, RespireFix appears to have a legitimate concern that Fracassi's replacement of ventilator valves could be non-compliant with essential principles and, therefore, trigger the Secretary to request a recall.[75] However, this claim is relatively weak for three possible reasons:

(1) adverse reporting is intended to ensure sponsors avoid the same reported issues from occurring when manufacturing new medical devices;

(2) even if Fracassi's repair was non-compliant, if other ventilators of the same kind comply with essential principles 2 and 4 when supplied by RespireFix, the law does not suggest that non-compliant post-market repairs warrant deregistration or recalls;

(3) if '[d]etermining the safety of a product is a holistic approach',[76] it may not be too removed to account for repairability within essential principle 4, which ensures a medical device can be 'regularly maintained and calibrated in accordance with the manufacturer's instructions'. Further, reducing the risk of harm caused by delayed repairs or unrepaired devices also ensures a device is 'not subjected to stresses that are outside the stresses that can occur during normal conditions of use'.[77]

The Australian Therapeutic Goods Regulatory Framework confines 'safety' considerations to pre-market risk assessments of medical devices. Essentially, the legislative framework imposes onerous obligations on sponsors and manufacturers (i.e. registration, essential principles, conformity assessment procedures) to minimise risk of harm or injury to patient health or safety. Yet the protection of long-term safety under essential principle 4 has been overlooked and deserves more attention because it, arguably, brings the safety issues of a device's

[70] *TG Regulations* sch 1 pt 1 rr 2(2)(b), 4.
[71] *Wilkes v Deputy International Limited* [2016] EWHC 3096 (QB) [13] ('*Wilkes*').
[72] Department of Health, Response to the Productivity Commission Issues Paper: Right to Repair, 4.
[73] *Wilkes* [13].
[74] Wiseman and Kariyawasam, "Restoring Human Dignity," 6.
[75] *TG Act* s 41KA(1) item 1.
[76] *Wilkes* [14].
[77] *TG Regulations* sch 1 rr 4(b), (c).

entire lifecycle into the TGA's scope of regulation. Nonetheless, the legislation's pre-market emphasis frustrates the potential to consider medical device repairability under compliance with essential principle 4.

*2.10.2 Repair post-market through recalls*

Surprisingly, the *TG Act* and *TG Regulations* do not clearly compel manufacturers to repair their medical devices post-market. Although some pre-market obligations, including compliance with essential principles and conformity assessment procedures, continue to apply post-market, they are typically imposed on newly manufactured devices. For example, upon knowing a device is defective, manufacturers must have a 'post-market monitoring, reporting and corrective action system'.[78] While a United States case interprets *corrective action* to mean a system to 'detect recurring quality problems'[79] this term is yet to be judicially interpreted in Australia. One way the TGA may facilitate post-market repair is by exercising its mandatory recall powers.[80]

There are several types of recall action:

(1) a traditional recall, which removes a therapeutic good from the market;

(2) a product defect correction;

(3) a hazard alert (for implanted medical devices); and

(4) product defect alert.[81]

Irrespective of whether a medical device is registered or not, one of the aforementioned recall actions may be triggered if the Secretary is satisfied the medical device does not comply with the essential principles or fails to apply the relevant conformity assessment procedures.[82]

In 2021, the TGA undertook 'product defect correction' to recall several models of Philips' mechanical ventilators because the inhalation of foam particles posed a safety hazard that risked non-compliance with the essential principles.[83] Contrary to the typical recall action of removing a defective good, this product defect correction process involved a 'repair/replacement program'.[84] Interestingly, the TGA clarified that such a program 'does not require regulatory approval in Australia'.[85] This is likely because not all recalls are mandatory so the TGA encourages sponsors to take the appropriate recall or non-recall action according to their evaluation of 'safety, quality, performance or efficacy'.[86] TGA's interpretation of its recall powers under the *TG Act* suggests that the TGA considers its regulatory ambit to extend to post-market repair of pre-existing devices if there are widespread safety concerns. However, recent recall and product defect actions have shown that the TGA is more likely to simply recall

[78] *TG Regulations* sch 3.
[79] *Ilarraza v Medtronic, Inc,* 677 F. Supp. 2d 582, 587 (E.D.N.Y. 2009).
[80] These are delegated to the TGA by the Secretary as a body under the Department of Health and Aged Care: *Therapeutic Goods Regulation 1990* (Cth) s 47; *TG Act* pt 4-9.
[81] Therapeutic Goods Administration, Uniform Recall Procedure for Therapeutic, 25-26.
[82] *TG Act* s 41KA(1)(b) items 1-4.
[83] Therapeutic Goods Administration, "Philips Recall Action."
[84] Therapeutic Goods Administration, "Philips Recall Action."
[85] Therapeutic Goods Administration, "Philips Recall Action."
[86] Therapeutic Goods Administration, Uniform Recall Procedure for Therapeutic, 51.

and/or replace a defective device, as opposed to requiring OEMs to conduct repairs.[87]

*2.10.3 Modifications*

Modifications to medical devices are of utmost importance for three parties: the manufacturer, the user, and the third party making the modifications (‘**modifier**’).

A manufacturer holding a conformity assessment certificate must comply with automatic conditions. One condition is issuing the Secretary with written notice of any plans to make ‘substantial changes’ to the ‘quality management systems’, ‘product range covered by those systems’ or ‘product design of kinds of medical devices’ by filing an application for a conformity assessment certificate.[88] In addition, the conformity assessment procedures require the manufacturer to notify the Secretary if they plan to make ‘substantial changes’ to the quality management system, type examination procedures, production quality management system and product quality management system.[89]

Although ‘substantial change’ is not defined in the *TG Act* nor *TG Regulations*, the TGA has published flowcharts as guidance to determine if a change to the quality management system, manufacturing process, product design and product materials is substantial.[90] If the substantial change alters the type of conformity assessment procedures, the manufacturer would need to apply for a new conformity assessment certificate.[91] Clearly, the requirement to notify the Secretary of substantial changes seeks to mitigate risks of unverified changes and consequently prioritise patient safety.

On the other hand, the TGA asserts that a modifier, in changing the device to cater to a patient’s needs, may be subject to the same obligations as the original manufacturer. In the *Consultation: Proposed Regulatory Scheme for Personalised Medical Devices, Including 3D-Printed Devices Paper*, the TGA states that ‘if an individual modifies or adapts a device which has already been placed on the market or put into service in such a way that compliance with the essential principles may be affected, that person shall assume the obligations incumbent on manufacturers and will be subject to the compliance and enforcement regime on that basis’.[92] We will now evaluate the accuracy of the TGA’s assertion against the *TG Act* and *TG Regulations*.

It should first be clarified that notification of substantial changes is separate from the TGA’s statement about modifications because the former is triggered when OEMs propose to make changes to devices entering the market. The definition of manufacturer excludes a person who assembles or adapts a supplied device for an individual patient without changing its intended purpose.[93] Consistently, the

[87] Therapeutic Goods Administration, “Recall: Space Saver Shower Stool RG554H2.”
[88] *TG Act* s 41EJ(3).
[89] *TG Regulations* rr 1.5, 1,6 2.4, 4.5, 5.5.
[90] Therapeutic Goods Administration, Changes Affecting TGA-Issued Conformity Assessment Certificates, 8, 12-3, 16-7, 19.
[91] *TG Act* ss 41E, 41EJ(3); Therapeutic Goods Administration, Changes Affecting TGA-Issued Conformity Assessment Certificates, 10.
[92] Therapeutic Goods Administration, Consultation: Proposed Regulatory Scheme for Personalised Medical Devices, 11.
[93] *TG Act* s 41BG(3).

TGA indicates that if an adaptable medical device is modified according to manufacturer instructions, the modifier will not be a manufacturer.[94] However, it is unclear when a modifier will assume manufacturer obligations for a medical device generally. While the *TG Act* lists when OEMs must notify any substantial changes, it merely states that a modifier's adaptation must not change the device's intended purpose (i.e. compliance with essential principle 3). The *TG Act* does not go further to clarify how a modifier may demonstrate their changes maintain compliance with the essential principles. Following on from our argument in section 2.10.1 to expand the concept of safety, a third-party may show that their modifications comply with essential principle 4 by ensuring the device is safe and suited to a patient's individual need.

Although a modifier should be responsible for their adaptations, the consultation paper's claim that modifiers 'assume the obligations incumbent on manufacturers' is an overstatement of the law because they are not 'responsible for the design, production, packaging and labelling of a device before it is supplied' nor do they assemble the device 'with a view to supplying the device under [their] name'.[95] This conclusion is consistent with the International Medical Device Regulators Forum's definition of 'manufacturer', which forms the basis of the Australian medical devices regulatory framework.[96] However, it is worth noting that the *TG Act*'s extended definition of a manufacturer may include sellers in the second-hand market.

The above introduction to the key sections of the *TG Act* and *TG Regulations* reveals that the legislation, at is core, regulates medical devices to safeguard patient safety. Against this purpose of the legislation, adverse reporting and recall actions offer limited protections for post-market repair, in which essential principle 4 – regular maintenance for long-term safety – is overlooked as a mechanism to strengthen a patient's right to repair.

# 3 Assistive Technologies and the Right to Repair

## 3.1 A hypothetical vignette illustrating repair issues for assistive technologies

***PowerWheels***[97]

20-year-old Leo received his powered wheelchair from a local supplier. The wheelchair is manufactured by a large multinational company, PowerWheels Pty Ltd ('**PowerWheels**'), based offshore with extensive international supply chains. PowerWheels uses a third-party controller for their products. The controller has external ports that allow switch input for turning the chair on/off and a range of other functions. Due to Leo's disability, he requires the external switches to provide accessible access to the chair's full functionality, including mobility and positional adjustment necessary for pressure care. One of the switch ports became damaged when Leo's chair was unintentionally driven into the edge of a

[94] *TG Act* s 41BG(3)(c); *TG Regulations* Dictionary; Therapeutic Goods Administration, Regulatory Changes for Custom-Made Medical Devices, 12-14.
[95] *TG Act* ss 41BG(1), (2).
[96] Global Harmonization Task Force, Definitions of the Terms Manufacturer, 5.
[97] This vignette was written by co-author, Iain Brown, and based on his experience as an engineering technician.

table. The damage was minor but is located inside the controller and would require the controller to be partially disassembled to give access to the part needing repair. Until the port is repaired, Leo is no longer able to independently manage his own pressure care throughout the day through the chair's seating features, putting him at elevated risk of developing a pressure injury. The needed repair requires a readily available $2 component to be replaced inside the controller.

PowerWheels has advised that Leo can send the controller back for repairs, but as the damage was not a manufacturing fault it will not be covered by warranty and would involve a repair fee. The quoted repair fee is several hundred dollars and Leo does not have sufficient funds remaining in his current government support funds. Leo can request a review of his funding, but this process would likely take several weeks if not longer. Leo has a friend who is happy to open the controller and repair the switch, but PowerWheels has advised that doing this would void the warranty for the whole chair.

Leo cannot move independently without his wheelchair, and risks developing a pressure injury without the ability to adjust his seating. He and his parents feel abandoned by PowerWheels. Leo, his family and support network, have adapted their lifestyles to be dependent on this single piece of medical equipment — and by extension, on an entire corporate system whose financial goals seem to contradict companies' aims to support clients over their lifetimes.

## 3.2 Disability, AT and repair and maintenance

### *3.2.1 Situating repairability in disability studies*

Approaching issues concerning the repairability and maintainability of AT necessarily entails engaging critical discussions of what Shew terms *techno-ableism* within the fields of disability studies and 'crip theory'.[98] Shew describes techno-ableism as a 'particular type of ableism', characterised by a 'belief in the power of technology that considers the *elimination of disability* a good thing'. In this sense, society's understanding of AT plays a particular role in the construction of disabled lives and bodies as a problem to be solved. Moser develops this line of analysis further by suggesting that 'the starting point is that disabled is not something one is but something one becomes, and, further, that disability is enacted and ordered in situated and quite specific ways. The question, then, is how people become, and are made, disabled – and, in particular, what role technologies and other material arrangements play in enabling and or disabling interactions'.[99]

As Shew argues, techno-ableism might be understood as a 'classic form of ableism', a structured 'bias against disabled people; a bias in favour of nondisabled life' and the use of technologies to reassert those biases, often under the guise of empowerment'.[100] In her ethnographic study of the use and deployment of

[98] Shew, Against Technoableism; Hamraie, "Crip Technoscience Manifesto"; Scully, Disability Bioethics; Goodley, Disability Studies.
[99] Moser, "Disability and the Promises of Technology," 373.
[100] Shew, Against Technoableism.

cochlear devices in India, Friedner explores the ways in these devices are encoded by what she describes as the '*magic* of normality'.[101] Friedner writes that:

> Physicians, surgeons, government bureaucracies, and family members stressed that cochlear implants create a capacity that brings someone close to or near to normal or makes someone almost normal. In this line of thought, cochlear implants create conditions of possibility for proximity or approximation to normal, with "normal" meaning and modifying an array of actions and ways of being: normally speaking, normally hearing, attending a normal school, having a normal job, and living a normal life, among other things. As a result of cochlear implantation and subsequent auditory and language training, deaf children potentially have the capacity—as evidenced through their performance in a sound booth—to move through life normally. Cochlear implants activate sensory normality and create potentiality for becoming normal in other aspects of life. They activate "*magic*."[102]

In a similar sense, Mauldin notes that the cochlear implant functions to redefine deafness to a neurological disorder. Issues of repairability therefore acquire a dual meaning in this context where AT are encoded with the capacity to repair 'broken' neurological links whilst the potential for breakdowns in the device – and challenges to repairability and maintenance – can be experienced as revealing forms of intimate technological lock-ins.[103] Friedner describes how manufacturers engaging in updates and costly repairs and maintenance can place device users in 'a hostage situation' where they may be 'reluctant to criticise cochlear implant manufacturers publicly because they are afraid of retaliation; they see this relationship as a potentially abusive one that they have to maintain'.[104]

And at the same time Friedner describes the 'liberatory power of tinkering and making' and points to 'the ways that disabled people have always made, hacked, and tinkered with ramps, curb cuts, online platforms, and kitchen aids, among other things'.[105] In this context repair is configured in structural and infrastructural terms in addition to concentrating on the specific issues concerned with the maintenance of AT and devices.[106] Taken collectively, this work across disability studies highlights the need to approach issues around the repair and maintenance of AT informed by the lived experience of disability and the specific socio-material affordances of specific technologies.[107]

### *3.2.2 Barriers to repairing AT*

The interdependent relationship between disability, AT, and repair and maintenance reinforces the claim that a right to repair is impeded by inclusive design challenges and limited accessibility to repair. While much of the regulatory environment explored in section 2 also applies to AT, the issues of repairing AT are more complex and, often, overlooked.

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[101] Friedner, Sensory Futures, 158 (book version).
[102] Friedner, Sensory Futures, 158 (book version).
[103] Mauldin, "Precarious Plasticity."
[104] Friedner, Sensory Futures, 139, 133 (ePub version).
[105] Friedner, Sensory Futures, 130, 124 (ePub version).
[106] Moser, "AGAINST NORMALISATION"; Moser, "Sociotechnical Practices and Difference"; Hamraie, "Crip Technoscience Manifesto"; Blanchard, "Cripping Assistive Tech Design."
[107] Guffroy, "From Human-Centered Design to Disabled User & Ecosystem Centered Design."

Taking Leo's powered wheelchair as an example, there are multiple design challenges because of the individual needs of each user. However, designing AT for diverse needs is difficult to maintain and repair and therefore not accounted for in the manufacturing process. Even if more features are added to 'improve' a wheelchair's function, this may make it more prone to breakdown and cause severe consequences for people with spinal cord injuries.[108] For example, wheelchair users may need to be in bed for several days (average of 5) waiting for repairs to happen.[109] Maintaining and repairing AT is also dependent on the accessibility of such services. As noted in section 2.3, access to repair services is often limited due to a lack of materials, skills or knowledge, especially in remote or underserved areas. Moreover, the cost of repairs and maintenance can be a significant economic burden for individuals with disabilities, often requiring out-of-pocket expenses. As the Convention on the Rights of Persons with Disabilities argues, access to AT is important to access human rights;[110] these concerns should not be disregarded because reliable maintenance is also key for individual users and society, as seen below.

#### *3.2.3 Maintenance as a key aspect of AT use*

Ongoing maintenance is essential to support the effective functioning of AT on which people with disabilities may rely for their daily life and independence. Societally, there is a link between disability inclusion and the sustainable approaches to producing AT. Having localised circular models of production may be beneficial to both repairability and maintenance of AT, and the climate.[111] However, Friedner argues that in India, a right to AT cannot 'solve disability' (right to hearing) as it overlooks the work required to maintain device infrastructures.[112] Further to the challenge of accessing maintenance due to the restrictions imposed by the OEM, users may also have limited funding for regular maintenance of their AT. Without their functional AT, people with disabilities may experience social isolation and reduced participation in community life.

### 3.3 The TGA's efforts to date

The TGA first opened a consultation into the regulation of low-risk medical devices in 2017. In 2019, the TGA published a consultation paper and welcomed submissions on their proposed amendments to the *Therapeutic Goods (Excluded Goods) Determination 2018* (Cth) ('***Determination***') that sought to clarify which AT products would be excluded from the TGA's regulation. The TGA appropriately recognised that some exclusions under the *Determination* – that is, 'household and personal aids, or furniture and utensils, for people with disabilities'[113] – have a 'lack of clarity which has led to significant confusion'.[114] Further, Audiology

[108] Worobey, "Increases in Wheelchair Breakdowns."
[109] Worobey, "Increases in Wheelchair Breakdowns."
[110] Borg, "The Right to Assistive Technology."
[111] Oldfrey, "Could Assistive Technology Provision Models Help Pave the Way for More Environmentally Sustainable Models."
[112] Friedner, "Disability Justice as Part of Structural Competency."
[113] *Therapeutic Goods (Excluded Goods) Determination 2018* (Cth) sch 1 item 9 ('*Determination*').
[114] Therapeutic Goods Administration, Consultation: Products Used for and by People with Disabilities, 10.

Australia's concern that replacing Schedule 1, Item 9 with 'assistive technology' would be too broad was also acknowledged.[115]

Consequently, the TGA proposed a new amendment in 2021 to only exclude low-risk assistive technology products that maintain or improve the functional capacity of persons with disability in their daily living settings. The TGA has expressed strong support for the World Health Organisation's 'reasonably well developed' definition of assistive technology, which is also endorsed by ISO 9999:2016 (now ISO 9999:2022).[116] This includes wheelchairs, hearing, communication or memory aids, spectacles and prostheses. It is worth noting that the phrase 'assistive technology', as a generic term, can encompass a wide range of diverse products which do not readily allow for wholesale treatment. ISO 9999 includes a taxonomy of devices, which could potentially be used to provide a terminology of subsets of assistive technology that could offer alternative groupings for low-risk AT exclusion.[117]

### 3.4 Is 'assistive technology' defined?

'Assistive technology' is not defined in the *TG Act* or *TG Regulations*. (Although it is arguable that AT may not need to be collectively defined unless the TGA intends to use it as a collective term for the purposes of a wide scope exclusion or inclusion.) Instead, there are three possible current regulatory categories into which an AT may fall. An AT may be:

(1) an excluded therapeutic good, including 'household and personal aids, or furniture and utensils, for people with disabilities', which are not regulated by the TGA;[118]

(2) a registration-exempt medical device. If so, no registration is required, but other regulatory obligations (from section 2.7 onwards) must be satisfied; or

(3) a non-exempt medical device, including accessories to medical devices, and all obligations must be met.

Examples of varied interpretations of the above three categories are discussed below.

Hand splints are thermoplastic materials moulded to a patient's hand to protect and support the injured hand or wrist. Since 'personal aid' is not defined in the *TG Act* nor *TG Regulations*, it is reasonable to use the ordinary meaning to classify a hand splint as a personal aid because it assists with the mobility of an injured hand or wrist. However, Otto Block Australia Pty Ltd has registered a hand splint manufactured by Orfit Industries NV as a Class I medical device because it is 'intended to be shaped into a splint to tread fractures, injuries, strains, etc'.[119] Yet a case study has confirmed that an opposition hand splint for a patient with severe burns and a partial thumb amputation can be used to improve disability and

[115] Audiology Australia, Consultation, 1; Therapeutic Goods Administration, Consultation: Products Used for and by People with Disabilities, 12.
[116] Therapeutic Goods Administration, Consultation: Proposed Amendment to the Therapeutic Goods (Excluded Goods) Determination 2018.
[117] International Organization for Standardization, *ISO 9999:2022*.
[118] *TG Act* ss 7AA, 3(1); *Determination* s 5, sch 1 item 9.
[119] Therapeutic Goods Administration, "Public Summary: Otto Bock Australia Pty Ltd; Splint."

improve a patient's activity of daily living skills.[120] These different affordances for the splint lead to a conundrum: would such a splint be considered in Australia as a 'medical device' for 'treatment, alleviation of or compensation for an injury or disability' or a personal aid for people with disabilities? The legislation needs to be made clearer on this: in the meantime, guidelines from the TGA would assist.

Another issue is identifying if an AT is an excluded 'personal aid' or an accessory, which falls within the *TG Act*'s extended definition of 'medical device'.[121] If an AT is an excluded 'personal aid', it may be easier for Fracassi, for example, to undertake unauthorised repairs without fear of potential legal action by manufacturers or sponsors. Related to the PowerWheels vignette, we consider the inconsistent registrations seen in wheelchairs and their accessories. For example, Specialised Wheelchair Company Pty Ltd has not registered the wheelchairs themselves but has registered two wheelchair accessories, a wheelchair cushion and control system.[122] Similarly, out of its collection of over 40 powered and manual wheelchairs, Glide Products Pty Ltd has only registered one wheelchair and one wheelchair accessory, despite being an Australian manufacturer and registered NDIS provider.[123] Our comparison reinforces that this 'misinterpretation of wording' is a 'current issue' the TGA should address.[124]

The following paragraphs briefly outline how the existing ambiguities in correctly identifying the relevant regulatory obligations for an AT further hinders users from asserting their right to repair because each category may have different pre-market and post-market obligations.

### 3.5 AT unregulated by the TGA

Excluded therapeutic goods includes AT that are 'household and personal aids, or furniture and utensils, for people with disabilities'.[125] These broad terms have prompted the Assistive Technology Suppliers Australia and the Australian Orthotic Prosthetic Association to voice the need to clarify what these 'personal aids…for people with disabilities' are. They welcome the replacement of Item 9 with a specified list to ensure only certain goods with minimal risk would be excluded.[126] In response, the TGA, in 2021, proposed to exclude low-risk AT from the regulation under the *TG Act*. Despite the TGA acknowledging there 'have been inconsistencies in the regulatory approaches taken by sponsors in relation to their products and variability in the level of compliance',[127] Item 9 has remained unchanged.

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[120] Dewey, "Opposition Splint for Partial Thumb Amputation," 79–87.
[121] *TG Act* s 41BD(1)(b).
[122] Therapeutic Goods Administration, "Public Summary: Specialised Wheelchair Company Pty Ltd; Custom Chin and Head Control System"; Therapeutic Goods Administration, "Public Summary: Specialised Wheelchair Company Pty Ltd; Custom Complex Seating System"; Specialised Wheelchair Company, "Wheelchairs."
[123] Glide, "We Offer Almost Limitless Customisation"; Therapeutic Goods Administration, "Public Summary: Glide Products Pty Ltd Wheelchair"; Therapeutic Goods Administration, "Public Summary: Glide Products Pty Ltd; Cushion, Custom-made".
[124] Assistive Technology Suppliers Australia, Submission in Response to: TGA Consultation, 3-4.
[125] *Determination* s 5, sch 1 item 9.
[126] Assistive Technology Suppliers Australia, Submission in Response to: TGA Consultation, 3-4; Australian Orthotic Prosthetic Association, Feedback for Consultation, 6.
[127] Therapeutic Goods Administration, Consultation: Products Used for and by People with Disabilities, 10.

Nonetheless, the absence of a definition for 'personal aid' is the cause of the existing ambiguity in how some forms of AT should be classified. As an example, TGA states powered wheelchairs, like PowerWheels' could be an excluded good.[128] However, some sponsors likely decided to err on the side of caution and registered their powered wheelchairs as a Class I medical device.[129] Some have curiously registered their wheelchair accessories, but not the wheelchair itself. While they may not be regulated by the TGA, excluded goods would be subject to other laws discussed in section 5.

### 3.6 Exempt from registration?

If PowerWheels' wheelchair is not an excluded good, it may be a medical device because it alleviates a disability.[130] Next, PowerWheels needs to establish if their wheelchair is registration-exempt or not. Registration-exempt medical devices include the first five patient-matched medical devices manufactured, in a financial year, with a 'specified design envelope' for a particular individual's features or conditions.[131] It also includes all custom-made medical devices that are manufactured for a singular 'intended recipient' at the written request of a health professional, who specifies design characteristics and believes a non-exempt medical device is not appropriate.[132] Applying these definitions to Leo's case, even if the powered wheelchairs were patient-matched, if PowerWheels manufactures more than five annually, their wheelchairs are no longer registration-exempt. Leo's wheelchair is likely not custom-made but an adaptable medical device because it is adapted after being mass-produced. Due to its silence, we assume the *TG Act* treats these adaptable medical devices (mass-produced medical devices adapted post-market) as non-exempt.[133]

### 3.7 Pre-market regulation

There are no pre-market obligations under the *TG Act* and *TG Regulations* for manufacturers or sponsors of personal aids for people with disabilities because the AT will be an excluded good. However, registration-exempt medical devices, which may include AT, have different pre-market obligations from non-exempt medical devices. For example, manufacturers and sponsors of custom-made medical devices must follow special conformity assessment procedures or conditions to which their exemption is subject respectively.[134]

Similarly, sponsors of patient-matched medical devices must also notify the Secretary about their intended supply for it to be registration-exempt.[135] Further, to comply with essential principles for adaptable medical devices, the instructions for their assembly should be followed to ensure the device complies with all relevant essential principles.[136] Generally, registration-exempt medical devices apply the

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[128] Therapeutic Goods Administration, Consultation: Products Used for and by People with Disabilities,10.
[129] Therapeutic Goods Administration, "Public Summary: Independent Living Specialists Pty Ltd."
[130] *TG Act* s 41BD(1)(a)(ii); Therapeutic Goods Administration, "Overview of Medical Devices and IVD Regulation.".
[131] *TG Regulations* Dictionary, reg 7.1(8), sch 4 pt 1 item 1.7, pt 2 item 2.14.
[132] *TG Regulations* Dictionary 'custom-made medical device'.
[133] *TG Regulations* Dictionary 'adaptable medical device'.
[134] *TG Regulations* reg 3.11(3), sch 3 pt 7 r 7.2; sch 4 item 2.12, 2.13.
[135] *TG Regulations* sch 4 pt 2 item 2.14.
[136] *TG Regulations* sch 1 pt 2 r 13.4 item 30; Therapeutic Goods Administration, Regulatory Changes for Custom-Made Medical Devices, 12.

conformity assessment procedures 'for medical devices used for a special purpose'.[137] The legislation's silence about pre-market obligations generally suggests any relevant essential principles and conformity assessment procedures that would apply to non-exempt medical devices also applies to registration-exempt AT.

### 3.8 Post-market regulation and its future directions

If manufacturers of registration-exempt devices must only comply with the nine essential principles (as discussed in section 2.8) and the conformity assessment procedures for medical devices for a special purpose, we echo our conclusion in section 2.10.2 that there are no clear obligations of repair post-market once ownership of the device has been transferred to the hospital or user. Nonetheless, since 2017, the TGA has been making concerted efforts to ensure its regulation adapts to the expanding scope of AT products and provides improved clarity over which AT products will be regulated by the TGA.[138] The TGA launched another consultation in July of this year (which closed on 31 October) to propose the removal of the 'personal aid' exclusion and introduce registration-exemptions for some AT to reduce the financial burden of complying with obligations for non-exempt medical devices.[139] Notably, the TGA states, in this consultation, that excluded medical devices would be required to comply with essential principles and registration and adverse reporting obligations. While the *TG Act* expressly states that reporting adverse events only applies to registered medical devices,[140] reporting obligations may also arise for registration-exempt medical devices under conformity assessment procedures.[141]

In hopes of improving traceability of registration-exempt medical devices, including 'other therapeutic goods', the TGA opened another consultation to seek industry feedback on its proposals to require further information about registration-exempt medical devices and their sponsors and manufacturers.[142]

## 4 How does the Australian Therapeutic Goods regulatory framework intersect with the right to repair?

### 4.1 Does the framework protect the right to repair for medical devices and AT?

The Australian Therapeutic Goods regulatory framework has limited repair and maintenance protections. As introduced in section 2.10, minimising a medical device or an AT's risk of harm to individuals has been paramount. This has naturally led the TGA to regulate pre-market safety – that is, onerous and extensive

[137] *TG Regulations* reg 3.10(2); sch 3 pt 7.
[138] Therapeutic Goods Administration, Consultation: Options for the Future Regulation of "Low Risk" Products; Therapeutic Goods Administration, Consultation: Products Used for and by People with Disabilities; Therapeutic Goods Administration, Consultation: Proposed Amendment to the Therapeutic Goods (Excluded Goods) Determination 2018.
[139] Therapeutic Goods Administration, Consultation: Proposed Changes to the Regulation of Assistive Technologies.
[140] *TG Act* ss 41FN(3)(d); 41MP(1)(a), 41MPA(1)(a).
[141] *TG Regulations* sch 3.
[142] Therapeutic Goods Administration, Consultation: Proposed Changes to the Regulation of Exempt Medical Devices and Exempt Other Therapeutic Goods, 4-10.

obligations are imposed on manufacturers and sponsors prior to the legal supply of any medical device or AT covered by the *TG Act*.

Conversely, there are only two main post-market repair obligations: adverse reporting and recall actions. We argue adverse reporting obligations are imposed on OEMs to prevent known malfunctions or deteriorations from occurring in medical devices or AT entering the market, which, again, does not extend to the post-market safety of existing devices. However, we contend that adverse reporting, when essential principle 4 is used to its full potential, can encourage repair. As the concept of safety should extend to post-market safety, the benefit of offering long-term safety through regular maintenance should be balanced against the risk of harm caused by a lack of, or a delay in, repairs. The second post-market obligation of recall has shown to be more promising in securing post-market repair. In 2021, the TGA took steps to implement product defect correction recalls requiring OEMs to repair and/or replace medical devices due to widespread safety defects. Consistent with the risk-adverse Australian Therapeutic Goods regulatory framework, these post-market repair obligations, at most, impose obligations to conduct repairs by an OEM, and not by unauthorised repairers, who may not need to comply with legal obligations, but instead face legal barriers.

### 4.2 Does the framework put barriers in the way of unauthorised repairers from repairing medical devices and AT?

The Australian Therapeutic Goods regulatory framework sidelines post-market safety, including repair, so the unauthorised repairers' obligations are not as definitive, in contrast to a manufacturer's or a sponsor's clear obligations. One example is the lack of legislative guidance on how an unauthorised repairer can show that their modification complies with the essential principles, or when a modifier will take on manufacturer obligations.

Due to varied interpretations of 'personal aid' or an 'accessory' of a medical device, determining whether an AT is regulated by the TGA is another barrier standing in the way of unauthorised repairers. If an AT is an excluded 'personal aid', the Australian Therapeutic Goods regulatory framework would not apply. Therefore, unauthorised repairers are afforded greater liberty to conduct their repairs without the TGA's oversight. However, unauthorised repairers should also be conscious of other legal barriers that may persist, even for personal aids.

## 5 Other Regulatory Issues relating to Repairing Medical Devices and AT

This section further delves into other key legal barriers impeding the repair of medical devices because the *TG Act* and *TG Regulations* intersect with a myriad of regulatory issues.

### 5.1 Tort law

The common law of torts entitles a victim to compel a wrongdoer to compensate for the harm caused. A tort in negligence requires the following elements: the

wrongdoer owed the victim a duty of care; the wrongdoer breached this duty of care; the breach caused harm to the victim, which was not too remote.[143]

### *5.1.1 Who owes a duty of care?*

It has been well accepted that manufacturers owe a duty to 'take reasonable care in the sense to avoid injury or harm being suffered by [consumers] using the product as intended'.[144] Similarly, repairers indisputably owe a duty of care to the users of the good they repair.[145] This then begs the question of whether or not sponsors also owe a duty of care to consumers of a medical device. Although the answer is not as clear cut, the Supreme Court of Victoria has held that a supplier (or sponsor in our case) has a 'continuing' duty of care because they are 'involved in the manufacture, distribution and supply of a product to the ultimate consumer'.[146] Further, in *Ethicon Sàrl v Gill* ('***Ethicon Sàrl***'), the Full Court of the Federal Court of Australia stated that, if the sponsor is 'a member of the same corporate group' as the manufacturer, a sponsor's duty of care is 'co-extensive' with a manufacturer's duty of care.[147] An overseas manufacturer, such as RespireFix and PowerWheels, may decide to create a shelf company or company with a sole director, based in Australia, to ensure an Australian entity can import and supply their goods in Australia. On normal principles, such companies, who act in their capacity as a supplier, also owe a duty of care to the consumer.

### *5.1.2 What is the duty of care of a manufacturer or sponsor?*

The scope of a duty of care owed by both manufacturers or sponsors should not be resolved in isolation from their legal obligations under the *TG Act* and the *ACL*. A cause of action in negligence is a 'legally distinct issue' from compliance with the *TG Act* and the *ACL*. Nonetheless, in *Quayle v Smith & Nephew Surgical Pty Ltd*,[148] the Supreme Court of the Australian Capital Territory confirmed that a question of duty of care 'will no doubt be informed by the assumption that a reasonable sponsor would have complied with the requirements of the *TG Act* and the *[TG] Regulations*'.[149] Thus, applying this case with *Ethicon Sàrl*, a reasonable manufacturer and sponsor would also be assumed to meet their standard of care by complying with their obligations under the *TG Act*.

Manufacturers or sponsors of medical devices owe a 'duty to exercise reasonable care to avoid injury to consumers'.[150] While there is limited Australian authority setting the scope of this duty, the Federal Court of Australia has remarked that consumers of medical devices are in a 'vulnerable position and depend on the manufacturer and the doctor to provide enough information'.[151] Therefore, RespireFix or PowerWheels would bear the responsibility to sufficiently inform consumers and any intermediary parties, such as health professionals, of foreseeable risks. Nonetheless, while a failure to warn of risks involved in the use

[143] *Donoghue v Stevenson*, [1932] AC 562.
[144] *Thompson v Johnson & Johnson Pty Ltd* [1991] 2 VR 449, 475.
[145] *Haseldine v CA Daw & Son Ltd* [1941] 2 KB 343.
[146] *Hardchrome Engineering Pty Ltd v Kambrook Distributing Pty Ltd* [2000] VSC 359 [503].
[147] *Ethicon Sàrl v Gill* [2021] FCAFC 29, [281]-[282] ('*Ethicon Sarl v Gill*').
[148] *Quayle v Smith & Nephew Surgical Pty Ltd* [2020] ACTSC 229 ('*Quayle*').
[149] *Quayle* [60].
[150] *Ethicon Sàrl v Gill* [278].
[151] *Gill v Ethicon Sàrl (No 5*) [2019] FCA 1905 ('*Gill v Ethicon Sàrl*').

does not necessarily constitute a breach, the manufacturer and sponsor bear a higher duty of care if there is a greater risk of injury.[152]

#### *5.1.3 How does a repairer's act affect a cause of action in negligence against the manufacturers?*

To answer this question, it is firstly well-established that a tortfeasor will be liable if harm would not have occurred but for their act or omission.[153] However, 'the "but for" test does not provide a satisfactory answer in those cases in which a superseding cause, described as a *novus actus interveniens*, is said to break the chain of causation which would otherwise have resulted from an earlier wrongful act'.[154] If a manufacturer or sponsor's negligence causes a defect, repair is the 'very kind of thing likely to happen'.[155] Due to the pandemic's exceptional circumstances, the Hospital's decision to ask Fracassi to 3D print the missing parts is not unreasonable because RespireFix could not deliver replacement valves under the strict lockdown. Therefore, unauthorised and functional repairs may not break the chain of causation from a manufacturer's or sponsor's initial negligence.

### 5.2 Intellectual property law

One key barrier for iFixit's publication of repair manuals (discussed in section d)) is that manufacturers will often cite intellectual property rights (particularly copyright infringement, patents and trade secret claims) as a reason to restrict access to repair manuals and proprietary parts. The manufacturers' justification to employ monopolistic practices is expected to rise as more medical devices become dependent on digital software and may be further regulated under copyright laws, such as the Australian *Copyright Act 1968* (Cth).[156] For example, an Italian engineer was faced with the prospect of litigation after 3D printing unobtainable respirator valves worth $11,000 for only $1.[157] Even if hospital staff have the necessary knowledge, material and skills to repair medical devices, intellectual property law may prevent them from keeping lifesaving equipment running.[158] Not to mention that hospital staff are already placed in a difficult situation because the legality of their repair practices are uncertain, especially in non-copyright intellectual property law, because the Productivity Commission fell short of making recommendations concerning patent, design and trademark laws.

Closely related to the restricted access to repair information under the guise of copyright infringement is the deployment of digital locks to prevent or limit third party repairers from accessing diagnostic tools or software to repair a medical device.[159] This has been a particular issue with ventilators during the pandemic, as described in our RespireFix vignette.[160] Contrary to the United States, Australian copyright law does not yet contain repair exemptions for medical devices.

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[152] *Norton Australia Pty Ltd v Streets Ice Cream Pty Ltd* (1968) 120 CLR 635.
[153] *Chapman v Hearse*, (1961) 106 CLR 112.
[154] *March v E & MH Stramare Pty Ltd* 171 CLR 506 ('*March*').
[155] *March* 518.
[156] Perzanowski, "Repair and Intellectual Property"; Montello, "The Right to Repair and the Corporate Stranglehold over the Consumer"; Lindgren, "The Right to Repair Software-Dependent Medical Devices".
[157] Moody, "3D-Print."
[158] Koebler, "Hospitals"; Koebler, "Repair Techs."
[159] Productivity Commission, Right to Repair, 19.
[160] Koebler, "Hospitals."

Manufacturers may also claim that the actual prices its hospital customers pay for medical devices are protectable as trade secrets. Bridy describes a rise in this practice as a 'creep'.[161] While the protection of pricing information as trade secrets impacts hospital budgeting and cost management, it is also often necessary to evaluate environmental, health and risk in hospitals.[162] The classification of operational details as trade secrets can hinder effective risk management and maintenance of medical devices.[163]

### 5.3 Contractual warranties

Another legal issue is the use of manufacturer warranties in sale contracts discouraging consumers from seeking independent repair because many consumers may not be well informed about their guarantees. For example, Leo was reluctant to allow his friend to repair his wheelchair controller as he feared this would void the warranty of the repair of his whole wheelchair. The Productivity Commission found manufacturers may include such a clause to void the warranty if unauthorised repair is undertaken. Another misconception is consumers may believe their consumer guarantee rights are only triggered if they use authorised repair or parts. As a result, the Productivity Commission recommended amending the mandatory 'warranty against defects' text provided under r 90 of the *Competition and Consumer Regulations 2010* (Cth) to obviate this confusion.[164] In particular, it was recommended that the text should add wording to clarify that consumers are entitled to remedies under the consumer guarantees, even if they did not use authorised repair services or spare parts. Such a change to the warranty text would be welcome because it will likely encourage users to tinker with their AT without the risk of voiding their warranty.

### 5.4 Australian Consumer Law

Under the *Competition and Consumer Act 2010* (Cth), the *ACL* promotes competition and protects the welfare of consumers, as enforced by the Australian Competition and Consumer Commission ('**ACCC**'). As of 11 April 2023, the TGA and ACCC have established a Memorandum of Understanding to co-regulate risk management and the recall of goods. Even if an AT is excluded from TGA regulation, if it is a 'consumer good', it will likely be regulated by the ACCC.[165] The scope of the ACCC's regulation of medical devices and AT that are also consumer goods is discussed below.

#### *5.4.1 Product liability regime*

The product liability regime under Part 3-5 of the *ACL* serves to 'promot[e] consumer confidence in the market through eliminating risks that cannot be mitigated by market forces alone and, in doing so, to enhance demand'.[166] This is achieved by placing a clear onus on manufacturers to appropriately manage

[161] Bridy, "Trade Secret Prices and High-Tech Devices."
[162] Lyndon, "Secrecy and Access in an Innovation Intensive Economy."
[163] For an in-depth discussion of the intersection of intellectual property and repair, see Manwaring, "Slowing down the Loop," 14-16.
[164] Productivity Commission, Right to Repair, 120-123, 154-156. *Competition and Consumer Regulations 2010* (Cth) r 90.
[165] Therapeutic Goods Administration, "Memorandum of Understanding," cl 2, sch 1 cl 2.
[166] Parliament of Australia, "Trade Practices Amendment (Australian Consumer Law) Bill (No 2) 2010: Explanatory Memorandum," [24.16]–[24.17].

product safety because they are 'better placed to control those risks at the design and manufacturing stage of a product's life'.[167]

A manufacturer is liable to compensate an individual if 'the manufacturer supplies the goods in trade or commerce', 'the goods have a safety defect' and the individual suffered injury as a result of the safety defect.[168] If patients were harmed by Fracassi's repair, they have a right to compensation against the manufacturer irrespective of whether he proves negligence on the part of RespireFix.[169] Further, under the *ACL*, the manufacturer and sponsor may be concurrently liable.[170] However, Fracassi is likely a supplier, and not a manufacturer, so he will not be liable under the product liability regime.[171]

A 'safety defect' occurs when a product's safety is not such as the persons generally are entitled to expect'.[172] The courts must have regard to a non-exhaustive list of circumstances, such as 'the time when [the goods] were supplied by their manufacturer'.[173] If Fracassi's replacement of ventilator valves were defective, RespireFix may defend that there was no safety defect 'at the time when the goods were supplied by their actual manufacturer'.[174] Indeed, this term has been construed to be when a good was first 'put into circulation by its manufacturer'.[175] Similar to the law of torts, there must be a 'necessary link [of causation] between defect and injury'.[176] OEMs are armed with this strong defence, which further deters unauthorised repairers from conducting repairs.

### *5.4.2 Consumer guarantees*

For our purposes, we assume the users in the Vignettes are 'consumers' and their medical device or AT is a 'good' under the *ACL*. Next, it is important to distinguish the different legal obligations of manufacturers, sponsors and repairers. According to the *ACL*, OEMs, such as RespireFix and PowerWheels, are actual manufacturers and their sponsors will be deemed a manufacturer because they import the goods on behalf of the manufacturer which does not have a place of business in Australia.[177] If 'manufacturer' is given the 'widest class of persons who have an involvement with the goods',[178] this raises the question as to whether repairers, such as Fracassi in our RespireFix vignette, would be a 'manufacturer' under the *ACL* for 3D printing replacement parts. As Fracassi does not hold himself out to be the manufacturer of the parts, nor does he supply the parts under RespireFix's

[167] Consumer Affairs Australia and New Zealand, Australian Consumer Law Review, 38.
[168] *Competition and Consumer Act 2010* (Cth) sch 2 s 138 ('*ACL*').
[169] Clarke, Australian Consumer Law.
[170] *ACL* ss 7(1)(e), 8; *Mayes v Australian Cedar Pty Ltd* [2006] NSWSC 597; *Leeks v FXC Corporation* [2002] FCA 72, [17].
[171] *ACL* ss 2(1) (definition of 'supply'), 7.
[172] *ACL* s 9(1).
[173] *ACL* s 9(2)(f).
[174] *ACL* s 142(a)(ii).
[175] *Gill v Ethicon Sàrl* [3167]; Parliament of Australia, "Trade Practices Amendment Bill 1992: Explanatory Memorandum," [20].
[176] *Carey-Hazell v Getz Bros & Co (Aust) Pty Ltd* [2004] FCA 853.
[177] *ACL* s 7(1).
[178] *ACL* s 7; *Glendale Chemical Products Pty Ltd v ACCC* (1998) 90 FCR 40, 44.

name,[179] he is not an actual or deemed manufacturer, but may be a 'supplier' of repair services.[180]

#### *5.4.2.1 Acceptable quality*

A medical device is of 'acceptable quality' if it is fit for purpose, has an acceptable appearance, and is defect-free, safe and durable for a reasonable consumer who is 'fully acquainted with the state and condition of the goods, (including any hidden defects of the goods)'.[181] This guarantee, which applies to suppliers, like Fracassi, adopts a 'reasonable consumer' test. Essentially, this test asks 'whether a reasonable consumer who was aware of the "defects" in the goods *at the time of the supply* would have considered them to be of acceptable quality' (emphasis added).[182] In *Medtel Pty Ltd v. Courtney*, an Australian distributor of pacemakers used solder that created a higher risk of short-circuiting and therefore an added risk of premature failure. In our PowerWheels vignette, even if Leo's wheelchair and controller are not initially defective, PowerWheels may be liable if its controller design increases the risk of defects occurring post-market. Similar to determining the scope of a duty of care in negligence, the court may refer to requirements under the *TG Act* to determine if the guarantees of acceptable quality and fit for purpose are breached.[183]

#### *5.4.2.2 Fitness for purpose*

Manufacturers and repairers must also 'guarantee that [medical devices] are reasonably fit for any disclosed purpose'.[184] Depending on the disclosed purpose, this guarantee may 'ordinarily require a higher standard of quality than the guarantee of acceptable quality'.[185] The supplier must also guarantee that their service is 'reasonably fit' for 'any particular purpose' disclosed by the consumer.[186] That is, 'where the consumer, expressly or by implication makes known to the supplier any particular purpose for which the services are being acquired by the consumer, there is a guarantee that the services will be reasonably fit for that purpose'.[187] If the consumer does not rely on the supplier's skills or judgment, they are not protected by this guarantee.[188] Had Fracassi's valve replacement been defective, his replacement would not be fit for the Hospital's disclosed purpose of using functional ventilators, which were crucial to treat patients with COVID-19.

#### *5.4.2.3 Repairs and spare parts*

This guarantee ensures manufacturers, not including repairers, 'take reasonable action to ensure that facilities for the repair of the goods, and parts for the goods,

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[179] Parliament of Australia, "Trade Practices Amendment (Australian Consumer Law) Bill (No 2) 2010: Explanatory Memorandum," [2.38].
[180] *ACL* ss 2, 11(e)(i).
[181] *ACL* s 54(2)-(3).
[182] *Prestige Auto Traders Australia Pty Ltd v Bonnefin* [2017] NSWSC 149, [132] (Adams J); *Medtel Pty Ltd v Courtney* (2003) 130 FCR 182.
[183] *Quayle* [59].
[184] *ACL* s 55(1); Clarke, Australian Consumer Law, 785.
[185] Parliament of Australia, "Trade Practices Amendment (Australian Consumer Law) Bill (No 2) 2010: Explanatory Memorandum," [7.43].
[186] *ACL* s 61(1).
[187] *Scenic Tours Pty Ltd v Moore* [2018] NSWCA 238 [219] (Sackville AJA).
[188] *ACL* s 61(3).

are reasonably available for a reasonable period after the goods are supplied'.[189] This means manufacturers 'will take reasonable steps to provide spare parts and repair facilities for a reasonable time after purchase'.[190] Assessed from the perspective of the manufacturer, not the user, the reasonableness of their steps depends on circumstances, such as the nature of the good, industry practice and reason for lack of repair facilities or spare parts.[191] Reasonable availability of repair facilities may include having repair services that do not cause undue costs or inconvenience. In the case of RespireFix, it may be exempted from liability if it reasonably acts to give a written notice to the Hospital or Leo, at or before the time of sale, that repair or spare parts would not be available.[192] In the PowerWheels vignette, if Leo cannot have his controller repaired within a reasonable time, he may be entitled to recover any reasonable costs of repair in an action against PowerWheels.[193]

#### *5.4.2.4 Due care and skill*

This guarantee requires the repairer to have provided their service, in trade or commerce, to a consumer with 'due care and skill'[194] by performing their common law duty to take reasonable care.[195] Although the *ACL* does not define 'due care', it likely suggests that the 'standard of care to be exercised by the supplier is an objective one, being the ordinary skill of an ordinary, competent person exercising the particular trade or profession at issue'.[196] As a composite phrase, it imposes a duty on the supplier to:

1. exercise 'reasonable care' and avoid negligence; and
2. provide the service with reasonability skill and ability; and
3. take all necessary steps to avoid loss or damage when providing the service; and
4. render the service in a 'rightful, proper and adequate manner'.[197]

Unlike Leo's friend, we assume that RespireFix's repairer is trained with the necessary skills to repair its own ventilators. Further, Fracassi likely possesses the requisite skills of developing an accurate 3D model to print replacement parts, given his position in a pharmaceutical company.[198] If Fracassi believed that no repair or replacement was prudent or necessary after issuing the replacement parts, he would have exercised due care and skill.[199]

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[189] *ACL* s 58(1); Paterson, Corones' Australian Consumer Law, 363.
[190] Lindsay, Regulation of Internet of Things Devices to Protect Consumers, 115.
[191] Parliament of Australia, "Trade Practices Amendment (Australian Consumer Law) Bill (No 2) 2010: Explanatory Memorandum," [7.52]; Clarke, Australian Consumer Law.
[192] *ACL* s 58(2).
[193] *ACL* s 259(2)(b).
[194] *ACL* s 60.
[195] *Wade v J Daniels and Associates Pty Ltd* [2020] FCA 1708 [330] (O'Bryan J).
[196] Clarke, Australian Consumer Law, 821.
[197] *Sayed v 116 Nicholson Street Pty Ltd (Civil Claim)* [2019] VCAT 144, [64].
[198] *Cheryl Foster v Mahamudur Rahman t/as Smarty Web Solutions* [2014] NSWCATCD 17.
[199] *TLK Transport Pty Ltd v Thornthwaite Pty Ltd t/as Yass Valley Mobile Mechanic* [2014] NSWCATCD 147 [97] ('*TLK Transport Pty Ltd*').

#### *5.4.2.5 Achievement of a desired result*

The supplier must guarantee that its services 'might reasonably be expected to achieve' a result disclosed by the consumer.[200] Similar to the guarantee as to fitness for a particular purpose, the consumer is not protected by this guarantee if they do not reasonably rely on the supplier's skills or judgement.[201] As this guarantee relates to the result a consumer seeks to achieve, breaching the fit for purpose guarantee will often establish a breach of this guarantee.

#### *5.4.2.6 Reasonable time for supply*

If a time has not been fixed by contract nor agreed to between the consumer and supplier, this guarantee provides that services 'will be supplied within a reasonable time'.[202] The nature of the service and any other relevant circumstances, such as delivery time for spare parts, will determine what a reasonable time is.[203]

To apply this guarantee to the Vignettes, the courts will account for correspondences between the consumer and supplier, the accepted commercial practice of repairing ventilators or wheelchairs, and any reasons for delays.[204] If RespireFix and PowerWheels cannot demonstrate why they were unable to issue replacement parts in a reasonable time, they would fail to meet this guarantee.

### 5.5 Conclusion

The right to repair movement in Australia has been moving at a slower than desired pace. In light of the Productivity Commission's Report, our white paper has extended the initial discussion of the existing challenges and implications of repair from consumer electronic devices to medical devices and AT in the healthcare sector. Through our Vignettes and contextual discussion of right to repair in healthcare, we sought to uncover the social, economic and legal barriers of accessing repair. Notably, the COVID-19 pandemic brought to light the importance of advocating for a right to repair for medical devices when hospitals experienced supply shortages of critical medical devices. As users of AT, such as Leo, have developed their independence through their AT, without repair and maintenance they may experience social isolation, a reduced quality of life, and financial burden from costly repair services. Disability studies also emphasise that the technology-powered design of AT has led to the rise of techno-ableism against disabled people. In addition to limited repair manuals, spare parts, specialised skills or knowledge to repair complex medical equipment, there has been a slow integration of circular economy principles to the predominantly linear supply chain in healthcare.

In fact, the Australian Therapeutic Goods regulatory framework of maintaining medical device safety (under the *TG Regulations*) and patient safety (under the *TG Act*) is a double-edged sword. While this framework is vital in ensuring all medical devices (which may or may not include AT) fulfil pre-market safety principles before being sold, it undervalues the post-market safety risks arising from a lack of

[200] *ACL* s 61(2).
[201] *ACL* s 61(3).
[202] *ACL* s 62.
[203] Parliament of Australia, "Trade Practices Amendment (Australian Consumer Law) Bill (No 2) 2010: Explanatory Memorandum," [7.64].
[204] *TLK Transport Pty Ltd* [159]-[160].

access to repair or maintenance. Essentially, the Australian Therapeutic Goods regulatory framework does not strike the appropriate balance in timely access to repair and our extended concept of safety. This has been supported in our section 2 overview of the *TG Act* and *TG Regulations*, which provide clear and comprehensive obligations relating to registration, classification, compliance with essential principles and conformity assessment procedures. In stark contrast, the Australian Therapeutic Goods regulatory framework does not cover the field of post-supply repair as it merely introduces obligations relating to adverse reporting, recall actions and post-market modification. The obligation to report adverse events is only triggered once an adverse event is known to the sponsor and compliance with essential principle 4 has not been adequately engaged to improve a device's repairability. Even if the TGA has demonstrated that it has mandatory recall powers to require post-market repair following the reporting of adverse events, repair is not guaranteed because the TGA also gives sponsors discretion to act as they see appropriate. Similarly, the law should clarify, if a person making post-market modifications becomes a manufacturer, how the modifier can demonstrate compliance essential principles. We have argued that these inadequate repair protections and barriers for unauthorised repair are inadvertent consequences of the Australian Therapeutic Goods regulatory framework's focus on pre-market medical device safety. Perhaps it is appropriate to reconsider safety holistically and account for the long-term safety afforded to patients when medical devices are designed with repair and maintenance in mind.

In section 3, we have underlined additional challenges in the Australian Therapeutic Goods regulatory framework's regulation of AT. Due to the lack of legislative guidance, manufacturers and sponsors of AT rely on their own varied interpretations of 'personal aid' and accessories of medical devices to determine whether their AT will be or will not be regulated by the TGA. This has downstream consequences as OEMs may argue that the repair of regulated AT (either registration-exempt or non-exempt medical devices) by unauthorised repairers risks deregistration or recalls, which is nevertheless a claim not supported by our interpretation of the *TG Act* in section 2.10.1. However, we recognise TGA's efforts to address these ambiguities in its recent consultation efforts.

Even if the *TG Act* and *TG Regulations* do not apply to post-market repair for medical devices or AT, we have highlighted other legal barriers to repair in section 5. Manufacturers may prevent unauthorised repairs to avoid liability in negligence. For example, in response to the use of 3D printed technologies to create spare parts, manufacturers asserted their intellectual property rights to hinder repair, even if it could be lifesaving. Manufacturers may exploit a consumer's lack of awareness of their statutory guarantees to insert voiding clauses in their contractual warranties. Depending on whether a good or repair service is being sold, the user will have certain consumer guarantees to hold manufacturers or repairers accountable. Manufacturers and sponsors may also resort to the product liability regime to argue that their product was not defective at the time of supply.

Our initial discussion of these non-legal and legal barriers to the repair of medical devices and AT may prompt greater debate within the medical device industry and the healthcare sector and encourage further conversations about upholding a right

to repair to ensure that the harm caused by the lack of timely repair services is not overlooked.

# 6 References

## 6.1 Primary Resources

### *6.1.1 Australia*


*Carey-Hazell v Getz Bros & Co (Aust) Pty Ltd* [2004] FCA 853.
*Chapman v Hearse* (1961) 106 CLR 112.
*Cheryl Foster v Mahamudur Rahman t/as Smarty Web Solutions* [2014] NSWCATCD 17.
*Competition and Consumer Act 2010* (Cth).
*Competition and Consumer Regulations 2010* (Cth).
*Commonwealth, Parliamentary Debates, House of Representatives, 14 February 2002, 191 (Patricia Worth, Parliamentary Secretary to the Minister for Health and Ageing).*
*Ethicon Sàrl v Gill* [2021] FCAFC 29.
*Gill v Ethicon Sàrl (No 5*) [2019] FCA 1905.
*Glendale Chemical Products Pty Ltd v ACCC* (1998) 90 FCR 40.
*Hardchrome Engineering Pty Ltd v Kambrook Distributing Pty Ltd* [2000] VSC 359.
*Leeks v FXC Corporation* [2002] FCA 72.
*March v E & MH Stramare Pty Ltd* 171 CLR 506.
*Mayes v Australian Cedar Pty Ltd* [2006] NSWSC 597.
*Medtel Pty Ltd v Courtney* (2003) 130 FCR 182.
*National Disability Insurance Scheme Act 2013* (Cth).
*Norton Australia Pty Ltd v Streets Ice Cream Pty Ltd* (1968) 120 CLR 635.
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*Prestige Auto Traders Australia Pty Ltd v Bonnefin* [2017] NSWSC 149.
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*Sayed v 116 Nicholson Street Pty Ltd (Civil Claim)* [2019] VCAT 144.
*Scenic Tours Pty Ltd v Moore* [2018] NSWCA 238.
*Therapeutic Goods Act 1989* (Cth).
Therapeutic Goods Bill 1989 (Cth).
*Therapeutic Goods (Medical Devices) Regulations 2002* (Cth).
*Therapeutic Goods Regulation 1990* (Cth).
*Thompson v Johnson & Johnson Pty Ltd* [1991] 2 VR 449.
*TLK Transport Pty Ltd v Thornthwaite Pty Ltd t/as Yass Valley Mobile Mechanic* [2014] NSWCATCD 147.
*Wade v J Daniels and Associates Pty Ltd* [2020] FCA 170.


### *6.1.2 United Kingdom*


*Donoghue v Stevenson* [1932] AC 562.

*Haseldine v CA Daw & Son Ltd* [1941] 2 KB 343.
*Wilkes v Deputy International Limited* [2016] EWHC 3096 (QB).

#### *6.1.3 United States*

Colo. Rev. Stat. (1973).
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### 6.2 Secondary Resources


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