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RESTORING HUMAN DIGNITY: SOME REFLECTIONS ON THE RIGHT TO REPAIR & MEDICAL DEVICES AND ASSISTIVE TECHNOLOGIES

LEANNE WISEMAN* AND KANCHANA KARIYAWASAM**

The Right to Repair movement, defined broadly as the ability to have products repaired at a competitive price using repairers of choice, gained even more support from the community during the COVID-19 pandemic as hospitals worldwide reported issues with the ongoing maintenance of crucial medical equipment. The ability to keep lifesaving medical equipment operational is not only relevant in hospital settings but is fundamentally important for those individuals in our community, particularly those in remote regions of Australia, who need to rely upon medical devices in their day-to-day lives. This article examines these complex issues in light of the findings of the Australian Productivity Commission's Right to Repair inquiry that barriers currently do exist to medical device repair and that a review be conducted of the medical device market and current regulations.

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I INTRODUCTION

We are used to being in control of not only ourselves but of the things we possess and own. Since the beginning of the industrial age, when machines were being built, the makers and users of those machines were always able to keep those machines in operation. Users and owners could tinker, modify, or fix the machines and devices they owned without seeking permission from anyone. In fact, during the depression, ‘make do and mend was the mantra, keeping our goods, clothes and possessions in use for longer was not only a matter of choice but a matter of necessity’.¹ Historically, the act of repairing goods or machines we owned was uncomplicated. It was simply a matter of using everyday tools to unscrew the base of your toaster or your household appliance or pop the hood on your motor vehicle or tinker with your tractor. Schematics and repair information were often supplied with the products and equipment sold, and spare parts were readily available at a reasonable cost. Many general household appliances, such as refrigerators and washing machines, were able to be routinely repaired and passed down from one generation to another, without even the consideration that they might need permission from the manufacturers to do so. Fast forward to today, and software is embedded in almost all the products, devices, and machines we rely upon and use. Many people feel hampered by manufacturers’ restrictions on their ability to repair their goods and machines and are rising up against original equipment manufacturers by demanding a Right to Repair. This movement has grown with strong business and community support over the past decade into an international Right to Repair movement.²

The Right to Repair (‘R2R’) has been defined as the ability of consumers to have their products repaired at a competitive price using a repairer of their choice.³ It gives owners

¹ In 1943, *Make Do and Mend* was a pamphlet that was issued by the British Ministry of Information which was ‘intended to provide housewives with useful tips on how to be both frugal and stylish in times of harsh rations. Along with its thrifty design ideas and advice on reusing old clothing, the pamphlet was an indispensable guide for households’. See ‘Make Do and Mend’, *British Library* (Web Page) <<https://www.bl.uk/learning/timeline/item106365.html>>. An updated version of the book was recently released to coincide with the economic recession, offering similar frugal advice for 21st-century families. Jill Norman, *Make Do and Mend: Keeping Family and Home Afloat on War Rations* (Michael O’Mara Books, 2nd ed, 2014).

² Aaron Perzanowski, *The Right to Repair: Reclaiming the Things We Own*, (Cambridge University Press, 2022).

³ Productivity Commission, Right to Repair (Final Report, No 97, 29 October 2021) 2 (‘Right to Repair inquiry’).

of products, machinery, vehicles, and medical devices three options to exercise their R2R: (1) obtaining a repair from the original manufacturer or obtaining the services of an authorised service provider, (2) using an independent third-party service provider for the repair, or (3) attempting a do-it-yourself repair.⁴ This movement is pushing back against the repair barriers created by manufacturers of digitally enabled goods who use not only the intellectual property ('IP') in the embedded computer software to "lock-up" the goods — in effect, tying us to the manufacturers for our products' repair and service — but also physical, design, and technical barriers to inhibit repair.⁵ The R2R movement has gained even more support and attention from the general community during the COVID-19 pandemic as hospitals worldwide were reporting issues with the ongoing maintenance and service of crucial medical equipment.⁶ The ability to keep crucial medical equipment and technologies operational is not only limited to equipment and devices in a hospital setting but is also fundamentally important to those individuals in our community who rely upon medical devices and assistive technologies ('ATs')⁷ in their day to day lives. The ability to keep crucial medical equipment and technologies operational becomes an even more urgent issue for those Australians living in rural and remote regions of Australia.

The *Australian Royal Commission into Violence, Abuse, Neglect and Exploitation of People with Disability* was recently told of the difficulty of being a wheelchair user or needing a mobility device in a remote community.⁸

⁴ Marissa MacAneney, 'If It Is Broken, You Should Not Fix It: The Threat Fair Repair Legislation Poses to the Manufacturer and the Consumer' (2018) 92 (2) *St John's Law Review* 331, 333.

⁵ Kyle Montello, 'The Right to Repair and the Corporate Stranglehold over the Consumer: Profits over People' (2020) 22(1) *The Tulane Journal of Technology and Intellectual Property* 165. This is best explained by Montello who states, 'Manufacturers maintain that consumers own the hardware, but the manufacturers really own the software': at 166.

⁶ Shuhan He, Debbie Lai and Jarone Lee, 'The Medical Right to Repair: The Right to Save Lives' (2021) 3 (9) *The Lancet* 1260. See also, Laura Bliss, 'Broken Ventilators Add Momentum to 'Right to Repair' Movement', *Bloomberg* (online, 6 May 2021) <<https://www.bloomberg.com/news/articles/2021-05-06/right-to-repair-movement-gains-momentum-as-states-consider-bills#xj4y7vzkg>>; An-Li Herring, "'Right-To-Repair' Advocates Worry That Hospitals Can't Fix Broken Ventilators', *WESA* (online, 20 April 2020) <<https://www.wesa.fm/economy-business/2020-04-20/right-to-repair-advocates-worry-that-hospitals-cant-fix-broken-ventilators>>.

⁷ Assistive Technology ('AT') is any item, piece of equipment, software program, or product system that is used to increase, maintain, or improve the functional capabilities of persons with disability. David Sinclair, 'Right to Repair – Assistive Technology Perspective' (Speech, Australian Repair Summit, 5 August 2022).

⁸ Celina Edmonds, "'Desperate situations' of First Nations people with disability living in remote communities laid bare at royal commission', *ABC News* (online, 16 July 2022) <<https://www.abc.net.au/news/2022-07-16/royal-commission-ndis-first-nations/101239698>>.

A wheelchair suitable for the suburbs of Sydney, Melbourne or Brisbane does not do well on gravel of the outback of Australia, senior counsel assisting Patrick Griffin told the inquiry. Witness Ronita Jackamarra, a Yawuru woman from Fitzroy Crossing, gave evidence that she'd been waiting years for a new wheelchair and three years for a hoist to assist her to get into vehicles. Her mother, Topsy, said there was always "trouble" with her daughter's wheelchair and once when it broke down, she drove around the community looking for a discarded wheelchair to use for parts.⁹

These statements provide shocking insights into the lived experiences of First Nations Australians living in remote communities and highlights the need for greater rights to repair medical devices, particularly for Australians with disabilities. It is the challenges and opportunities that the repair of medical devices and assistive technologies pose for Australian hospitals, biomedical technicians, caregivers, and individuals that we wish to focus on in this article.

II REPAIRING MEDICAL DEVICES AND ASSISTIVE TECHNOLOGIES

There is no denying that Australian hospitals and their biomedical technical staff experience significant barriers to accessing reasonably priced repair services for their medical devices and assistive technologies.¹⁰ However, when thinking about the Right to Repair medical devices, it is important not only to focus on the medical equipment and devices in hospital settings but also on those medical devices and assistive technologies that individuals rely upon to participate fully in society.¹¹ Some individuals are faced with insurmountable problems when the medical equipment and assistive devices that give them mobility, accessibility, and increase their quality and participation in life break down or stop working. The consequence of a broken wheelchair or medical device is that the owner and user of that device becomes more

⁹ Ibid.

¹⁰ Department of Medical Technology and Physics – Sir Charles Gairdner Hospital, Submission No DR233 to Productivity Commission, *Right to Repair* (July 2021).

¹¹ The restricted ability to repair essential items such as wheelchairs and medical devices can render individuals unable to fully participate in society. For example, the *Human Rights Act 2019* (Qld) states that it is the right of every person to access health services, of every child to access education appropriate to their needs, and of every person to access further education 'that is equally accessible to all' based on their abilities: *at* ss 36-7. Queensland and the Australian Capital Territory are the only two Australian jurisdictions to have enacted human rights acts. The Victorian *Charter of Human Rights and Responsibilities Act 2006* (Vic) and the *Anti-Discrimination Act 1977 No 48* (NSW) do not provide for the above rights. The *Human Rights Act 2004* (ACT) similarly states that it is the right of all children to access education appropriate to their needs, and of individuals to 'have access to further education': *at* s 27A.

vulnerable, rendering some individuals immobile and helpless. Put simply, people who depend on medical devices and assistive technologies to participate fully in society are disproportionately affected by the barriers imposed by manufacturers on repairing their devices.

While it is important to analyse the repair of medical devices from the perspective of the use and users involved, it is also advantageous to categorise medical devices in two ways. Firstly, medical devices that are effectively managed and facilitated by health professionals in their practice, including expensive medical devices used in hospitals.¹² Secondly, medical devices that are used by patients as consumers with minimal intervention by health professionals, such as assistive technologies and mobility equipment.¹³

A Repair of Medical Devices in Hospital Settings

Debate regarding the importance of the right to repair medical devices became headline news during the COVID-19 pandemic as the potentially life-threatening consequences of broken medical equipment were highlighted by frustrated hospital biomedical technicians who were struggling to keep ventilators operating.¹⁴ While hospitals and their staff being unable to repair their medical equipment is not a newfound challenge, it was highlighted and exacerbated by the tragic spread of COVID-19. The importance of being able to keep medical equipment functioning in times of crisis was reinforced by one commentator who put it very succinctly as *The Medical Right to Repair: The Right to Save Lives*.¹⁵ Inability to repair medical equipment can take many forms, including contractual limitations for purchasers and lessees; technological protection measures on software

¹² The department uses two categories: those directly used by health professionals such as MRI scanners and those where professionals facilitate the selection, such as pacemakers, or hip or knee replacements. See Department of Health, Submission No 121 to Productivity Commission, *Right to Repair* (February 2021) 6 ('Submission No 121').

¹³ These in some ways can further be distinguished from the second category above.

¹⁴ Isaac Scher, 'Hospitals need ventilators to keep severe COVID-19 patients alive. They might not be able to fix them without paying the manufacturer \$7,000 per technician', *Insider* (online, 4 June 2020) <<https://www.businessinsider.com/ventilator-manufacturers-dont-let-hospitals-fix-coronavirus-right-to-repair-2020-5>>.

¹⁵ He, Lai and Lee (n 6). See also, Industry Commission, *Medical and Scientific Equipment Industries* (Report No 56, 20 December 1996) <<https://www.pc.gov.au/inquiries/completed/medical-scientific-equipment/56medsci.pdf>>.

embedded in medical devices and equipment; restricted training, repair, parts, tools, manuals and information for bio-medical staff; and various intellectual property claims.¹⁶

The issue of repair of medical devices was brought to the attention of the Productivity Commission in its 2021 *Right to Repair inquiry* (Right to Repair inquiry).¹⁷ The Commission's brief was 'to examine the potential benefits and costs associated with the "right to repair" in the Australian context, including (current and potential) legislative, regulatory and non-regulatory frameworks and their impact on consumers' ability to repair products that develop faults or require maintenance.'¹⁸

The inability to repair medical devices was touched on in a number of submissions to the Productivity Commission ('Commission').¹⁹ It was highlighted in those submissions that the current Australian medical device regulatory regime may not necessarily discourage the right to repair but it may allow manufacturers to 'limit, restrict or prohibit the repair of the medical device'.²⁰ The *Therapeutic Goods Act 1989* (Cth) ('TGA') requires manufacturers, especially of medical devices, to show that they have taken all measures to 'eliminate or reduce risks as far as possible'.²¹ The TGA regulates the supply, import, export, manufacturing, and advertising of therapeutic goods to ensure that those available in Australia are safe and fit for their intended purpose. The Commission recognises that this requirement could effectively limit any incentive to allow independent repairs.²²

The range of submissions on the repair of medical devices made to the Commission highlighted an interesting dichotomy regarding the right to repair. The submissions made by medical manufacturers argued that medical devices must be excluded from any

¹⁶ Ofer Tur-Sinai and Leah Chan Grinvald, 'Repairing Medical Equipment in Times of Pandemic' (2021) 52(1) *Seton Hall Law Review* 459, 459.

¹⁷ On 29th October 2020, the Productivity Commission was commissioned to undertake a 12-month inquiry into the Right to Repair in Australia. *Right to Repair* (n 3).

¹⁸ The terms of reference were very broad. See 'Right to Repair: Terms of Reference', *Australian Government Productivity Commission* (Web Page, 29 October 2020) <<https://www.pc.gov.au/inquiries/completed/repair/terms-of-reference>>. See also, Productivity Commission, *Right to Repair* (Draft Report, June 2021) iv. These broad terms encompassed many of the key issues that the US and EU approach to the right to repair were similarly grappling with.

¹⁹ 'Right to Repair: View Submissions and Brief Comments', *Australian Government Productivity Commission* (Web Page) <<https://www.pc.gov.au/inquiries/completed/repair/submissions>>.

²⁰ Submission No 121 (n 12).

²¹ 'Therapeutic Goods: A Quick Guide', *Parliament of Australia* (Web Page) <https://www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Library/pubs/rp/rp1819/Quick_Guides/TherapeuticGoods>.

²² *Right to Repair inquiry* (n 3) 16.

‘right to repair’ considerations to ensure their ‘continued safety and effectiveness’.²³ Among other justifications, the argument rested on patient safety and preventing ‘unintended consequences’ arising out of third-party repairs.²⁴ However, it was accepted that medical device manufacturers most often block the owners or users of these devices from undertaking repairs, either independently or through third parties, due to the alleged risks posed to assistive devices because non-authorised repairers might not have all the relevant information and expertise to affect the repairs.²⁵

Although the concern of manufacturers is understandable, these concerns were not accepted as genuine concerns by the Commission, as they were unable to find any such significant risk.²⁶ The Commission considered this to be a detrimental trade-off, especially when it comes to the right to repair medical devices as each hospital would have well-trained bio-medical staff who could affect the repairs. They acknowledged that in the medical field such repairs would be incredibly time-sensitive and recommended that regulations should account for the low risk of repair. It was found that the current legal regime

fails to 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. In addition, risks are likely to be low for some devices, or for repairs by highly qualified independent repairers (including those employed by hospitals).²⁷

²³ Ibid; Medtronic Australasia Pty Ltd, Submission No DR186 to Productivity Commission, *Right to Repair* (23 July 2021) (‘Submission No DR186’).

²⁴ Submission No DR186 (n 24).

²⁵ The planned obsolescence is another strategy in medical devices, in which manufacturers may manufacture machines to have a shortened life span that would need replacing sooner than is necessary. This was also raised as a matter of concern. The issue of medical device obsolescence could be particularly harmful to Australians who are in vulnerable communities. This has resulted in increased health care expenditure on vulnerable people. The community of Australians with disabilities squarely falls within this category.

²⁶ *Right to Repair* (n 3) 128.

²⁷ Ibid 16. It was also found that the current legal regime under the *Therapeutic Goods Act and the Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) does not address the right to repair medical devices; rather it is focused on the device’s marketability and safety. See also John McEwen, *A History of Therapeutic Goods Regulation in Australia* (Therapeutic Goods Administration, 2007) <<https://www.tga.gov.au/sites/default/files/history-tg-regulation.pdf>>.

In addition to the issues raised within the *Right to Repair* inquiry, the Commission's *Report on Government Services 2022* investigated how the right to repair medical devices would be relevant in the context of public hospitals, which focuses on public hospitals, also indicated where the right to repair medical devices may be relevant in the context of public hospitals.²⁸ The report rightly highlights that public hospitals' focus on equitable access, efficiency, timely delivery of high-quality and safe services, and reducing mortality and waiting times for patients, depends on the working conditions of high-quality medical equipment. This highlights the critical importance of their maintenance and repair. Delays or unreasonable expenditures on such repairs, therefore, become a public health issue.²⁹

B Assistive Technologies and Mobility Equipment

The challenges and opportunities for the medical right to repair are also illustrated through an examination of assistive mobility devices such as motorised wheelchairs and hoists (or devices that do not necessarily require health professional intervention). Unfortunately, the TGA's requirements are not particularly helpful when it comes to assistive technologies, as 'household and personal aids, or furniture and utensils for people with disabilities' are excluded goods for the purposes of the Act.³⁰

The cost of purchasing complex rehabilitation technology ('CRT'), such as wheelchairs, as well as AT's has become exorbitant.³¹ The increased expenditure is due to Medicare's unconsidered decision to abandon having fixed prices for competitive bidding, which has resulted in smaller wheelchair manufacturers and repairers going out of business. Larger

²⁸ 'Report on Government Services: 12 Public Hospitals', Australian Government Productivity Commission (Web Page, 1 February 2022) <<https://www.pc.gov.au/ongoing/report-on-government-services/2022/health/public-hospitals>>.

²⁹ Ibid. The report does not address this aspect, therefore, there is a need to gather data on challenges in hospitals due to being unable to repair on time and the expenditure of time and money.

³⁰ See *Therapeutic Goods (Excluded Goods) Determination 2018* (Cth) sch 1 item 9. Although the schedule uses broad terminology, assistive technology such as wheelchairs and 'scooters, walkers, crutches, prosthetic and orthotic devices, hearing aids, cognitive aids, voice recognition software, and hardware, screen readers, mobility devices that enable people with disability to play sports and be physically active, etc' may be broadly recognised as falling within this category. Department of Health, *Therapeutic Goods Administration, Consultation: Products used for and by people with disabilities: Options for amendment to the Therapeutic Goods (Excluded Goods) Determination 2018* (Report, September 2019).

³¹ 'My current hearing aid is really ugly and always have a loud noise that annoys me all the time, I know there is a [brand of] hearing aid that is much lighter and better designed than my current one, but it is too expensive, and my insurance does not cover the cost for that brand'. See Franklin Mingzhe Li et al, "I Choose Assistive Devices That Save My Face": A Study on Perceptions of Accessibility and Assistive Technology Use Conducted in China' (Speech, Conference on Human Factors in Computing Systems, 22 January 2021) <<https://arxiv.org/abs/2101.09348>>.

companies have bought up smaller sellers, leading to two United States firms dominating the CRT industry.³² Ultimately, the owners and users of these devices pay the price of this monopoly. Increased prices, less tailored services and excessively long waits for repairs and replacements are direct effects of this monopoly.³³ Whereas devices in the first category (those used by health professionals) are directly relevant to the provision of medical services, the second category (devices used by patients) highlights a host of other issues. For instance, a delay in repairing a wheelchair means that the wheelchair user is unable to fully participate in many facets of their daily life.

There are several obligations that are potentially violated when the repair of wheelchairs is inaccessible or delayed, as was highlighted by the Australian Human Rights Commission.³⁴ The National Disability Insurance Scheme ('NDIS')³⁵ provides a ray of hope. The NDIS has included the cost of repairs and maintenance of AT or medical devices used by people accessing NDIS plans, which is a welcome step.³⁶ However, the potential for delays or whether third parties or consumers themselves have the right to repair is yet to be further clarified. An issue with the NDIS scheme is that it only provides guidance with respect to ATs relevant for the consumer, such as when a situation calls for replacement rather than repair.³⁷ Given the breadth of evidence being provided to the current Disability Royal Commission about challenges experienced in accessibility and mobility support, particularly for rural and remote Australians with disabilities, it is beyond the scope of this article to provide a detailed analysis of all of the repair challenges facing individuals who rely on assistive devices and mobility equipment.

³² Paul Roberts, 'Two behemoths dominate the motorized wheelchair industry. Disabled customers pay the price', (May-June 2022) Mother Jones <<https://www.motherjones.com/politics/2022/05/motorized-wheelchairs-numotion-national-seating-mobility/>>.

³³ Ibid.

³⁴ *Access for all: Improving Accessibility for Consumer with Disability* (Australian Human Rights Commission, 2016) 4 <<https://humanrights.gov.au/our-work/employers/access-all-improving-accessibility-consumers-disability>> citing *Disability Discrimination Act 1992* (Cth).

³⁵ Functioning under the *National Disability Insurance Scheme Act 2013* (Cth).

³⁶ 'Assistive Technology Repairs, Maintenance and Replacement', *NDIS* (Web Page, 8 September 2022) <<https://www.ndis.gov.au/participants/assistive-technology-explained/assistive-technology-repairs-maintenance-and-replacement>>.

³⁷ Two further steps with respect to the right to repair medical devices are important: (1) gathering data on the effect of delayed or expensive repairs of medical devices used in hospitals, and the subsequent effect on health service provision; and (2) providing the right to repair specifically for assistive technologies such as wheelchairs, focusing on prompt repair facilities and considering the detrimental impacts of delays on daily life.

III THE NEED FOR REGULATORY REFORM FOR MEDICAL DEVICE REPAIR

To address the challenges posed by an inability to maintain and repair medical devices and ATs in Australia, it is essential that regulators pay heed to regulatory initiatives in other jurisdictions, particularly those that have occurred recently in the US. Interestingly, it was during the COVID-19 Pandemic in 2020, that the United States government attempted to regulate medical device repair by the introduction of *The Critical Medical Infrastructure Right-to-Repair Act of 2020*.³⁸ Although the Act was not successfully passed, the attempt might constitute the foundation upon which future legislators can build. It contained many positive provisions that Australian regulators should consider. The main features of the Act were three-fold. First, the Act had a limited timeline as it was only meant to cover the ongoing COVID-19 emergency. This shows commendable awareness and willingness to compromise on the fact that the right to repair is a complex issue that has multiple strongly contested viewpoints. Second, it restricted manufacturers' ability to rely on intellectual property rights or contracts when it came to repairing 'critical medical infrastructure'.³⁹ It also protected medical repairers from contractual limitations regarding repair.⁴⁰ Third, the Act required manufacturers to provide access to service materials, tools, and equipment necessary for the diagnosis, service, maintenance, and repair of critical medical infrastructure on 'fair and reasonable' terms.⁴¹ Despite the failure of this proposed regulatory regime, there has been more (though limited) success with the regulation of wheelchair repair in Colorado US.

On the 3rd of June 2022, State Representatives introduced a Bill that would provide some relief to wheelchair users in Colorado.⁴² The Bill will 'require manufacturers to provide

³⁸ Ron Wyden and Yvette Clarke, 'Wyden and Clarke Introduce Bill to Eliminate Barriers to Fixing Critical Medical Equipment During the Pandemic: Restrictions Can Prevent Medical Providers from Repairing Ventilators and Other Essential Equipment, Worsening Shortages; The Critical Medical Infrastructure Right-to-Repair Act will Allow Emergency Repairs During COVID-19 Crisis' (Press Release, Ron Wyden United States Senator for Oregon, 6 August 2020), cited in Tur-Sinai and Grinvald (n 16) 482. See also He, Lai and Lee (n 6).

³⁹ See Critical Medical Infrastructure Right-to-Repair Act of 2020, HR 7956, 116th Congress (2020) ss 3-5. These state that a 'covered service provider' could make copies of 'service materials' incidental to the repair or maintenance of critical medical infrastructure in response to the COVID-19 emergency. It also allowed for technological protection measures to be circumvented. Exemptions from patent law were also allowed regarding non-commercial use of critical medical infrastructure: at s 4473 § 4.

⁴⁰ *Ibid* § 5.

⁴¹ *Ibid* § 6.

⁴² This was passed with a landslide approval of 30-5 votes by the Colorado General Assembly. See Andrew Kenney, 'Wheelchair users could get the "right to repair" in Colorado as bill heads to governor's desk', *CPR*

parts, embedded software, firmware, diagnostic documentation, and more to consumers'.⁴³ The legislation allows wheelchair users to repair their wheelchairs through their own means or through independent repairers. The Bill mandates that the requisite parts, software, tools, manuals, and other documentation should be provided at a reasonable price.⁴⁴ For people living in rural areas, there is to be a separate wheelchair-related Bill to address alternative rates for repairs.⁴⁵ The Bill was signed into law on 2 June 2022⁴⁶ and while there was much excitement, there are a number of limitations that have been highlighted.⁴⁷ However, of relevance here is the fact that regulators have chosen to intervene in this field. While not the panacea for medical repair, this is a huge development for medical device repair both in the United States and in the rest of the world.

IV CONCLUSION

This article has highlighted the complex issues posed by the inability to repair medical devices and it concludes by proposing that, without recognising the right to repair, the inability to repair life-saving equipment and other medical infrastructure will continue to cause patients and individuals to suffer or, in some cases, lose their lives. The health of Australians should not have to wait for Australian regulators to recognise the important

News (online, 25 March 2022) <<https://www.cpr.org/2022/03/25/wheelchair-users-could-get-the-right-to-repair-in-colorado/>>.

⁴³ Angela Ufheil, 'How a Right to Repair Bill Could Speed Up Wheelchair Fixes' (8 April 2022) 5280 <<https://www.5280.com/2022/04/how-a-right-to-repair-bill-could-speed-up-wheelchair-fixes/>>. See also, Federal Trade Commission, *Nixing the Fix: An FTC Report to Congress on Repair Restrictions* (Report, May 2021).

⁴⁴ Kenney (n 43).

⁴⁵ *Ibid.* This bill requires a manufacturer to provide parts, embedded software, firmware, tools, or documentation, such as diagnostic, maintenance, or repair manuals, diagrams, or similar information, to independent repair providers and owners of the manufacturer's powered wheelchairs to allow an independent repair provider or owner to conduct diagnostic, maintenance, or repair services on the owner's powered wheelchair. A manufacturer's failure to comply with the requirement is a deceptive trade practice. In complying with the requirement to provide these resources, a manufacturer need not divulge any trade secrets to independent repair providers and owners. Any new contractual provision or other arrangements that a manufacturer enters into that would remove or limit the manufacturer's obligation to provide these resources to independent repair providers and owners is void and unenforceable.

⁴⁶ COPIRG, Colorado Governor signs Wheelchair Right to Repair Law into Law, 2 June 2022. See Alina Lee, 'Colorado governor signs nation's first Right to Repair wheelchair bill into law', *FOX 21 Local News* (online, 4 June 2022) <<https://www.fox21news.com/news/colorado-governor-signs-nations-first-right-to-repair-wheelchair-bill-into-law/>>.

⁴⁷ Markian Hawryluk, 'Despite a First-Ever "Right-to-Repair" Law, There's No Easy Fix for Wheelchair Users', *KHN* (online, 2 June 2022) <<https://khn.org/news/article/power-wheelchair-users-right-to-repair-law-no-easy-fix/>>.

role that the right to repair can play in their future. If Australians are not allowed the right to access reasonable repair for their medical devices and assistive technologies, this will continue to interfere not only with their sense of autonomy but with their human rights to access services and participate fully in society.⁴⁸ There is much for Australia to learn from jurisdictions such as the US that have attempted to come up with a meaningful and efficient solution to the current problem they are grappling with. A very good place for Australian regulators to start is to reflect upon the finding of the Productivity Commission that:

current regulations of medical devices ... *in the Therapeutic Goods (Medical Devices) Regulations 2002* [which] aim to minimise safety risks to patients and device users ... has the effect of encouraging manufacturers to restrict access to repair. The regulations do not appear to account for the potential harm from reduced access to repair services (such as medical delays and additional costs), or that risks are likely to be low for some devices or for repairs completed by highly-qualified independent repairers.⁴⁹

We believe that improving repair access for low-risk medical devices, or for highly-qualified independent repair technicians, is of the utmost importance to ensuring equity and access to quality healthcare for all Australians.⁵⁰ We conclude by urging the adoption of the Productivity Commission's recommendation, based on this finding, that there is an urgent need for Australia to 'conduct an independent public review of existing medical device regulations to assess whether they strike a balance between repair access and device safety that maximises community wellbeing.'⁵¹

⁴⁸ Tur-Sinai and Grinvald (n 16) 468.

⁴⁹ *Right to Repair* (n 3) 32.

⁵⁰ *Right to Repair* (n 3) 146.

⁵¹ *Right to Repair* (n 3) 32. The review should consider whether current regulations create incentives for manufacturers to restrict repair and examine potential ways to improve repair access for low-risk medical devices or for highly qualified independent repair technicians.

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