

Developing New Zealand Regulation: Lessons from Pelvic Mesh Devices

Word length: 15,038

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A dissertation submitted in partial fulfilment of the requirements for the degree of Bachelor
of Laws (Honours), the University of Auckland

5 June 2018

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Acknowledgements:

I would like to thank Professor Ron Paterson for giving his time to supervise this dissertation.

Additionally, I want to acknowledge the value of information provided by advocacy groups working in women's health in New Zealand.

Finally, I must thank Dr. Katie Palmer du Preez for her help with this project and for her patience over the late nights and lost weekends of the last four and a half years.

Abstract

The global impact from the use of pelvic mesh devices (PMDs) in patients has been considerable in terms of patient harm and large-scale litigation. As with past healthcare scandals including the thalidomide and cervical screening incidents, women in particular continue to be harmed in situations where they should expect protection. There are also novel issues that present with PMDs. As globalisation influences international trade and regulation, harmonisation requirements create new risks and benefits. The introduction and use of PMDs has revealed problems with several international regulatory regimes. At present New Zealand is considering new legislation to regulate therapeutic products including medical devices. While the law is under development, we can learn from the issues that have presented with medical devices from pre-market assessment through to complaints handling and options for remediation. This dissertation takes PMDs in New Zealand and abroad as a case study to illustrate how regulation can affect the incidence of patient harm at four stages of the introduction and uptake of a medical device, in: pre-market regulation, pre-implantation disclosure requirements, post-market monitoring, and complaints and compensation mechanisms. It then assesses the proposed New Zealand law, as described in documents released in 2006 by the Ministry of Health, in the light of learnings from PMD. There follows a series of recommendations to consider for this regulation. These include that greater care should be taken when adopting international assessment; that systems for assessment and monitoring should be designed to improve transparency and avoid conflicts of interest; that safety information should be better communicated between healthcare consumers, providers and government; and that New Zealand's compensation and complaints mechanisms need to be assessed for appropriateness when harm of this nature occurs.

Developing New Zealand Regulation: Lessons from Pelvic Mesh Devices

1. Introduction

1.1. The global impact from the use of pelvic mesh devices (PMDs), both in harm to patients and consequent legal battles, has been significant. Commentators have likened it to the thalidomide scandal of the 1950s and 1960s, given the resultant suffering of thousands of women across the world.¹ New Zealand is among the affected nations, as are those with whom we have close ties: Australia, Canada, the United Kingdom (UK), and the United States of America (US). In New Zealand, representatives from Medical Device Safety Authority (Medsafe) and the Medical Technology Association and have asserted that confidence in medical device safety can be derived from the way that New Zealand takes guidance from the robust pre-market approval schemes of overseas jurisdictions.² Nonetheless the similarity in experiences of harm and resulting litigation around the world should serve as a warning of shared deficiencies in regulation.

1.2. A PMD comes under the category of “medical device”, which engages certain requirements around regulation different to those for medicines. Regulatory regimes that deal with medical devices are tasked with striking a balance between providing patient access to innovative products as quickly as possible, while ensuring those products have been sufficiently tested to ensure safety. Regulators are often criticised for being inefficient and slowing down the introduction of quickly evolving and potentially beneficial new health products. Such efficiency should not be at the expense of patient safety. The use of PMDs has highlighted gaps in regulatory regimes across the world. It has also revealed issues that arise with the harmonisation of law.

1.3. The extent of international litigation relating to harm suffered from the use of PMDs is suggestive of inadequate state-level protection. For example, when so many individuals have suffered from state-approved products, why has it become responsibility of individuals, and not governments to bring claims against

¹ Steven Matthews “Thousands of women HAVE suffered unbearable pain because of their controversial vaginal mesh implants, confirms review - but campaigners warn it 'doesn't show the true scale of the disaster'” *Daily Mail* (online ed, United Kingdom, 18 April 2018).

² Medical Technology Association of New Zealand “Consumers assured of surgical mesh products’ quality” *Scoop* (online ed, New Zealand, 22 March 2017); See quote of Senior Medsafe Advisor Robert Jelas in “Auckland Women’s Health Council Submission On Medicines Amendment Bill” (13 April 2012) at 7.

manufacturers? In Australia a ground-breaking class action of 700 women against Johnson & Johnson Medical Pty Ltd and Ethicon was launched in the Federal court in 2017.³ After the release of a Senate inquiry into the extent of harm, it is currently anticipated that further legal action may follow.⁴ In the US, plaintiffs in personal injury cases have been awarded multi-million dollar sums as compensation,⁵ and since public product safety announcements in 2011, over 73,000 patients have filed claims.⁶ Class actions have also arisen in the UK and Canada.⁷ For New Zealand the Accident Compensation Corporation (ACC) no fault scheme has meant that there is a barrier to pursuing similar personal injury claims. With problems reflected world-wide there is an opportunity to reflect on what New Zealand might do to better protect health care consumers.

2. *Pelvic Mesh Devices (PMDs) and harm*

2.1. A PMD is a medical device⁸ used in urogynaecological surgery. PMDs are involved in tissue repair and have served in procedures undertaken as an alternative to more invasive types of surgery⁹ for the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP).¹⁰ One reason for introducing these devices was that the alternative initial and revision surgeries involved higher failure rates estimated at

³ Joanne McCarthy “Australian pelvic mesh victims launch their case against Johnson & Johnson” *Newcastle Herald* (online ed, Australia, 4 July 2017).

⁴ Sophie Scott “Pelvic mesh implants: Further legal action on the table after scathing Senate report” *ABC News* (online ed, Australia, 29 March 2018); “American Medical Systems Mesh Class Action” Shine Lawyers <www.shine.com.au>.

⁵ Sara Teller “J&J To Pay Record \$35 Million in Product Liability Case” (26 March 2018) *The Legal Reader* <www.legalreader.com>.

⁶ Colby Souders and others “The Truth Behind Transvaginal Mesh Litigation: Devices, Timelines, and Provider Characteristics” (2018) 24 (1) *Female Pelvic Med Reconstr Surg* 21.

⁷ “Calls for suspension of transvaginal mesh while audit is undertaken” (3 April 2018) *International Federation of Gynecology and Obstetrics* <www.igo.org>.

⁸ See Medicines Act 1981, s 3A. This definition includes a device, apparatus or other article for a therapeutic purpose use in human beings that does not achieve its principal intended action by pharmacological, immunological, or metabolic means. Broadly, this includes everything from sticking plasters to pacemakers. Blood pressure monitors, breast implants, catheters, contact lenses and tongue depressors all come under the same definition.

⁹ This surgery - known as a fascial repair - involves making use of the patient’s own tissues. Such technique generally involves excision of weaker tissues with plication and resuturing of the remaining vaginal wall.

¹⁰ Laparoscopic procedures can be conducted in around 30 minutes, without the need for patients to remain overnight.

around 30%.¹¹ PMDs were intended to augment surgery and reduce this failure rate. However, more recent research has indicated that, in relation to POP, evidence does not support the finding that permanent mesh is more effective than native tissue repair.¹²

2.2. Physically a PMD is a synthetic net-like substance that allows the body's own tissue to grow into it.¹³ When inserted it is soft and over time it hardens. Once implanted a PMD is intended to remain in the body permanently. In the event that removal is sought, the process involves both removing the PMD vaginally, and chiselling it out from the abdomen. This is a difficult procedure that is not within the skill set of a vast majority of surgeons.¹⁴

2.3. Originally there was a considerable body of data supporting the conclusion that the incidence of harm from PMDs is very low.¹⁵ The acceptability of these findings has been challenged in recent years. Research conducted by *The Guardian* in August 2017 indicated that approximately 1 in 15 women who have had PMDs implanted have had follow up surgery for removal due to experiencing complications.¹⁶ In April 2018 an audit conducted in the UK by the National Health Service (NHS) revealed that risks of complications from mesh were around the 45% mark.¹⁷

2.4. In New Zealand information gathering on PMDs has been limited owing to the absence of mandatory or standardised reporting of adverse events or of tracking or flagging systems.¹⁸ Following a 2014 petition to government by advocates Carmel

¹¹ A L Olsen and others "Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence" (1997) 89 (4) *Obstet Gynecol* 501.

¹² Christopher Maher and others *Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse* (Cochrane Gynaecology and Fertility Group, 9 February 2016).

¹³ The Senate Community Affairs References Committee *Number of women in Australia who have had transvaginal mesh implants and related matters* (March 2018) at [1.22]

¹⁴ Hannah Devlin "'Scandal' of vaginal mesh removal rates revealed by NHS records" *The Guardian* (online ed, United Kingdom, 15 August 2017); The Royal Australian and New Zealand College of Obstetrician and Gynaecologists "Response to the Health Committee of New Zealand House of Representatives Report on Surgical Mesh" (Communiqué, June 2016) at [6].

¹⁵ *ACC Surgical Mesh Review Analysis of Treatment Injury Claims 1 July 2005 to 30 June 2014* (13 March 2015) at 21; Hemendra N Shah and Gopal H Badlani "Mesh complications in female pelvic floor reconstructive surgery and their management: A systematic review" (2012) 28(2) *Indian J Urol* 129.

¹⁶ Devlin, above n 14.

¹⁷ Devlin, above n 14.

¹⁸ A reportable adverse event is one occurring in relation to a medical device that results in, or risks resulting in, death; life threatening illness or injury; permanent impairment of a body function or permanent damage to a

Berry and Charlotte Korte, the ACC collaborated with Mesh Down Under™ and Medsafe to generate a report on the use of surgical mesh. This found that there had been 810 surgical mesh related ACC claims from 1 July 2005 to 30 June 2017.¹⁹

2.5. Without longitudinal follow-up studies it is difficult to gain a comprehensive understanding of all potential forms of harm suffered by patients. Anecdotal evidence indicates that the incidence of injury increases with the length of the period of PMD implantation.²⁰ Of New Zealand patients who have experienced complications, reported effects have included the following:

- Chronic, debilitating pain. This is the most common and considered to be the most difficult experience.
- Tremors, nausea, and vomiting as a foreign body response. This response does not subside as should occur 48 hours after surgery.
- Erosion or extrusion of mesh through tissue and organs.
- New onset incontinence or voiding complications.
- Dyspareunia, or pain during sexual intercourse.
- Recurrence of the original condition that the PMD was intended to treat.
- Nerve damage.
- Scarring.
- Infection. This can be related to the larger pore size of mesh.
- Organ or implant site ‘shrinkage’ for instance, vaginal shortening.
- Continuous bleeding and discharge.
- Emotional distress and mental health issues, particularly in connection with a long-term diagnosis of chronic pain.
- Neuro-muscular problems.

body structure; or a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

¹⁹ ACC Treatment Injury Claims Surgical Mesh-Related Claim Data From 1 July 2005 to 30 June 2017 (12 fiscal years) (18 October 2017).

²⁰ “Prolift mesh: What did Johnson & Johnson know?” (21 September 2015) RADAR <radar.avrotros.nl>.

- New onset autoimmune diseases.²¹

2.6. Such complications have understandably resulted in many women seeking removal of PMDs. For some the outlook of living with SUI or POP is preferable to the effects described above. Unfortunately, while the surgery to implant a PMD is relatively quick and simple, the removal procedure is considerably more difficult. Full removal can involve hours of surgery and risk damage to nerves and organs including the bladder and bowel. Essentially, it is not always possible to remove a PMD. Even when it is, such surgery does not necessarily alleviate the side effect(s) that the patient sought to avoid. Dr Hanifa Koya, a Wellington-based specialist in gynaecology gave the opinion that once a mesh related complication has developed pain symptoms remained permanent in 22-46% of patients and were not corrected by mesh removal.²²

3. New Zealand Legislation

3.1. In New Zealand the governing legislation for medical devices is the Medicines Act 1981. It was under this law that PMDs entered the New Zealand market. The relevant body engaged in the regulation of medical devices is Medsafe, a business unit of the Ministry of Health. Medsafe's mission statement provides that it applies accepted international practice to the regulation of therapeutic products and provides services that are both efficient and minimise the costs of regulatory action.²³ The difference between New Zealand regulation of medical devices and that of comparable jurisdictions is the process by which products enter the market.

3.2. Rather than being registered, devices must be "notified" to Medsafe's Web Assisted Notification of Devices (WAND) database. This involves the sponsor of the device providing information, including a risk classification, to the Director General of Health.²⁴ If there is a safety issue with a device, the WAND database can be used to identify the sponsor(s) of that device. This may be contrasted to jurisdictions including Australia, the US and Europe where the state requires a medical device to

²¹ Carmel Berry and Charlotte Korte "Surgical Mesh in New Zealand Submission prepared for The New Zealand Health Select Committee"; *Health Committee report on Petition 2011/102 of Carmel Berry and Charlotte Korte* (July 2014).

²² Hanifa B Koya "Mesh Training Regulation" (21 March 2013).

²³ *Adverse Event Reports Relating to Surgical Mesh Implants Summary of reports received by Medsafe* (August 2017) at 5.

²⁴ Medicines Regulations 2003 cl 9.

pass through an assessment process, which may include classification and testing, before particular it can come onto the market.

3.3. In November 2014 former health minister Jonathan Coleman announced that a New Zealand-based regulatory regime would be developed.²⁵ At the time of writing, the New Zealand Government is working on draft legislation for therapeutic products. The draft “Therapeutic Products Bill” is intended to replace the Medicines Act 1981 and its Regulations.²⁶ In February 2018 the progress of the bill was said to be in its 18th iteration, with an exposure draft expected to be released for consultation by the 25th iteration. The interim decisions released in April 2016 provide an indication of the trajectory of the proposed law. Of note are signals of a minor alteration to the regulation of medicines, and considerable changes to the regulation of medical devices. Broadly, anticipated changes have three major aspects: lean legislation; an independent regulator; and fitting in with international approaches.²⁷ While lean legislation is intended to assist in a more future-proof system, this may involve inadequate formal constraints when dangerous products enter the market. Inclusion of an independent regulator is a technical step up from the current system, however the effectiveness of this entity may be hampered depending on the degree to which fitting in with international approaches is prioritised.

3.4. As an overview, the high level objectives of the regime are that:

- (a) the expected benefits of therapeutic products should outweigh the known risks of causing harm in the treatment population
- (b) regulation of therapeutic products should be across the product lifespan and proportionate to the benefits and risks associated with their correct use
- (c) regulation of therapeutic products should be impartial and independent of political, industry, or other vested interests
- (d) an identified person is responsible for managing the risks associated with each therapeutic product on the market, and will generally be the person who is responsible for marketing that product

²⁵ Ministry of Health *Regulatory Impact Statement: Ministry of Health - Therapeutic Products Regulation* (11 November 2015) at [3].

²⁶ Ministry of Health *Annual Report for the year ended 30 June 2016* (October 2016) at 32.

²⁷ Letter from Jonathan Coleman (Minister of Health) to Office of the Minister of Health and Chair, Cabinet Social Policy Committee regarding the Therapeutic Products Regulation Paper 2: Proposals for a Therapeutic Products Bill.

- (e) regulation should promote safe use of therapeutic products and ensure appropriate information about them is provided to the public
- (f) regulator should co-operate with international peer regulators and take relevant international standards and practice into account
- (g) compliance costs should be appropriate to the benefit:risk profile
- (h) regulation should support innovation and competition.²⁸

3.5. This list highlights some potential tensions. Protective measures for consumers, as listed in objectives a, b, c and e may be contrasted with the industry-supportive objectives of d, g and h. Objective f is likely to also fall within the latter category. For PMDs, the use of international information has enabled efficient introduction rather than efficient removal of a medical device. Reference to the European model as increasingly adopted or actively considered by other jurisdictions is important to note as a likely direction for New Zealand.²⁹ An aspect of this model under consideration includes the use of conformity assessment bodies to be discussed later.³⁰ These objectives focused on efficiency and flexibility – even as high-level goals – reveal the potential for protective measures to be weakened.

3.6. This dissertation will assess the proposed law as described in the 2016 documents in light of the lessons to be taken from the use of PMDs in New Zealand and abroad.

4. Importance of advocacy

4.1. Advocacy groups around the world have played a key role in bringing government and media attention to focus to the experience and needs of patients who suffer from PMD complications. Addressing all key recommendations made to legislators is beyond the scope of this dissertation, but will be mentioned briefly to provide a broader view of the issue.

4.2. In the Australasian context the advocacy group Mesh Down Under™ has been a major player in bringing about change. Their mission statement includes raising awareness amongst New Zealanders about PMD complications; providing information to enable informed consent for anyone considering having a PMD implanted; calling on providers and government bodies to acknowledge PMD harm as a public health issue; and demanding that adverse events associated with medical

²⁸ above n 27 at [9].

²⁹ Letter from Jonathan Coleman (Minister of Health) to Office of the Minister of Health and Chair, Cabinet Social Policy Committee regarding the Therapeutic Products Regulation Paper 1: Context and Overview at [29].

³⁰ Above, n20 at [36.1]

devices be reported to Medsafe.³¹ Following a review of a petition made by Mesh Down Under™ representatives Carmel Berry and Charlotte Korte in 2011, the Health Select Committee made the following recommendations to the Government:

- (a) that it work with relevant medical colleges to investigate options for establishing and maintaining a centralised surgical mesh registry
- (b) that a registry be informed by the International Urogynaecological Association classification for recording mesh surgery complications
- (c) that it suggest that the Colleges take note of the petitioners' and others' experiences and review best practice around informed consent for mesh procedures
- (d) that it encourage health providers to ensure that coding for mesh surgery is consistent. This should include a system to allow patients with mesh complications to be identified and monitored
- (e) that it encourage utilisation of the adverse events reporting system as applicable to medical devices
- (f) that it endorse the provision of ongoing education for surgeons on the use of surgical mesh and mesh removal surgery
- (g) that it consider expanding Medsafe's role over time to assess the quality and safety of a medical device before it can be used in New Zealand³²

4.3. Further recommendations followed and included the reclassification of PMDs from Class II to Class III; for the Director General of Health to exercise his powers to require manufacturers to satisfy him of product safety; to provide for mandatory reporting of adverse events; to provide for mandatory post-market surveillance; coding and flagging systems to track patients; and requiring training for mesh excision.³³

4.4. These further recommendations are relevant the evolution of the law concerning PMDs and medical devices in general. The following sections use PMDs as a case study to illustrate how regulation can affect the incidence of patient harm at four

³¹ Mesh Down Under™ <www.meshdownunder.co.nz>.

³² Carmel Berry and Charlotte Korte "Petition 2011/102".

³³ Letter from Carmel Berry and Charlotte Korte to Simon O'Connor (Chairperson Health Select Committee) regarding the prioritised list of key recommendations (1 June 2015).

stages of the introduction and uptake of a medical device: in pre-market regulation; in pre-implantation disclosure requirements; in post-market monitoring; and in complaints and compensation mechanisms. Provided present the opportunity to feedback on proposed legislation concerning therapeutic products in New Zealand, the following seeks to draw out the lessons from PMDs in New Zealand and internationally to make recommendations for regulation of medical devices in order to reduce harm.

Pre-market regulation: ensuring only safe products enter the market

5. Adopting the results of problematic international assessment processes

5.1. In New Zealand, while some post-market actions can be taken when safety issues become apparent in medical devices, there is no nationally-based pre-market assessment and approval process.³⁴ When it comes to pre-market assessment, the current New Zealand regulatory regime is highly dependent on international evidence and processes. This is likely to continue under future legislation as adoption of findings from overseas assessors enables efficiency in product introduction.³⁵ Unfortunately problems arise with information sourced from imperfect regulatory frameworks. As demonstrated by the introduction of PMDs, in the case of the Australian, US and European Union (EU) regimes, efficiency has at times been at the expense of safety. A further issue for New Zealanders is that international regulators are not accountable to the New Zealand public.

5.2. The April 2016 proposals for a New Zealand regulatory system recommend a mixed model for pre-market assessment of medical devices. In this framework the regulator would be capable of undertaking full assessments, partial assessments, and recognise the work of other regulators.³⁶ Specifically the proposal advanced that:

“The choice of approach (unilateral recognition, use of others work, or full assessment) would be determined by the regulator and would depend on the nature of

³⁴ Interview with Dr Stewart Jessamine, Director Protection, Regulation and Assurance, Ministry of Health (Guyon Espiner Morning Report, Radio New Zealand, 12 December 2017).

³⁵ above, n 27 at [9.6].

³⁶ Ministry of Health *Regulatory Impact Statement: Ministry of Health - Therapeutic Products Regulation* (11 November 2015) at [7].

*the therapeutic product and its risk profile. For the majority of products the international standards for risk classification will guide the choice of process.”*³⁷

5.3. The potential issues with this approach become evident when relevant regulatory regimes are held to greater scrutiny. The following sections will critically examine the processes in gaining US Food and Drug Administration (FDA) approval, inclusion on the Australian Register of Therapeutic Goods (ARTG), and receiving the European CE Mark. These processes are relevant to New Zealand as they reflect the standards commonly referred to at present. In the absence of a national assessor, the current practice is that District Health Boards and private hospitals will look to these particular standards as well as inclusion on the WAND database before making use of a medical device.³⁸

6. *US Food and Drug Administration (FDA) approval*

6.1. In the US there are two main paths by which manufacturers can bring medical devices into the market. The first involves conducting clinical studies and submitting a premarket approval (PMA) application including evidence of a device’s safety and effectiveness. The FDA then reviews a PMA application which takes an average of 1,200 hours.³⁹ The second involves submitting what is called a 510(k) notification to demonstrate that a device is substantially equivalent to another already on the market.⁴⁰ The FDA review process for this clearance is around 20 hours. The latter 510(k) process was used for the introduction of PMDs onto the US market. The following provides an illustration of how the adoption of international approvals can result in the introduction of a risky product, and why there should be a degree of scepticism of such an approval.

6.2. In 1997 the US Food and Drug Modernization Act introduced a clearance and review procedure for new medical devices. The process of “510(k) clearance”, so named for the enabling section in the Act, provided an expedited means of introduction. It operated through low and medium risk devices being reviewed to determine if there

³⁷ above, n 27 at [30]; Letter from Jonathan Coleman (Minister of Health) to Office of the Minister of Health and Chair, Cabinet Social Policy Committee regarding the Therapeutic Products Regulation Paper 3: Context and Overview at: further policy approvals at [4]; also see endorsement in Medical Technology Association “Proposal for a New Zealand Regulatory Scheme for Medical Devices” (White Paper, March 2015).

³⁸ This roughly reflects the Product Evaluation Health NZ (PEHNZ) process.

³⁹ *Medtronic Inc v Lohr* 518 US 470 (1996) at 477.

⁴⁰ Judith A Johnson *FDA Regulation of Medical Devices* (Congressional Research Service, R42130, 14 September 2016).

was “substantial equivalence” with a device already existing on the market, called a “predicate”. In making this assessment the FDA was instructed to require scientific evidence at the least burdensome level.

6.3. Substantial equivalence is defined in the Act as meaning that the new device has the same intended use as the predicate. This required that the device:

- has the same technological characteristics as the predicate; or
- has different technological characteristics; and
 - the information submitted in support of substantial equivalence to the predicate device contains information, including clinical data if deemed necessary, that demonstrates that the device is as safe and effective as a legally marketed device; and
 - does not raise different questions of safety and efficacy than the predicate device.

6.4. Having 'different technological characteristics' means there is a significant change in the materials, design, energy source, or other features as between the new device and the predicate. In addition, a new device cannot be found to be substantially equivalent to a predicate that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.⁴¹

6.5. The nuance in what constitutes a different product, or an important change in design will be more fully explored in section 18. To be addressed initially is the issue of how the chronology of device removal can undermine the protective intention behind assessment procedures.

6.6. The process of 510(k) clearance is used primarily for the market introduction of Class II devices. Detail on what constitutes such a device will be described in section 9, but generally they can be understood as having a medium risk. It is estimated that over 80% of devices being cleared through the process in 2011 were in Class II. PMDs were originally given this classification.

6.7. In a 2011 review by the US Institute of Medicine on the effectiveness of the 510(k) clearance process, there were two key findings. The first was that as long as the

⁴¹ Safe Medical Devices Act of 1990 Pub L No 101-629 Stat 4511 (1970).

“substantial equivalence” standard continues, the process cannot be an effective pre-market safety and effectiveness evaluation. The alternative process for Class III or high risk devices involves the requirement for an independent demonstration of the device’s “reasonable assurance of safety and effectiveness.” The 510(k) assessment is simply whether the new device is as safe as a predicate. The US Supreme Court has acknowledged that substantial equivalence does not guarantee the safety and effectiveness of a medical device; rather it determines “whether the later device is no more dangerous and no less effective than the earlier device.”⁴²

6.8. Broadly, it is possible that a predicate could fall into one of the following categories:

- (a) Pre-amendment device⁴³ that has been put in the Class II category based on review of an outside advisory panel.
- (b) Post-amendment device⁴⁴ originally approved as safe and effective by the pre-market approval process and reclassified into Class II.
- (c) Post-amendment device placed in Class II through the de novo review process showing safety and effectiveness.
- (d) Post-amendment device cleared through 510(k) found to be substantially equivalent to another device in one of the first 3 categories.

6.9. Most devices enter on the basis of substantial equivalence to an (a) or (d) product. That is to say the assessment will mostly be whether there is similarity to a device that was never evaluated for safety and effectiveness in the first instance. Given the frequency that this process is used, it leaves open an opportunity for unsafe devices to enter the market with insufficient testing. The introduction of PMDs provide an illustration of how the 510(k) loop hole was exploited

6.10. Surgical mesh has been in circulation since the 1950s. In the 1970s it was thought to have potential in gynaecological use, and by the 1990s it was in use for SUI and POP surgeries in Europe and the US. In 1996 Boston Scientific introduced

⁴² *Medtronic Inc v Lohr*, above n 39, at 493.

⁴³ This is one introduced before the Medical Device Amendments of 1976 when the 3 grade classifications system was introduced and before which the assessment standards were different.

⁴⁴ A device introduced after the Medical Device Amendments of 1976 when the 3 grade classifications system was introduced and before which the assessment standards were different.

the ProtoGen Sling (“ProtoGen”), a device for the treatment of SUI. This device was approved by the FDA on the basis of its similarity to an earlier product.⁴⁵

6.11. The ProtoGen was recalled in 1999 after several patients reported injuries including vaginal bleeding, organ perforation and infection. Prior to recall, a competing product, the Gynecare TVT Vaginal Sling (TVT VS), was introduced by Johnson & Johnson / Ethicon. Its approval by the FDA was given on the basis of its substantial equivalence to the ProtoGen. This form of approval meant that clinical trials or studies were not required. Alarming, the recall of the ProtoGen upon which the TVT VS’s approval was based did not signal a need for further investigation or testing of the substantially equivalent product still on the market. Multiple similar products were introduced in the same way shortly afterwards. Only in 2002 did the FDA approve PMDs for POP.⁴⁶ POP kits developed by major manufacturers were then released, including the ProLift system by Johnson & Johnson / Ethicon.⁴⁷ From 2008, following increasing reports of injuries, the FDA began issuing safety warnings for PMDs.

6.12. For incoming New Zealand regulation to allow for uncritical acceptance of FDA approval when devices have been assessed via the 510(k) process is plainly problematic. The benefits of process efficiency cannot outweigh the significant risks when little substantive assessment is undertaken. New Zealanders are also removed from this overseas regulatory process and limited in their ability to influence change. A further problem is the way in which the truth around independent assessment can be obscured as is demonstrated by the Australian context.

7. *Australian Register of Therapeutic Goods (ARTG)*

7.1. Presently inclusion on the Australian Register of Therapeutic Goods (ARTG) is likely to be influential in determining whether a device is considered suitable for introduction into New Zealand.⁴⁸ Still, even with Australia’s own forms of pre-market assessment in place, Australian citizens have suffered harm from PMDs and

⁴⁵ The “Vesica Bone Anchoring System”, used for the treatment of urinary incontinence was not inserted transvaginally, but its design was a precursor for devices that followed.

⁴⁶ “The History of Transvaginal Mesh” Transvaginal Mesh Lawsuit Guidance <sites.google.com/site/transvaginalmesh>.

⁴⁷ “A Brief History of Transvaginal Mesh” Dunkan, Miller, Valentino & Weeks, P.C. <www.dmvwmeshcenter.com>.

⁴⁸ Australian certification is listed on the PEHNZ Supplier form of December 2014 for Healthcare providers.

Australian regulators have been criticised.⁴⁹ PMDs were first available for clinical use in Australia in 1998, and their efficacy was only later supported by data from randomised controlled trials in 2002. This “robust regulatory regime” from which New Zealand takes guidance has permitted a sell first, test later approach. The first adverse event report by following the implantation of a PMD was in 2006.⁵⁰

7.2. As indicated above, a class action of over 700 women against Johnson & Johnson Medical Pty Ltd and Ethicon commenced in 2017 in Australia. The allegations against the medical device manufacturers included that there was a failure to properly test devices; that risk of the procedure was minimised to both surgeons and patients; that testing that was conducted was too short-term; and that the product was aggressively marketed to surgeons as part of a simple and cost effective process.

7.3. A Senate inquiry conducted in early 2018 surveyed 2,400 women who had had PMDs implanted. An extract echoing the key concern over regulation regarding approval is this: “How did over 100 variants of a poorly tested device make their way into the market without adequate clinical testing for safety and efficacy?”⁵¹

7.4. In Australia regulatory responsibility for the introduction and use of PMDs lies with the Therapeutic Goods Administration (TGA), the medical colleges and the Australian Commission on Safety and Quality in Health Care (ACSQHC), which is overseen by the Council of Australian Governments Health Council.⁵² Nonetheless, in Australia, as in New Zealand, the majority of medical devices are imported and for this reason the Australian market authorisation process relies predominantly on regulatory assessment undertaken in the EU. When a sponsor seeks to supply a device they can rely on supporting evidence of conformity assessment certification issued by a European Notified Body.⁵³ Overall the TGA is highly dependent on reference to the standards adopted by external international bodies, in particular:

- the International Organisation for Standardization

⁴⁹ Christopher Knaus “Transvaginal mesh inquiry criticises Australia's medical device regulation” *The Guardian* (online ed, UK, 28 March 2018).

⁵⁰ above, n 13, at 1.

⁵¹ Danny Vadasz “Trans vaginal mesh injuries – is anyone accountable?” (November 2017) Health Voices Journal of the Consumers Health Forum of Australia <healthvoices.org.au>.

⁵² above, n 13, at 8

⁵³ above, n 13 at 9.

- the International Electrotechnical Commission
- the European Committee for Standardization, and
- the European Committee for Electrotechnical Standardization.⁵⁴

7.5. The problem with assuming that a device is safe on the basis of inclusion in the ARTG is that such inclusion is itself based on another international assessment; when New Zealand takes into account such evidence it is second-hand information. While explaining the protective measure in New Zealand’s regulation of medical devices Senior Medsafe Advisor Robert Jelas answered that the findings of other countries with “robust regulatory regimes” were taken into account.⁵⁵ Given how influential Australian decisions have been on New Zealand medical devices regulation, and how reliant they are on overseas assessors, this may be misleading. As with the problem of accepting US approval, New Zealanders are less able to influence overseas governments to rectify any issues with processes when they are identified. To better understand what Australian pre-market approval truly indicates it is necessary to discuss the European pre-market approval process.

8. *European Union Conformité Européenne (CE) mark*

8.1. The European CE Mark is another of the international “stamps of approval” likely to be valued as verification of safety and efficacy by New Zealand.⁵⁶ As described above, this is already influential in Australia. Unfortunately there are also issues that arise with this original form of approval. Though seen as something of a gold standard by manufacturers, the processes around gaining the CE mark are have been critiqued for lacking transparency by using externalised assessors which in turn raises concerns around the potential for conflicts of interest.

8.2. In the EU, while devices of a lower risk category than PMDs – those that are non-implantable - can be self-marketed, higher-risk devices must undergo outside review. These review processes have been identified in New Zealand and Australia as aspirational. Making use of outside experts better equipped to assess highly specific technology has been presented as both progressive and inevitable. The 2016 proposal documents for the new New Zealand regime, with a local regulator, indicate that

⁵⁴ Therapeutic Goods Act 1989, s 41CC.

⁵⁵ “Auckland Women’s Health Council Submission on Medicines Amendment Bill” (13 April 2012) at 7.

⁵⁶ CE certification is listed on the PEHNZ Supplier form of December 2014 for Healthcare providers.

there will be only a “modest increase” in size of such an entity.⁵⁷ Given likely capacity constraints, reliance on international assessment may well continue.

- 8.3. Marketed medical devices in the EU must carry the CE mark. This shows that a device conforms with one of the relevant directives under the EC Medical Device Directives. More specifically, it indicates that it has been tested by a third party Notified Body in one of the member states. Notified Bodies are private entities accredited by the regulator of a member state to evaluate a new product. The evaluations of Notified Bodies are then assessed by regulators as required. Once the CE mark has been granted a device may enter the market of any member state of the EU. Compared with the centralised FDA process, the EU model involves a more hands off approach.
- 8.4. While the United States introduced the FDA assessment framework as a measure for customer protection, the impetus for harmonised assessment regulations across European nations had an underlying economic interest with the formation of the European Union. The EU system was arranged with the different goal of synchronisation.⁵⁸ These origins are relevant. FDA processes have been criticised as cumbersome, depriving US citizens of access to the kinds of innovative products available in Europe. By contrast the EU process has been criticised as putting patients at risk. Appendix 1 provides an overview of the comparative schemes.
- 8.5. Notified Bodies involved in the assessment process have also been viewed as on the side of the manufacturer. A UK investigation conducted by Debora Cohen illustrated a risk of this kind in the EU system. Undercover reporters used a fake product the “Changi Total Metal Hip” (TMH) to see what the processes of a Notified Body entailed. The TMH was introduced to the Notified Body as a product that was substantially similar to three products already on the market. Two of the products had been recalled, and one was subject to legal action in the US. Further, a fictitious set of reports accompanying the product stated that “tests had shown that [the] hip prosthesis produced potentially toxic levels of metal ions in the body.” Nonetheless, the implant was passed with the design deemed acceptable for use in European

⁵⁷ Above, n 29, at [33].

⁵⁸ Gail A Van Norman “Drugs and Devices Comparison of European and U.S. Approval Processes” (2016) 5 JACC Basic Transl Sci 399.

patients.⁵⁹ If such an accompanying safety warning does not preclude a device's introduction onto the market, requiring clinical trials that indicate safety warnings will also be redundant. The potential for a manufacturer to shop around for a more permissive assessor, and for that assessment to effectively provide entry to all of the EU and as well as many non-member states poses a risk on a large scale.

8.6. The EU process has been criticised by the FDA's device chief, Dr. Jeffrey Shuren. His critique centred on the lack of publicly available information regarding the award of a CE mark. This was pointed out as problematic for the lack of transparency in process. Requirements for approval are dealt with between the device company and the one of many Notified Bodies that the device company may choose from. Shuren compared US and EU processes as follows: "*If a manufacturer wishes to market a laser to incise heart tissue to treat arrhythmia (abnormal heart rhythm) in the EU, the manufacturer must show that the laser incises heart tissue only. In the US, however, the manufacturers must show that the laser incises heart tissue and also treats the arrhythmia.*"⁶⁰ In other words, an assessor taking a sufficiently narrow view of their task could also find a way to provide sign-off on a dangerous device.

8.7. When New Zealand regulators have the opportunity to assess new devices in terms of their appropriateness for the local market, entirely independent clinical trials in all instances will be unrealistic. Instead it is proposed that the opportunity should be taken to look behind the supplied stamp of approval. A regulator may ask: what was the nature of the process by which this device was determined to be safe and effective? If a medium to high risk device passed through a fast-tracked assessment as in US 510(k) clearance, it seems reasonable that, at the very least, a patient should be informed of that. Similarly, when the CE mark is granted, identifying the relevant Notified Body and the state of origin may be important to record and be available to consumers. If entry into the ARTG is deemed good reason for use in New Zealand, was that inclusion largely based on a European standard; if so, what was it? This form of information gathering and sharing may serve to identify where there are more permissive assessors and create pressure on Notified Bodies to maintain a certain standard of protective measures to avoid a loss of credibility.

⁵⁹ Debora Cohen "How a fake hip showed up failings in European device regulation" (2012) 345 BMJ 19.

⁶⁰ Lisa Richwine "Guinea pig" remark spurs U.S., EU device spat" *Reuters* (online ed, United States of America, 25 February 2011).

9. *Getting classification right*

9.1. A trend that has been brought to light by advocacy and inquiries around the world is that PMDs have been reclassified from Class IIb (or Class II in the US) to Class III. The classification system has some variation across jurisdictions, but in broad terms it is relatively consistent. The stated intended purpose of a device, as provided by the manufacturer, determines its class in a risk-based system. The system common to New Zealand, Australia and the EU has four classes from low to high risk. In the EU it is understood as follows:

- Class I - generally regarded as low risk;
- Class IIa - generally regarded as medium risk;
- Class IIb - generally regarded as medium to high risk; and
- Class III - generally regarded as high risk.

9.2. In the US the 1976 Medical Device Amendments granted the FDA authorisation to pre-approve medical devices. These amendments also set up the classification of medical devices in order to determine the amount of control needed over each one.⁶¹ The classification of a medical device determines aspects of its regulation. Classification in the US is based on a 3 class system; Class I being the lowest risk, and Class III being the highest. PMDs, being introduced as a non-active implantable device, were initially classified as a Class II device. US regulations state that a device should be classified as Class III if it has a biological effect or undergoes a chemical change in a patient's body. In January 2016, FDA reclassified mesh for POP from a Class IIb device to a Class IIIb device.

9.3. Under the current regulation in New Zealand it is surprising that a PMD should have ever been classified as Class IIb. The more appropriate classification, as has been updated overseas, is high risk or Class III. New Zealand's Medicines Regulations provide guidance on medical device risk classification. Rule 9, regarding surgically invasive medical devices intended for long-term use, specifies that a device will come under Class III if it is intended by the manufacturer to "have a biological effect" or to be "wholly, or mostly, absorbed by a person's body."⁶² This description

⁶¹ Carol Rados "Medical Device & Radiological Health Regulations Come of Age" *FDA Consumer magazine* (online ed, United States of America, January 2006).

⁶² Medicines Regulations 2003, sch 2.

benefits PMDs as they are designed to have tissue grow into them to the extent that surgical removal is very difficult.

- 9.4. It is the device sponsor who provides this classification information to the WAND database. It may be appreciated that a sponsor would be inclined to choose a lower risk classification if it were within possible options. The problem of inappropriate classification overseas has not escaped advocates in affected states. A Scottish review conducted in 2017 anticipated the new EU Medical Device Regulations would provide for the new classification. All “surgical mesh” devices intended for “long term or permanent use” would likely come under be Class III⁶³.
- 9.5. Had PMDs been originally classified as Class III, they would certainly have been required to undergo more thorough testing. How was this missed? Given the differences in testing requirements it isn’t surprising that manufacturers might attempt to shoehorn a Class III device into a Class II description for intended use. In part this may also be tied to the difficulties manufacturers have when they seek to enter different jurisdictions with inconsistencies in assessment procedures, as will be discussed in section 25.⁶⁴
- 9.6. In designing new regulation, it should be asked whether it is appropriate for the initial determination of classification to be in the hands of the manufacturers. As has been identified under the FDA process, there is compelling reason for a manufacturer to downplay the risk of a device in order to take advantage of an expedited process. Perhaps the option should never be presented.

Pre-implantation: enabling consumers to make informed choices

10. Once a product that poses risks is introduced to the market, regulatory protection should again be provided through informed consent requirements. Patients should be given the best opportunity to understand and decide on the right course of treatment for their situation. In New Zealand informed consent is regulated through the Code of Health and Disability Services Consumers' Rights, which imposes information sharing obligations on healthcare providers to enable patients to exercise their rights.⁶⁵ In the case of PMDs

⁶³ *Scottish Independent Review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women: Final Report* (March 2017).

⁶⁴ Oriana Ciani and others “Linking the Regulatory and Reimbursement Processes for Medical Devices: The Need for Integrated Assessments” (2017) 26(1) *Health Econ* 13 at [1.1].

⁶⁵ Health and Disability Commissioner Regulations 1996, right 6.

there are several factors that inhibit genuine informed consent. Firstly, as occurs in the absence of thorough clinical trials, the limited information available on the safety and efficacy of PMDs makes it difficult to disclose and explain the potential risk to patients. Secondly, where requirements to disclose are imposed on healthcare providers, there is evidence of a failure to inform patients of options, and about the information (or lack thereof) on the efficacy of a product. When considering the future of New Zealand law, the effectiveness of existing information requirements should be considered. In treatment situations where there is a power imbalance, and patients are reliant on providers to give them full information, are the systems in place sufficient to enable independent decision-making?

11. Effective communication when data is lacking and technology is emerging

11.1. The earlier absence of information on PMDs is an issue that has affected individuals around the world. Only recent studies, for instance the NICE report, have concluded that “[e]vidence of long-term efficacy is inadequate in quality and quantity. Therefore, this procedure (transvaginal mesh repair of anterior or posterior vaginal wall prolapse) should only be used in the context of research.” In addition, the committee commented that there was no evidence in the trials to indicate that the use of mesh was more efficacious than native tissue repair.⁶⁶ In the case of PMDs reports of manufacturers intentionally misleading governments and providers to gain access to markets is a further block to enabling information sharing.⁶⁷ Nonetheless, some blame for failing to disclose what was known must still sit with the relevant healthcare providers.

11.2. Satisfying informed consent obligations is likely to be increasingly complicated by development in treatments and technologies that are difficult to explain to patients, and around which there may be limited common knowledge.⁶⁸ In New Zealand the obligation to provide a patient with information arises under right 7

⁶⁶ National Institute for Health and Care Excellence “Transvaginal mesh repair of anterior or posterior vaginal wall prolapse Interventional procedures guidance [IPG599]” (December 2017) at 1.1 and 6.4.

⁶⁷ As an example, a May 2018 report by US current affairs programme “60 minutes” indicated that Boston Scientific had sourced counterfeit plastic materials from a Chinese supplier needed in the production of mesh. These plastics were repackaged to hide that they were an imitation product. The decision to access this supplier was prompted by US-based producers of the material “Marlex” stopped providing it to Boston Scientific due to concerns that the material should not be used in for permanent implantation into the human body.

⁶⁸ Matthew E Falagas and others “Informed consent: how much and what do patients understand?” (2009) 198 (3) *Am J Surg* 420 at 433.

of the Code of Rights regarding the presumption of competence of a consumer to make an informed choice. It may be anticipated that with novel treatment procedures, even a mature, intelligent patient could have difficulty understanding what could be involved. Nonetheless, the information sharing requirement is not an impossible standard to meet. At the very least patients should be informed about the level of research supporting a product; for example if clinical trials were minimal, this can be explained. Informing a patient about the absence of information is still sharing information.

11.3. A different limit on the ability of providers to share information is related to the instructions for use (IFU) that should accompany medical devices. While Medsafe recommends that manufacturers provide IFUs in line with international practices, there is no regulatory requirement for this under the current law.⁶⁹ Further, when IFUs are supplied, the detail of possible risks can be limited. As an example, a side-effect may be mentioned, but not the likelihood of its occurrence.⁷⁰ Mandating such limited disclosure – a potential side effect without its probability - could be rendered meaningless.

11.4. In New Zealand one of the tools developed for providers was guidance to informed consent particular to the use of PMDs. This was included in a statement developed by the Women’s Health Committee and approved by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists. This statement gave specific recommendations on the nature of discussions that should be had with patients where mesh is considered an option. This can be summarised in the following recommended disclosures for patients considering PMDs in treatment:

- Data is lacking. There is very limited robust data available on the efficacy and safety of the transvaginal mesh products available in Australasia. There is little longitudinal data on certain kinds of prolapse to support a decision for surgery.
- There are alternative treatment options. Surgical management may not be necessary for certain kinds of prolapse. There may be alternatives to surgery such as pelvic floor muscle training and vaginal support pessaries. Conventional native tissue repair and abdominal sacrocolpopexy are also options

⁶⁹ “Instructions for Use (IFU)” Medsafe <www.medsafe.govt.nz>.

⁷⁰Carmel Berry and Charlotte Korte “Supplementary Submission: Follow up to previous petition and communication with The New Zealand Health Select Committee” (19 May 2015) at 27.

- There are potential benefits and complications of transvaginal mesh. The kinds of complications experienced should be disclosed. Complications may occur years after implantation. One such complication is unprovoked pelvic pain at rest that can be difficult to treat.
- The treatment of complications may be difficult. Treatment involving additional surgical intervention may be needed and complications may not completely resolve even with mesh removal. Such removal will not always be possible.⁷¹

11.5. As can be seen from the above disclosure recommendations initially developed in 2007, better patient consent could have been achieved even without the benefit of research published 10 years later. Multiple accounts from patients indicate that providers were not meeting informed consent obligations them under the Health and Disability Commissioner regulations.⁷² This lack of information has impacted patients, not only in undermining their chance to determine what happens to their own bodies, but also making it difficult to discover the cause of complications. For many patients misinformation about the likely cause of pain, for instance a deficiency in the surgical procedure rather than the PMD itself, meant that they experienced additional stress, confusion and frustration with providers and agencies that should be able to assist in such areas.

Post-market regulation: understanding harm to reduce its incidence

12. Even at the time of writing news from around the world includes scathing commentary about the time it has taken for governments to acknowledge the extent of harm caused by PMDs. Multiple contributory factors have been well identified by advocacy groups. These can be separated into cultural and technical issues. The cultural issues discussed relate to problematic positioning of women in healthcare systems. Health care regulation scandals over the past century have seen a repeat in these problems which can be difficult to regulate. The other aspect of post-market regulation occurs in technical impediments to adequate monitoring of patients that have devices implanted. As such monitoring can be a prerequisite for supplying the data to validate government intervention, this is an important area to regulate in order to reduce harm.

⁷¹ Royal Australian and New Zealand College of Obstetricians and Gynaecologists “Polypropylene vaginal mesh implants for vaginal prolapse” (November 2016) at 4.

⁷² “Surgical mesh costs millions” *New Zealand Herald* (online ed, Auckland, 30 Sep 2012).

13. Cultures of silence

13.1. The problem of the medical profession taking a patronising attitude towards women's health issues can be connected to the underreporting of adverse events. Anecdotal evidence from multiple jurisdictions reveals patients feeling condescended to and that their complaints were minimised. In New Zealand, the difference in the number of reported cases of PMD harm grew exponentially once a few women went public with their stories.⁷³ There is also a culture of silence around the kinds of harm experienced from PMDs,⁷⁴ and this is understandable given the deeply personal and private nature of the surgeries involved and side effects experienced. These realities should be considered carefully in the design of systems to enable the reporting and monitoring of adverse events. Issues experienced in the New Zealand context will be further discussed in section 20.

14. A need for regulation of reporting and tracking

14.1. Beyond social issues, there are also technical barriers to adequate post-market monitoring and tracking of devices. If it were known how many devices were implanted, who had received them, and when side effects had been felt, the gravity of the situation may have become apparent sooner. Further, had this led to earlier product recalls, this would have likely resulted in a reduction in the number of women suffering harm from having PMDs implanted, or at least a reduction in the number who had procedures with insufficient information as to the risks and alternatives. While post-market regulation is less relevant in terms of reducing harm for the women who have already had devices implanted, it can play a role in harm minimisation at a population level.

15. International lessons from post-market monitoring

15.1. The following sections review the systems used for post-market surveillance of PMDs in Australia, the US and the EU for possible lessons to be taken up in the New Zealand system. In Australia the shortcomings of possible registries were revealed in the recent Senate inquiry. These can be contrasted with the success of the

⁷³ Cate Broughton "Kiwi mum warns of surgical mesh nightmare that destroyed her life" *Stuff* (online ed. New Zealand, 19 March 2017).

⁷⁴ Jane Akre "Suffering In Silence From A Medical Device - Surgical Mesh (Part 1)" Injury Board National News Desk (30 March 2009) < news.legalexaminer.com >.

Australian Orthopaedic Association National Joint Replacement Registry. In the US developments have been made through applying standards used for the monitoring of medicines to medical devices. While in the US communication has flowed from regulators to the public, later analysis has indicated that the form of such communication may be wanting. Finally, in the EU – the system likely to be followed by New Zealand⁷⁵ – there are concerns about attempting to harmonise in a pro-industry manner.

16. Australia: the problem of non-centralised data capture

16.1. As in New Zealand, one of the questions the Australian Senate Inquiry sought to answer was how many women actually had PMDs implanted, and of those how many were harmed by such implantation. While 555 submissions were received from those who had experienced harm, there are conceivably more women who are yet to experience harm over the lifecycle of the PMD. Additionally, it could be expected that many opted not to submit given privacy concerns. The reality is that it unreasonable to expect patients to carry the burden of reporting all incidents.

16.2. Ultimately the Senate report highlighted the difficulty in gaining information in the absence of standardised post-market reporting on PMD use. This was not due to a lack of mechanisms, but rather that the arrangement of those was incompatible with effective monitoring of PMDs. For instance, while there are mesh supply records from industry sponsors, these do not indicate how many devices have been used or when multiple devices have been used for one patient. Another option might have been to use the Medicare Benefit Schedule coding system based on SUI and POP procedures; however this does not distinguish between when a PMD or native tissue is used.

16.3. In Australia the status quo leaves hospitals the responsibility to record devices. The manner in which this data is collected and stored varies between those hospitals and between states. Additionally, while some medical practitioners maintain databases, reporting is voluntary. Essentially, all of the systems that might be used for data collection were not organised around getting the kind of information needed for a full picture of the problem. But it isn't just for the sake of supporting product removal. There remains a strong voice from industry that suggests a PMD implanted

⁷⁵ above, n 27, at [60].

with adequate training and skill is likely to be successful.⁷⁶ If better data were kept on the use of PMDs, patterns may emerge as to which surgeons or hospitals were conducting procedures with better patient outcomes.

16.4. An example of a system to learn from is the Australian Orthopaedic Association National Joint Replacement Registry (AOA NJRR). This was pointed to in submissions by Women’s Health Action in relation to mesh in New Zealand⁷⁷ and has a number of design aspects that overcome some of the issues described above. In the set-up of the AOA NJRR the issues that emerged included that numerous products could be more or less efficacious depending on design, technology changes and surgical technique. It was also identified that in many instances information was scarce in terms of the effects of long-term implantation; the patients receiving such implants were living longer than those who had gone before and better information was needed. The AOA NJRR provides a mechanism for device tracking meaning that patients – in particular those who have an implanted device that has been recalled – are able to be contacted.⁷⁸

16.5. The experience in Australia demonstrates the level of consideration that needs to be given for the monitoring of different kinds of devices. It shows the need for registries that are maintained with consistency, as well as having systems with the flexibility to suit different styles of devices and procedures so that data is properly captured.

17. US: Efficacy of post-market safety communications

17.1. In some respects the FDA has been a good example of responsiveness to reports of adverse events. The 2008 safety warnings pre-date the removal of certain PMDs from the New Zealand market by almost a decade. Still, when looking to the response to safety warnings, there may be lessons in how best to communicate with consumers.

17.2. In post-market regulation the FDA uses the 522 Postmarket Surveillance Studies Program so named for the relevant section of the Federal Food, Drug and

⁷⁶ Megan Gattey “Surgical mesh ban a 'knee-jerk reaction' that may hurt women: Doctors” *Radio New Zealand* (online ed, New Zealand, 13 December 2017).

⁷⁷ Sandra Hall, Women’s Health Action Trust “Background Paper to the Health Select Committee on the use of Surgical Mesh in Aotearoa New Zealand” (2016) at 7.

⁷⁸ Stephen E Graves and others “The Australian Orthopaedic Association National Joint Replacement Registry” (2004) 180 (5) *Med J Aust* S31.

Cosmetic Act. The programme involves design, tracking, oversight, and review responsibilities when studies are conducted. The results of these studies are publicly available from the FDA site.⁷⁹ Following adverse reports from the use of PMDs the FDA arranged an advisory panel to make recommendations, and in 2011 those suggesting more data was needed to establish PMD safety were taken seriously. In the same year a second set of warnings were issued to doctors and consumers.

17.3. Unlike the Australian system, the FDA has a mandatory reporting mechanism. Adverse events are submitted through the FDA's Manufacturer and User Facility Device Experience (MAUDE) system. Manufacturers, importers, and device user facilities have mandatory reporting requirements. It was the reports issued through this system that led to the 2008 and 2011 safety reports. Later, in 2012, manufacturers were ordered to conduct post-market surveillance studies. The FDA website provided updates as to the progress of monitoring and orders made. In January 2016 the FDA issued orders requiring the reclassification of surgical mesh used in POP and SUI procedures from Class II to Class II. Along with these orders came the requirement for manufacturers to submit a PMA application in support of the safety and effectiveness of those products. Additionally, manufacturers who already had PMDs on the market were given a 30 month time limit to supply supporting PMAs.⁸⁰

17.4. While these aspects are favourable, a study of the impact of the FDA's communication methods suggests there is some room for improvement. The study used data from the MAUDE reporting system to assess the impact of safety announcements. It compared the difference in the frequency of reports following the 2008 and 2011 safety announcements and the later Ethicon product recall. The study found that it was the recall announcement that resulted in the only significant impact to the number of Medical Device Reports.⁸¹ Although this may be indicative of a cumulative effect from the series of communications, it still raises the possibility that the public safety communications were relatively ineffective.

⁷⁹ "522 Postmarket Surveillance Studies" US Department of Health & Human Sciences <www.accessdata.fda.gov>.

⁸⁰ "FDA strengthens requirements for surgical mesh for the transvaginal repair of pelvic organ prolapse to address safety risks" (4 January 2016) U.S. Food & Drug Administration <www.fda.gov>.

⁸¹ Valerie Leiter "Adverse Event Reports Associated with Vaginal Mesh: An Interrupted Time Series Analysis" (2017) 27(3) Women's Health Issues 279.

17.5. A further factor worth noting is that the 2008 communication was directed at healthcare providers, whereas the 2011 announcement was directed at both providers and patients. This resulted in only a minor increase to the number of reported incidents. So, while the model and intent behind issuing announcements is positive, it appears that the impact may be lacking. The same study looked into the potential for conduits, for instance media reports, to affect the incidence of adverse event reports. Again, it was the Ethicon recall that coincided with the increase in media attention. Ultimately it is difficult to identify whether the recall, or the response to recall alerted those suffering from complications to understand that the implanted PMD was the source of their pain. The lesson to be taken is that the channels of communication in issuing safety warnings need to be assessed for their accessibility to patients.

18. FDA: the introduction of Unique Device Identifiers

18.1. When assessing the regulation of medical devices, medicines are often looked to as a comparator. Medicines can be beneficial or toxic depending on the dosage, so trials are important. Given the variance in potential risk within medical devices as compared to medicines, implementing the same safeguards will not be always be logical. For example, registering expensive standalone medical devices like hip joints may seem more obvious, but registering sticking plasters or tongue depressors, which are also categorised as medical devices, will not. Registration and tracking of PMDs is a new proposal.

18.2. Even though the assessment and tracking requirements of devices are not equivalent to those of medicines, serious harm in high risk devices has been experienced before, for example in silicone breast implants, synthetic joints and devices related to cardiac function. It is because of these past incidents that Unique Device Identifiers (UDIs) are now being applied to certain Class III devices in the US. The FDA's Sentinel Initiative is a long-term program for the design and build of a national electronic monitoring system. As well as the staged inclusion of medical devices and medicines, this system has benefits that may be contrasted with the EU's Eudamed to be discussed in the next section. Sentinel is a move away from a passive system that is largely reliant on reports from manufacturers, consumers and providers, to one in which the FDA itself can initiate safety evaluations.⁸² Such an

⁸² U.S. Department of Health and Human Services "The Sentinel Initiative" (July 2010).

option may be looked to for post-market surveillance in New Zealand. Currently the likely direction of the New Zealand system appears to be closer to the EU system described below.⁸³

19. Eudamed: false promises of a centralised system?

19.1. In the EU one of the means of improving patient safety has been through the recent development of a centralised reporting system called Eudamed. Should the ideals of this system be realised, it would be instrumental in disseminating information about PMDs across the EU, including safety warnings. As will be described, this scenario is yet to be realised.

19.2. Eudamed is the European Databank on Medical Devices that is used throughout the EU. It is a web-based portal for National Competent Authorities (NCAs) to exchange information, and its use has been mandatory since 2011. Its purpose is to enhance market surveillance and transparency around the use of medical devices, as required by the Medical Devices Directives. The Directives also require that adverse incidents are evaluated and an NCA report is generated when it is seen to be appropriate. This harmonisation still allows for individual nations to withdraw or introduce products, though ideally such decisions are based on a union-wide decision. The gap between ideal results and the reality of negotiating compliance within a system of independent member states is demonstrated in the regulation of PMDs.

19.3. When it comes to the system of notification and evaluation of adverse events the Medical Device Vigilance System is utilised. This system is intended to assist in a harmonised approach to corrective action across member states. It requires co-operation between manufacturers and Notified Bodies. For example, should there be an adverse event report about a PMD in Scotland, this would be available for review and consideration in Poland. The devices that are monitored include those with the CE Mark.⁸⁴ Despite the intent to provide protective measures through harmonisation, there is evidence of a separation between the positions of states in the EU. By way of example, the Scottish and the European Commissions gave very different reports on concerns around PMD harm. The European Commission's (EC's) final report of the

⁸³ above n 29 at [29].

⁸⁴ Ibim Tariah and Rebecca Pine "Effective post-market surveillance" The British Standards Institution (White paper, 2014).

safety of surgical meshes used in urogynecological surgery from 2015 was largely concerned with aspects of risk. Rather than questioning the appropriateness of mesh being available on the market, the recommendations focused on the factors affecting risk such as surgical procedure and patient counselling.⁸⁵ This risk-based approach could be seen as further evidence of a pro-industry position. In the EC's analysis the question is not whether to exclude PMDs but how best to include them given the risks they present. In this report the window for receiving submissions was approximately 1 month.⁸⁶ By contrast, an independent Scottish enquiry provided the publication of an interim report 2 months before that of the European Commission, which was later followed by a final report in 2017. In the 2015 report the focus was centred on the experiences of patients - the report was consumer-centric rather than product focused. Interim findings included the identification of gaps in governance and limits in data provided in support of the use of mesh.⁸⁷ A patient-centred approach was solidified in the 2017 final report with conclusions 1 and 8 that:

“Fundamental to the treatment of patients with SUI and POP is patient-centred care which should include patient choice and shared decision making supported by robust clinical governance... the Scottish Government should consider the alternative methods for the capture of adverse events set out in chapter 8 to determine the most effective way to ensure complete notification.”

and

“In the surgical treatment of POP, current evidence does not indicate any additional benefit from the use of transvaginal implants (polypropylene mesh or biological graft) over native tissue repair. Transvaginal mesh procedures must not be offered routinely. The Expert Group must develop appropriate pathways to meet clinical needs and also for the management of those suffering complications.”

19.4. These excerpts demonstrate a divergence from a purely pro-industry approach. It is not simply a case of gathering quality information, but establishing appropriate terms of reference for assessors. While it is important to support the development of beneficial products, a regulator needs to have the ability to admit an error in

⁸⁵ Scientific Committee on Emerging and Newly Identified Health Risks *The safety of surgical meshes used in urogynecological surgery* (3 December 2015).

⁸⁶ “Final Opinion on Surgical Meshes” European Commission <ec.europa.eu>.

⁸⁷ above, n 63.

introduction and, if necessary, suspend or control the use of a product that is evidently dangerous.

19.5. In New Zealand, for post market regulation the proposal letters indicate that both the regulator and approval holders will have obligations in respect of on-going monitoring.⁸⁸ If the approval holder is relied upon to monitor device issues, depending on their level of vigilance,⁸⁹ this could involve a gap in the safety net. Other than to protect a brand's reputation, an approval holder has little incentive to do more than the bare minimum in relation to device monitoring.

19.6. In general, the proposed New Zealand legislation appears to attempt to lift the standards in respect of medical devices to meet with similar international levels, but will be susceptible to their flaws. The interest in light-handed legislation, and the potential reliance on third parties and self-reporting of adverse events by approval holders, may mean that the new system suffers from the same inadequacies as the EU and US models.

Complaints and compensation processes: minimising trauma in remediation

20. The available procedures and compensation for those who have been harmed by PMDs are problematic. New Zealand is unique in having the ACC scheme under which those who have suffered harm can claim without engaging in litigation. This may not be appropriate with harm from PMDs. Collected stories from those who have suffered from PMD complications describe difficult relationships with the agencies meant to protect healthcare consumers.

20.1. While certain claimants in PMD cases in the US have received multi-million dollar awards, New Zealanders must work through the ACC system and accept rather more modest sums as compensation for potentially life-long complications. Irrespective of the sums awarded, when considering the kinds of harm suffered by many claimants, involvement in long-term litigation as a solution is far from ideal. Better protection is needed at the legislative level.

20.2. Ideally the respective agencies already in place in New Zealand: Medsafe, ACC and Health and Disability Commission (HDC) would operate together and

⁸⁸ above, n 27, at [18].

⁸⁹ The approval holder is the legal person who brings a device into New Zealand and is responsible for aspects of its registration and monitoring under the Medicines Act 1981.

provide channels for claimants to report their experiences, receive financial support and relay complaints respectively. Unfortunately this is not reflected in the experiences of many of those harmed. The following excerpt provides an illustration:

“None of us sick ladies ever consented to this cruel, unjust, rotten product in us. NZ Government Agency HDC fend of my letters saying write to ACC, and ACC write to me and say write to HDC.

I have hundreds of questions I need to ask. Who can help? I think HDC and ACC and Medsafe are a joke. Even the NZ Medical council stated in writing to me that ‘we are fobbed off’... Why is it that all countries except NZ have a tort based malpractice system to provide compensation for medical injuries and to hold doctors accountable? (All suing is barred by the no fault ACC scheme and so it lets doctors and government agencies off the hook). Yet I am left disabled with no recourse.”⁹⁰

20.3. The story above reflects the frustration of others attempting to complain via the HDC process. Operating at its best, the HDC process can be a vehicle to collate complaints information and contribute to quality improvement in healthcare.⁹¹ One avenue that can be taken up when systemic issues are revealed is an own initiative enquiry. In 2011 the Auckland Women’s Health Council made a request that the HDC investigate the issue of unsafe PMD approval in New Zealand. Unfortunately, the request was declined.⁹² Despite articles and submissions indicating mesh-related complaints to the HDC, a website search of HDC decisions concerned with problems from the use of mesh yielded only 3 results, and all of these were in relation to hernia repair.⁹³ The decision that most closely resembles the issue with PMDs concerned the actions of the surgeon Mr Ian Breeze. The patient in that case was “left in the dark” by not being informed of the potential side effects experienced by 6 – 10% of patients of permanent pain following hernia repair with mesh. The pain and

⁹⁰ Carmel Berry and Charlotte Korte “The Book of Personal Stories as told by Mesh Injured New Zealanders” (1 July 2014) at 47.

⁹¹ Ron Paterson “The Patients’ Complaints System in New Zealand” (2002) 21(3) Health Aff 70 at 75.

⁹² “Surgical Mesh Petition” (June 2014) Auckland Women’s Health Council <www.womenshealthcouncil.org.nz>.

⁹³ “Management of postoperative pain following inguinal hernia repair” Case 03HDC18813 (30 November 2004); “Repair of incisional hernia performed as a day procedure” Case 07HDC00329 (20 November 2007); “Management of laparoscopic hernia repair” Case 13HDC00478. (1 May 2015).

despondency experienced by the patient was linked to the lack of information regarding the possible source of the pain.⁹⁴

20.4. The patient under Mr Breeze' care was found to have been failed in terms of his rights to be given sufficient information about his treatment. Considering that hundreds of women have laid claims with ACC for harm from PMDs, and anecdotal evidence pointing to attempts to complain to the HDC, it is surprising how little can be found within HDC investigations.

21. Discussion

22. Amplifying public voices

22.1. The case study of PMD harm has demonstrated the importance of communication between the public and medical professionals and government bodies. Advocacy groups have brought media attention, prompted governmental action and contributed to inquiries after harm has occurred. Improved public participation at all stages of a device's introduction and use can similarly promote a reduction in harm through a customer-centric approach.

22.2. The Netherlands, the U.K., South Africa, Australia and New Zealand have all had patient advocates petitioning governments to ban PMDs.⁹⁵ This pressure has catalysed state-level inquiries and subsequent changes to regulation and procedures. In New Zealand the work of Mesh Down Under™ alongside government agencies provided an enhanced quality and quantity of information including submissions from those directly affected. The impact of these groups validates the importance of public participation to protect patients.

22.3. Further systems that enable and encourage communication of the views of health care consumer should be protected. One of the most significant events in alerting the public to the harm of PMDs occurred in 2011 following the FDA establishing an advisory panel to make recommendations. Similarly, in New Zealand a method of public inclusion that could be employed is the use of national ethics committees such as the Health and Disability Ethics Committees (HDECs) in decision-making around device approval. Fast and furious approval processes will

⁹⁴ Case 03HDC18813, above, n 93, at 24.

⁹⁵ Lana Keeton "Save the Date 1st International Mesh Patient Health Congress" Truth in Medicine <truthinmedicine.us.com>.

continue to be advanced by the medical device industry. Given sufficient government support, ethics committees with adequate consumer representation⁹⁶ can provide a consumer-centric approach to decisions around device introduction. In the case of HDECs, this would represent a reversal of changes that came into force in June 2012, which reduced consumer representation and instituted an orientation towards the timely approval of clinical trial research.⁹⁷

22.4. How government communicates with the public can also enable better public participation. As the study into the impacts of FDA safety announcements has revealed, the form of public communications can affect when information is received; a website safety warning can be ineffective in harm reduction if such a communication is unlikely to catch the attention of the most relevant people. In developing systems to protect consumers, a useful framework would enable effective communication channels to and from consumers as well as healthcare providers and industry.

23. *Addressing problems with harmonisation*

23.1. The message received from advocates, through inquiries, and via litigation is that the systems in place are flawed, and those flaws are shared in different jurisdictions. New medical device regulation in New Zealand will continue to make use of the benefits of international standards, in doing so the risks must also be acknowledged.

23.2. To take a more consumer-centric approach to regulation, overseas safety warnings should be given the same weight as overseas approvals. The gap of time between PMD approval overseas in the late 1990s and its use in New Zealand in the early 2000s was small. This can be contrasted with the ten years that passed between the early FDA safety warnings and the New Zealand government-issued requests for further information from PMD manufacturers. This kind of discrepancy is reflected in the legislated requirements for device introduction and removal in New Zealand. While substantial clinical trials were not needed as the basis for PMD introduction,

⁹⁶ “The right to say no to research trials - when did we lose it?” (August 2014) Auckland Women’s Health Council <www.womenshealthcouncil.org.nz>.

⁹⁷ “New ethics committees system start work” (July 2012) Auckland Women’s Health Council <www.womenshealthcouncil.org.nz>.

they were needed to prove the risk of harm before PMDs could be removed from the market.⁹⁸

23.3. Harmonisation should still allow the ability to communicate to consumers that assessment processes are not all created equal. A consumer should be able to know when the US 510(k) clearance process has been used to introduce a product to be used in their treatment. Similarly, when the CE mark is relied on, the relevant Notified Body and the state of origin of approval may be important information to provide to patients, in a similar way that “Made in China” has become relevant to consumers in making decisions. If entry into the ARTG is deemed good reason for use in New Zealand, it should be identified if that inclusion is largely based on a European standard. In these ways consumers can be provided with opportunities to make decisions based on better information.

24. Minimising conflicts of interest

24.1. The global medical device market was valued at €210 billion in 2015 and was estimated to grow to €403 billion by 2018. Around 25% of the market is accounted for by Western Europe, led by Germany, and followed by France, the UK and Italy.⁹⁹ This state of affairs creates a system in which power is centralised in Europe, which has already been identified as being susceptible to industry influence. The case of Johnson & Johnson Medical Pty Ltd and Ethicon has revealed how much power an entity can exert. Aggressive marketing campaigns to surgeons, sponsorship of device reports, and apparent knowledge of the real risks to patients before their particular brand of PMD was placed on the market all speak to the problems of dominance and coercion. Where reliance is placed on expert advice and opinion there risks a loss in the transparency of assessment processes. Unfortunately, the emphasis on efficient product introduction more often involves decentralised systems and outside experts¹⁰⁰ who risk being susceptible to industry influence.

24.2. As is indicated in the documents supporting the proposed Therapeutic Products regime in New Zealand, it is likely that intermediaries will play a part in assessing new medical devices. That need not mean the failure of transparency.

⁹⁸ “Medsafe, doctors and ACC have failed patients – gynaecologist” *Radio New Zealand* (online ed, New Zealand, 12 December 2012).

⁹⁹ above n 64, at 4.

¹⁰⁰ above, n 29, at [12.2].

When considering international examples, it is possible to distinguish between those assessors working under the regulator and those that are entirely external. Those in the former category might rely on resources of the regulator or, for instance, take the form of an appointed advisory committee. The latter may be seen as similar to independently operating Notified Bodies as in the European context.¹⁰¹ Where Notified Bodies are involved the conflict arises in the commercial and mutually dependent relationship between the sponsor and the Notified Body; the sponsor needs the certification, and the assessor needs to be paid.

24.3. Such determination around how much leeway to permit an assessment body might be informed by factors including the risk classification of the device, the likelihood of pressure from interests groups and, over time, the standing of the assessor itself.

25. *Constructing an assessment framework for diverse technology*

25.1. PMDs fit into the legal category of medical device; a product that could be as benign as a tongue depressor, or as complex as a pacemaker. Given this diversity classification must be taken seriously to guard against manipulation of systems to fast-track introduction. This is one of the reasons that it can be difficult to promote schemes of assessment and monitoring that are unnecessarily difficult to comply with. Then the question becomes: are industry players taking advantage of loopholes because they are there, or are such loopholes the only way to survive an otherwise impossible process? Medical devices are also dissimilar to medicines in the governmental guarantees that are provided following introduction. A well-tested medicine will be purchased differently to a medical device.

25.2. The PMDs that are the source of harm today were introduced on the basis of substantial equivalence to a range of products that did not make use of a polymer. The product that did was marked as unsuitable for long-term implantation. As technologies develop and become more complex it is important that the assessors are sufficiently trained in identifying what product changes indicate new risk and require testing.

¹⁰¹ Martino Maggetti, Christian Ewert and Philipp Trein “Not Quite the Same Regulatory Intermediaries in the Governance of Pharmaceuticals and Medical Devices” (2017) 670 (1) *Ann Am Acad Pol Soc Sci* 152

25.3. Pre-market and post-market evaluation regulation across the world is more stringent for drugs than for medical devices. As an example, health technology assessment reports for medical devices are far more likely to include methods such as observational and non-randomised controlled trial evidence based on smaller clinical studies.¹⁰² This presents a problem as medical devices can be more complex than drugs in several respects. These include that minor alteration to material can involve a major change to effectiveness, as can the skill and training of medical practitioners in making use of a device. This latter aspect in particular can mean that after being used on a patient, information regarding the safety and effectiveness of the device itself may be obscured by blame being laid at the skill of a surgeon. The Mesh Down Under™ survey revealed this issue in anecdotal evidence of dismissive or defensive responses by surgeons when complications were brought to their attention, for instance: “[complications] were often put down to the operation itself rather than to issues with the mesh. For example, one respondent stated that “They suggested that the problems would diminish over time”, while others stated “[The] implant surgeon didn't believe there was a problem. [They] seemed dismissive & defensive [and] said it was post-surgery pain or neuropathic pain.”¹⁰³

25.4. It may be considered that the categorisation of ‘medical device’ is rather arbitrary. If so, the class-based categorisation should be given greater attention. The current system enables manufacturers to suggest a class. In a situation like PMD introduction where the choice is between a rigorous, time-consuming and expensive process, as opposed to a fast-tracked option, it is not surprising that the path of least resistance is taken. The later re-categorisation by various governments appears not to be based on new information; rather the correct category was not used in the first instance.

26. Engaging manufacturers to promote safe practices

26.1. Both manufacturers and consumers will continue to exert pressure on regulators to make medical devices available. While loopholes persist these are being used, not simply because it is cost effective, but because certain processes can be

¹⁰² above n 64, at 4.

¹⁰³ “Full and Detailed Analysis of Surgical Mesh” (September 2016) Mesh Down Under™ <meshdownunder.co.nz>.

prohibitive. The non-standardisation around required testing has led manufacturers to pursue an expedited process in order to survive.

26.2. While the strict requirements imposed on medicines might seem an obvious model to extend to medical devices, there are industry differences that make this unworkable. Firstly, medicines have chemical properties that lend themselves to be tested and refined within a different set of variables to that of a medical device. Secondly, financial aspects are different. The approval of a medicine into New Zealand can mean certain financial guarantees as to contracts for supply at a national level. PHARMAC does not manage the purchase of medical devices, and such management is expected to be far into the future. In short, medical device suppliers can include much smaller players than those involved in medicines. This difference in financial backing can mean that it isn't economically viable for medical devices to undergo the stringent testing required of medicines.

26.3. Here it can be seen that manufacturers of medical devices will continue to have a reliance on low risk classifications of medical devices to access the market through an expedited process.¹⁰⁴ To avoid this tension a different approach might be taken. By way of example, in Canada and the US governments incentivise manufacturers working on critical devices, by subsidising and assisting them through the approval processes.¹⁰⁵ This is one way of checking for compliance with the correct procedures and reducing the motivation of manufacturers to pursue an inappropriate form of approval.

27. Recommendations

28. The following is a summary of the recommendations for the regulation of medical devices under Therapeutic Products Bill

- The level of assessment by the New Zealand-based regulator should not be solely determined by the manufacturer's classification.
- When relying on international standards, particular care should be taken with devices that enter through expedited process for Class II or medium risk devices.
- Additional product disclosure requirements may be considered, for instance indicating the location and method of original approval if original assessment

¹⁰⁴ The Regulatory impact statement provided that with only 10% of devices being Class III or high risk costs are expected to be moderate.

¹⁰⁵ above, n 64.

occurred outside of New Zealand. In the EU context, this may include identifying the Notified Body providing approval.

- Inclusion on the ARTG should not be presented as an independent and original form of approval in instances that inclusion is largely based on another international approval scheme.
- IFUs should be required, and the level of detail in risks should be specified to include the likelihood of harm.
- In anticipating technology involved in medical devices will become more complicated and difficult to understand (and potentially consent to) a proactive approach to educating providers and consumers should be taken.
- To satisfy existing requirements to inform patients, it should be made clear to providers that a lack of testing (or other information) is in itself important information to pass on to a consumer.
- The importance of providing a consumer with their full treatment options should be emphasised.
- There should be consideration given to enhancing HDEC powers to sanction non-compliant providers who breach consumer rights.
- Investment in and communication around reporting and tracking mechanisms is needed in post-market regulation
- Adverse event reporting should be mandatory and obligations should be placed on providers and the manufacturer.
- Device registration should be mandatory, and the onus should be on providers to carry out such registration.
- Device registration and reporting channels, and data collection requirements should be specified to avoid the confusion around agency responsibility.
- Consideration needs to be given of alternative compensation to ACC in events where harm suffered involves chronic pain.

29. Conclusion

29.1. In the 1960s the harm caused by thalidomide led to better testing and drug approval procedures. In the 1980s the Cartwright enquiry into cervical screening led to reforms in a more patient-centred healthcare system. In the 2010s the use of PMDs has revealed a return of some of these fundamental problems in healthcare: patients can still be treated like guinea pigs and providers can still fail in their duties around

informed consent. Women in particular continue to be harmed in situations where they should expect protection. As long-time women's health activist Lynda Williams said "Sometimes we have to fight for the same things again and again and again."¹⁰⁶

29.2. The introduction and use of PMDs as a case study has also revealed novel issues for medical devices. As globalisation influences international trade and regulation, harmonisation requirements create new risks and benefits. New Zealand relies on international regimes in assessment of medical devices, and such reliance is likely to continue under the new legislation. While the law is under development, we can consider learning from issues that present from pre-market assessment through to complaints handling and options for remediation.

29.3. There are certain international fast-tracked processes that can enable the introduction of medical devices that have been found to be neither safe nor efficacious. There are problems of transparency and the potential for conflicts of interest to arise when manufacturers have the ability to shop around for private assessors. The design of a new framework should not obscure the power relations and influences operating behind the assessment process. Given that international approvals will in all likelihood be utilised it is suggested that the New Zealand-based assessor should look behind the stamp of approval. When a device enters New Zealand the nature of the process by which it was determined to be safe and effective should be understood. Patients should also be able to find out if a provider is proposing to use a medium to high risk device in their treatment, and whether it has passed through a fast-tracked assessment

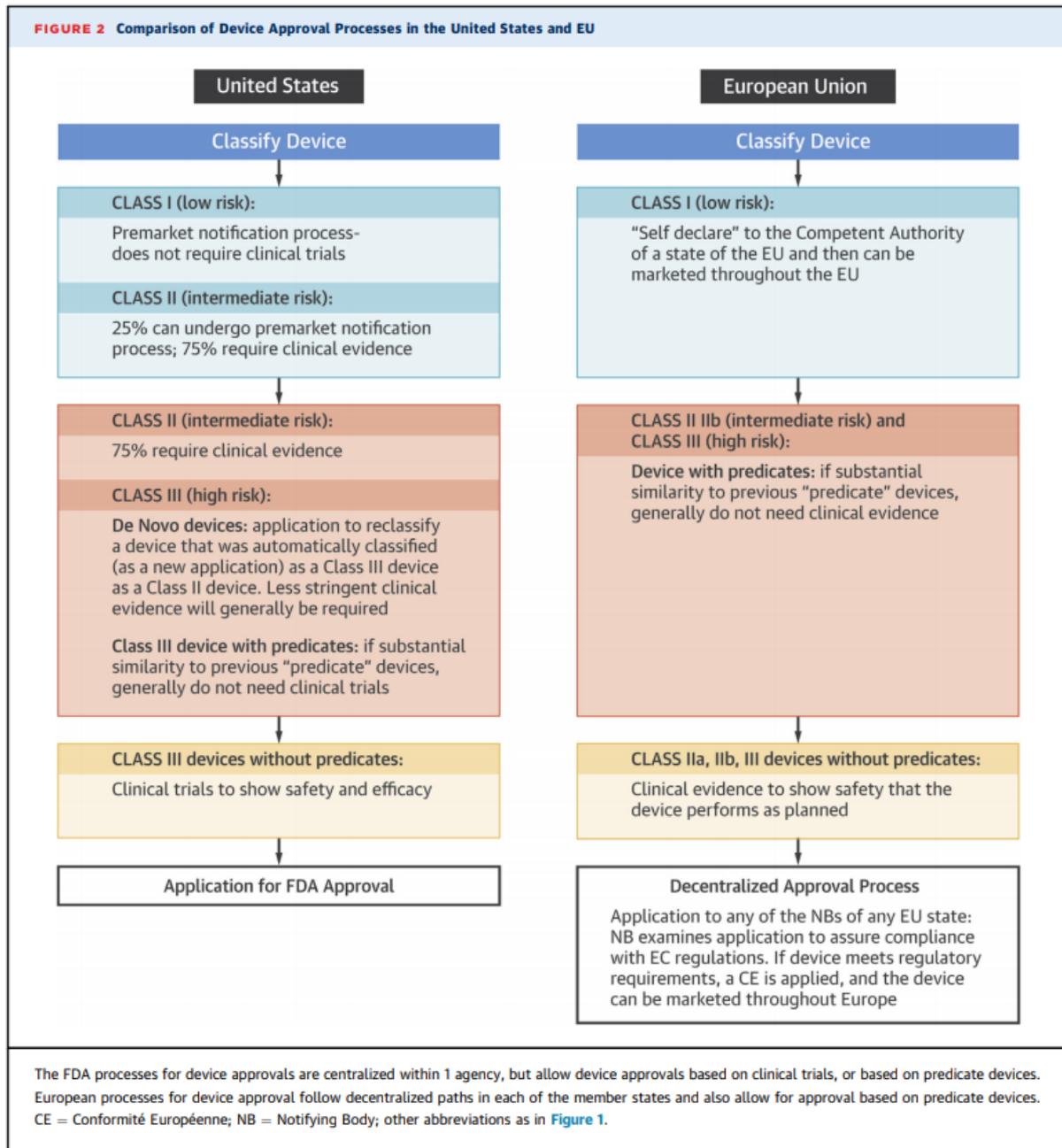
29.4. It is also important to address the deficiencies in existing New Zealand regulation. There is already a code of consumer rights that includes informed consent requirements. This was of little effect in the case of PMDs where patients were not adequately informed of the potential risks, or alternative treatment options, or of the absence of robust trials of the device about to be permanently implanted in them. Difficulties in dealing with ACC Medsafe and the HDC also highlight the need for better organisation for monitoring and complaints handling processes. Leaving patients to pursue remedies in private litigation is insufficient, costly, and of little help in the New Zealand context. Specific attention should be given to the limitations

¹⁰⁶ "History forgotten will be repeated" *Metro Magazine* (online ed, Auckland, March 2017).

of ACC cover for someone who is not only unable to access the financial benefits of a working life, but who may have lost access to many forms of joy in everyday life.

29.5. While seeking to improve access to innovative technology we must be ever mindful of the risk posed by industry influence. As the law in New Zealand is likely to follow the EU example of decentralised decision-making and greater reliance on technology experts, better inclusion, information-sharing and involvement of the public is crucial. However evolved and complex new health treatments may become, the ethical considerations provided by and for ordinary people must remain at the heart of decision-making.

Appendix 1



Sourced from: Gail A. Van Norman "Drugs and Devices Comparison of European and U.S. Approval Processes" *JACC: Basic to Translational Science*. 5, (August 2016) at 401.

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