Auckland Women's Health Council

Submission of the Auckland Women's Health Council on the Therapeutic Products Bill

Executive Summary

1. **General support for the Therapeutic Products Bill:** The Auckland Women's Health Council (AWHC) is generally in support of the Therapeutic Products Bill, as the existing Medicines Act 1981 is well past its 'use-by-date'. We strongly support the purpose of the TPB, to protect, promote, and improve the health of all New Zealanders; the health, well-being and safety of New Zealanders is of paramount importance.

   We also strongly support the Bill's purpose to ensure acceptable safety, quality, and efficacy or performance of therapeutic products, and that therapeutic products must be regulated across their lifecycle. We agree that regulation should support choice of, and equity of access to, therapeutic products.

   We support the establishment of a new independent regulatory body that will authorise therapeutic products and have compliance and enforcement powers. However, we harbour significant concerns about whether or not this new Regulator will fulfil the promises made in the TPB, and are concerned that there are shortcomings in the legislation.

2. **Te Tiriti o Waitangi:** we are disappointed that the proposed legislation does not acknowledge te ao Māori and te Tiriti. While the AWHC is not a tangata whenua organisation, and we do not speak for or on behalf of Māori, we believe that Māori should be consulted on how best to honour and empower Te Tiriti o Waitangi and the articles of Te Tiriti in this Bill. We believe that our collective national obligations to Te Tiriti o Waitangi should be embedded in all modern legislation.

3. **A health system for the people: consumer rights and consumer representation:** There are significant indications that, despite the stated purpose of the Act being to "to protect, promote, and improve the health of all New Zealanders", this Bill is focussed on giving pharmaceutical companies, manufacturers and suppliers, and any other profit driven entity, access to consumers. It is clear that the Bill is market-focussed, favouring corporates within the medico-pharmaceutical industrial complex, rather than being truly focussed on benefit to the health consumer.

   We strongly believe that ALL consumers have an inalienable right to be involved at ALL levels of the health system, in line with the Pae Ora (Healthy Futures) Act 2022. Promises made by the New Zealand Government that the "new" health system would be a people-centred one must to be upheld, and independently monitored to ensure it is. We expect that the Therapeutic Products Regulator will, like other health entities under the Pae Ora (Healthy Futures) Act 2022, "act in accordance with the code approved under section 59 when engaging with consumers and whānau" and "report annually on how it has given effect to the code". We are disappointed that this is not explicitly set out in the TPB and expect that the proposed legislation will be amended to ensure that the Therapeutic Products Regulator complies with both the letter and spirit of the Pae Ora (Healthy Futures) Act 2022.

4. **The new Therapeutic Products Regulator:** The AWHC welcomes a new Therapeutic Products Regulator; along with the new regulatory regime, a new Regulator is very much needed. However, we don't want Medsafe with a new name. The independence of the Regulator from the MoH and DGoH is vital; the Regulator must have "teeth" and must have the appropriate legislative power and resourcing to act on cases of patient harm.

   We believe that the Therapeutic Products Regulator must be accountable to Parliament but also to consumers. Consumers must have an engagement and consultation role in a variety of the Regulators functions, including the three yearly reviews of strategy and cost recovery and in reviews on decisions. Consumers with relevant lived experience must be appointed to advisory committees.

   The Regulator must take care regarding reliance on overseas regulators in making decisions on product authorisations, particularly regarding implantable medical devices that are grossly under-regulated globally. The Regulator must also share information with other health entities in New Zealand, such as ACC, HQSC and the HDC, regarding harm from therapeutic products and treatment injury, so there is a comprehensive understanding of the level patient harm that occurs.

5. **Patient/consumer safety:** patient/consumer safety is of paramount importance in any legislation or regulatory regime that controls therapeutic products. The stated purpose of the Act is to protect, promote and improve the health of all New Zealanders. Whatever means the legislation sets out for achieving that purpose, consumer/patient safety must be paramount; all other considerations are secondary. No New Zealander should be worse off for the use of a therapeutic product. The needs and interests of health practitioners, sponsors, suppliers, the pharmaceutical industry and manufacturers must all be secondary to the health and well-being, and safety of health consumers.

   We have significant concerns about reliance on the concept that “likely benefits should outweigh the likely risks”. How benefit and risk is balanced is crucial to whether or not the Bill protects consumers. A simple calculation of “benefits outweigh risks” is a low threshold, and risks permitting products that are deemed to be not harmful just 51% of the time. Using such an inadequate measure, results in situations like the surgical mesh issue, where a therapeutic product could cause catastrophic harm for thousands of people, yet still be evaluated as having benefits, even with a lack of data or evidence of this.

   We want to see extremely robust regulations and enforcement around surveillance and monitoring, with an emphasis on the Regulator’s ability to respond swiftly and decisively on reports of harm, and a focus on taking a precautionary approach to ensure the safety of consumers.

   We also are concerned about the Regulator’s possible reliance on decisions made about products by regulators in other jurisdictions, in particular with regard to market authorisations for implantable medical devices.

6. **Regulation of implantable medical devices:** this Bill represents not only the means by which our lawmakers can ensure that we have a regulatory regime that protects our citizens from dangerous implantable medical devices, but might place New Zealand in a position to lead the rest of the world to a better future for everyone who is recommended an implantable device by their health practitioner.

   We have commented throughout this submission on the need for stringent regulations that ensure the safety of consumers particularly related to implantable medical devices. We have also commented throughout on the critical need for robust surveillance and monitoring, collecting and collating notifications of harm and PROMs, and the critical need for the Regulator to respond swiftly and err on the side of caution when it comes to protecting consumers from harm. Nowhere else is this more important than in the regulations for implantable medical devices.

However, we are extremely disappointed in the transitional provisions in this Bill that will ensure that we have another six and a half years to wait before sponsors of implantable medical devices are held accountable for the lack of safety of their products. We submit in the strongest possible terms that this provision must be amended! There must be the enactment of stopgap or temporary legislation or regulation that covers those medical devices already identified as causing harm, and provide for an immediate reassessment of their safety, quality and performance, or force them to be withdrawn until such time as they can undergo a full market authorisation under the new Act.

7. **Regulation of natural health products:** While we believe that natural health products (NHPs) should be regulated, we don't believe this Bill is the appropriate place to do it. NHPs are an entirely different class of therapeutic product; the regulations for NHPs in this Bill are far too heavy-handed and in places written in such a way that the Bill could have unintended consequences for consumers.

   If NHPs are to remain in the Therapeutic Products Bill, there needs to be some considerable alterations to the wording of the Bill to ensure that New Zealanders can continue to maintain their own health and well-being through foods and plants that also have therapeutic value, in the way in which such activities have been undertaken for thousands of years.

   There is nothing that says a consumer 'manufacturing' their own therapeutic 'product' from plants that they grow is exempt from the controlled activities regulations, so that must mean that the Regulator could make rules to prohibit such activities. In theory, even a consumer making a lemon and honey drink for therapeutic purposes could be prohibited from doing so as it could be seen as a controlled activity. We have additional concerns about the regulations about health benefit claims given that NHPs often cannot be assessed by the normal clinical standards used for pharmaceuticals. Additionally, 'natural health practitioner' is not properly defined, nor are registered naturopaths, medical herbalists and homoeopaths recognised as experts in natural health products in this Bill.

8. **Direct to consumer advertising:** we are extremely disappointed that direct to consumer advertising (DTCA) has been retained. We remain strongly opposed to DTCA and this new legislation is the ideal opportunity for the Government to take note of the widespread opposition to DTCA and ban this practice. It is clear that research demonstrating harm from DTCA, and opposition from much of the medical fraternity and the majority of New Zealanders, has failed to counter what can only be the lobbying of those with a vested financial interest in seeing the continuation of DTCA, most notably the pharmaceutical industry. It is alarming that policy makers, advisors and/or those writing the Therapeutic Products Bill seem to have been unduly influenced by those vested interests.

9. **Contradictory regulations and regulations that are vague and poorly worded:** the proposed legislation is, in part, unnecessarily vague, in places contradictory, and in many cases untenably permissible enabling the Regulator to make rules on an *ad hoc* basis and as it pleases often to the detriment of consumers. The legislation is riddled with highly subjective language and with wording that will ultimately lead to unwelcome regulatory creep: a process by which regulation is developed or enforced in a less than transparent way, and leads to rules and regulation that give rise to unintended consequences.

   It is concerning that there are many clauses that state that something is a specific thing until the rules says it is not, that it is something else altogether. In places, there are sections that say something has a meaning set out under another section, but that other section simply says something is a thing if the rules say it is, while in other sections there are instances of what can only be described colloquially as a "get out of jail free card".

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Background to the Auckland Women's Health Council

The Auckland Women's Health Council was founded almost 35 years ago (July 1988) just after the Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital (the Cartwright Inquiry), which had a significant influence on the establishment of the AWHC. We have a special interest in patient rights, informed consent and decision-making in health care, health consumer advocacy, the Code of Health and Disability Services Consumers' Rights ('Code of Rights'), consumer voice and representation, and medical ethics.

Subsequent to the Cartwright Inquiry, the AWHC played a significant role in assisting with the establishment of the National Cervical Screening Programme and in monitoring the implementation of many of the other recommendations contained in the Cartwright Report. Several of our members were involved in a variety of the working groups set up following the release of the Cartwright Report and one was appointed as the first patient advocate at National Women's Hospital, fulfilling one of the key recommendations from the inquiry. Subsequently, AWHC made submissions on the Health and Disability Commissioner Act 1994 and during the development of the 'Code of Rights'.

The AWHC has had a long and sustained interest in patient rights, advocacy and consumer representation; and patient safety. Our goal is to provide an independent feminist voice focused on women's and family/whānau health and health services. Over the last three decades we have been active in advocating for patient/consumer rights, including making formal submissions on a wide range of health topics, such as the legislation and regulations governing various health and disability services, and in consumer representation roles relating to health and disability services. Of particular relevance to this submission, are the submissions we made on the *Therapeutics Regulatory Scheme* consultation document 2018, the Medicines Amendment Bill 2012, and the Ministry of Health's 2006 consultation document *Towards a New Zealand Medicines Strategy.*

Structure of Our Submission

Our submission will start with detailed sections on the issues of greatest concern to us (Key Considerations in the Therapeutic Products Bill). These sections are those that set out the issues of highest priority for us and the reasons for our views.

This will be followed by a section in which we make brief comment, in order, part by part and section by section as the Bill is laid out (Specific Comments on the Therapeutic Products Bill). In many cases we will refer back to our more detailed comments in the Key Considerations section.

Finally, we present our Conclusions and Recommendations for changes to the Bill.

Key Considerations in the Therapeutic Products Bill

General Support for the Therapeutic Products Bill

The Auckland Women's Health Council (AWHC) is generally in support of the Therapeutic Products Bill (TPB). The existing Medicines Act 1981 is well past its 'use-by-date' and it was enacted before many critical developments in medical practice and therapeutic products. It significantly predates many technological developments outside medicine (such as the internet), that have had a significant impact on the way in consumers and health services providers interact and practice, and how information is disseminated.

We strongly support the purpose of the TPB, to protect, promote, and improve the health of all New Zealanders. The health, well-being and safety of New Zealanders is of paramount importance and should be foremost in any considerations and deliberations leading to the final legislation.

Similarly, we strongly support the TPB's purpose to ensure acceptable safety, quality, and efficacy or performance of therapeutic products, but submit that the paramount consideration is safety.

We agree that therapeutic products must be regulated across their lifecycle, and believe that this is particularly important for implantable medical devices and medicines that, despite short term safety studies and follow-up, may cause harm many years after implantation or prescribing (e.g. devices such as breast implants and surgical mesh; and drugs such as Cox 2 inhibitors, Primados and Diethylstilbestrol (DES), among many others).

We agree that regulation should support choice of, and equity of access to, therapeutic products. This principle is not only important in addressing existing inequities and disparities in healthcare and health outcomes in New Zealand, but because there is no such thing as "one size fits all". There are many medicines that are effective or safe for a limited number of people and alternatives must be available. No therapeutic product works all the time for all people, and choice, and informed decision making about therapeutic products is a critical principle that must be applied.

We support the establishment of a new independent regulatory body that will authorise therapeutic products and have compliance and enforcement powers. Stringent regulation of implantable medical devices has been catastrophically lacking in our longstanding regulatory regime and it is vital that this is corrected. We have high hopes for the Therapeutic Products Regulator but also harbour significant concerns about whether or not this new Regulator will fulfil the promises made in the TPB; we are concerned that there are shortcomings in the legislation, which are discussed in the remainder of our submission.

There are two issues related to other legislation that we find to be grossly inconsistent with the purpose of the TBP, and what is effectively an overhaul of our medicines regulatory regime and legislative tools.

First, the TPB "does not disturb current regulatory arrangements relating to medicinal cannabis or drugs controlled under the Misuse of Drugs Act 1975, or psychoactive substances controlled under the Psychoactive Substances Act 2013."

Given the now widespread recognition of the medicinal benefits of cannabis, recent improvement in regulation of medicinal cannabis, making it less expensive and more accessible (albeit still very expensive and out of reach of very many people who could benefit), the increased therapeutic use of it, and increased legal availability, it seems ridiculous that it is not included in this Bill and regulated in the same manner as all other medicines.

The fact that it is controlled under the Misuse of Drugs Act perpetuates the idea that cannabis is more dangerous than legal drugs (e.g. alcohol and tobacco) and medicinal/pharmaceutical drugs (despite the fact that some OTC drugs, such as paracetamol, are incredibly dangerous with a very fine line between a therapeutic and toxic dose). It also perpetuates the idea that medicinal cannabis users are still criminals but have been given a "pass" to use cannabis medicinally without fear of criminal consequences. It is very much analogous to abortion being within the Crimes Act 1961 until the enacting of the Abortion Legislation Act in 2020.

Associate Professor in Criminology at Victoria University, Fiona Hutton, advocates that some therapeutic cannabis products be "reclassified as natural health products, allowing them to be purchased over the counter as has happened in the United States and Europe."[1]

"This approach could bring relief to thousands and give legitimacy to patients, growers and producers seeking to alleviate pain and suffering."

Not including medicinal cannabis in the TPB is inconsistent with changes in cannabis laws in New Zealand and the other countries that we regularly compare ourselves with, and we submit that medicinal cannabis must be covered by the TPB along with all other therapeutic products.

Second is the issue of pharmacy ownership. Regarding **Section 10 Controlled activities, subsection 2, clause g**, it is entirely bizarre to have carrying on a pharmacy business as a controlled activity in the TPB, for the TPB to regulate all pharmacy and prescription medicines and pharmacy activity and business (including sections 50-52, and 76-81), for the TPB to replace the Medicines Act 1981, and yet not transfer the entire legislation regarding pharmacy ownership and operation to the TPB. It seems unnecessarily complicated – ludicrous, in fact – to retain a 42-year-old piece of legislation – that will be renamed just for one issue, pharmacy ownership. Surely there is a mechanism by which that entire piece of legislation can be written into the new Therapeutic Products Act, as many other issues relating to pharmacy and supply of medicines are held in this new Act, rather than spend time amending and renaming a completely outdated piece of legislation to regulate a single issue.

Te Tiriti o Waitangi and Te Ao Māori

We are disappointed that the proposed legislation does not acknowledge te ao Māori and te Tiriti.

While the Auckland Women's Health Council is not a tangata whenua organisation, and does not speak for or on behalf of Māori, we believe that Māori should be consulted on how best to honour and empower Te Tiriti o Waitangi and the articles of Te Tiriti in this Bill. We believe that our collective national obligations to Te Tiriti o Waitangi should be embedded in all modern legislation.

The first mention of Māori engagement in the legislation is in **Section 332, subsection (1) (l).** The proposed legislation needs to be amended to reflect a greater acknowledgement of te ao Māori and te Tiriti, as is the case in much recent legislation and health agency and Government documents. This should occur with the addition of a new section in **Part 1 Preliminary Provisions** where the guiding principles are included.

A Health System for the People, Consumer Rights and Consumer Representation

There are significant indications that despite the stated purpose of the Act being to "to protect, promote, and improve the health of all New Zealanders" this Bill is focussed on giving pharmaceutical companies, manufacturers and suppliers, and any other profit driven entity access to consumers. It is clear that the Bill is market-focussed, favouring corporates within the medico-pharmaceutical industrial complex, rather than being truly focussed on benefit to the health consumer.

The AWHC has a role in consumer advocacy, and advocates for and participates in consumer engagement in health entities. We are members of the Health Forum Aotearoa and support the Code of Expectations for

[1] Hutton F, 2022: Cannabis for therapeutic use is still out of reach for many sick New Zealanders, despite changes in the law, *New Zealand Doctor*, 8 June 2022.

health entities' engagement with consumers and whānau.[2] The Code of Expectations was required under the Pae Ora (Healthy Futures) Act 2022 (Section 59 and Section 60). We strongly believe that ALL consumers have an inalienable right to be involved at ALL levels of the health system, in line with the Pae Ora (Healthy Futures) Act 2022, and promises made by the New Zealand Government that the "new" health system would be a people-centred one.

We advocate that approach in the Therapeutic Products legislation as it will affect every New Zealander over the course of their lives.

We expect that the Therapeutic Products Regulator will, like other health entities, "act in accordance with the code approved under section 59 when engaging with consumers and whānau" and "report annually on how it has given effect to the code".[3]

We are disappointed that this is not explicitly set out in the TPB and submit that the proposed legislation must be amended to ensure that the Therapeutic Products Regulator complies with both the letter and spirit of the Pae Ora (Healthy Futures) Act 2022.

Similarly, there is no reference to the Code of Health and Disability Services Consumers' Rights with regard to the rights of consumers. We fail to see how there can be legislation that regulates the provision of therapeutic products to consumers without acknowledging the Code of Health and Disability Services Consumers' Rights, particularly when it comes to issues such as the provision of information about therapeutic products to enable consumers to make informed decisions, and participation in clinical trials (see page 9).

We expect these omissions to be rectified and consumer rights properly acknowledged and upheld.

The wording of **Section 380 Consultation** is concerning because it relies on the Regulator determining who will be affected by any regulations rather than taking the standpoint that ALL New Zealanders may be affected and are entitled to be consulted. Limiting consultation is contradictory to the intent of the Pae Ora (Healthy Futures) Act 2022. It is not consumer-centred to have any Government agency or health entity, including the new Regulator, decide who should or should not be consulted. Ideally consumers should have a "seat at the table" throughout, to be involved in developing the rules and regulations to ensure that consumer safety is paramount.

Subpart 4—Review of Act
382 Minister must review Act

We strongly agree with a regular review of the Act and believe that consumer engagement is vital in these reviews. Consumer groups/key consumer stakeholders should be invited to participate in the review and to provide feedback.

The Explanatory note in the Bill states that "A very large amount of secondary legislation will need to be made before the Bill comes into force." At the very least, in the same manner this proposed legislation is currently open to public consultation and feedback, it is vital that the secondary legislation and regulations and rules are too.

2 https://www.hqsc.govt.nz/resources/resource-library/code-of-expectations-for-health-entities-engagement-with-consumers-and-whanau/

3 As per Section 60 in the Pae Ora (Healthy Futures) Act 2022.

With regard to **Section 36 Clinical trial**, it is of concern that there is no reference here to informed consent or protection of consumers' rights or safety. While there may be no legislative requirement to address these issues in this Bill there is a moral obligation at all times to uphold and protect the rights and safety of consumers.

36 Clinical trial

(1) A clinical trial of a medicine or medical device, means an investigation—

(c) to which any of the following apply:

(i) the assignment of each participant to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice:

(ii) the decision to administer or use the product is taken together with the decision to include the participant in the trial:

(iii) diagnostic or monitoring procedures additional to those used in normal clinical practice are applied to the participant.

The wording of these clauses is problematic and ignores any practice of informed consent. The legislation should acknowledge and be consistent with the Health and Disability Commissioner Act 1994 and the Code of Health and Disability Services Consumers' Rights. **Clause (c), sub-clause (ii)** should read "the decision to administer or use the product is taken subsequent to obtaining informed consent from the consumer or patient to participate in the trial". The decision regarding the participation of a consumer or patient is one made by the consumer or patient, not the principal investigator or person with the authorisation to run a clinical trial. The principal investigator or person with the authorisation to run a clinical trial can only invite a consumer or patient to participate in a trial.

There is a moral obligation to reinforce the rights and safety of consumers/patients within this legislation. It is entirely inconsistent to say that recruiting participants is not part of a clinical trials for the purposes of the Act (see **Subsection (2)** below). Participants will be administered medicines or have devices implanted, and if the Act or Regulator has any authority or power to enact regulations regarding clinical trials it should also have authority or power to enact regulations regarding the safety and rights of participants in those trials, or powers of enforcement and penalty if the investigators breach those rights.

(2) However, the following activities are not part of a clinical trial (for the purposes of this Act):

(a) preparatory activities carried out before activities intended to obtain the information referred to in subsection (1)(b) begin (such as recruiting participants):

The New Therapeutic Products Regulator

The AWHC welcomes a new Therapeutic Products Regulator; along with the new regulatory regime, a new Regulator is very much needed. However, we don't want Medsafe with a new name. The independence of the Regulator from the MoH and DGoH is vital; the Regulator must have "teeth" and the power and resourcing to act on cases of patient harm. Regulation of implantable medical devices and certain procedures (e.g. surgical mesh, endometrial ablation) has been consistently woeful and inept, leading to significantly greater harm caused to consumers over many years, than would have been the case if medical devices had been properly regulated.

The Regulator must have the power, ability and legal requirement to respond to notifications of patient harm, and to suspend or ban the use of harmful products. Any product causing harm below a threshold for suspension or banning, must attract a "black box" warning that the Regulator must have the power to enforce.

Comment on Specific Sections with Regard to the Regulator

In terms of proposed legislation regarding the Therapeutic Products Regulator, we submit the following comments:

332 Functions of Regulator: as an independent health entity, the Regulator should be required to present an annual report to Parliament and to the New Zealand public/consumers, as is the case with other such agencies, such as the Health and Disability Commissioner.

The Regulator must also be required to comply with the Code of Expectations for engagement with consumers. As the Regulator will be established subsequent to the Pae Ora (Healthy Futures) Act 2022, and as an independent health entity, it must be required to be a signatory to the Code of Expectations as are Te Whatu Ora and Te Aka Whai Ora. The HDC and ACC cannot be compelled to be signatories because their legislation does not allow for it, as it was enacted before the Pae Ora (Healthy Futures) Act 2022; as the TPB will be enacted subsequent to the Pae Ora (Healthy Futures) Act there is no excuse for the Therapeutic Products Regulator to not be compelled under this legislation to be a signatory to the Code of Expectations.

We have concerns about the reliance of the Regulator on overseas regulators, as set out in **Section 332, subsection 1 (e) – Engagement with other entities**. This is highly problematic, and the Regulator should be careful about which international regulatory organisations it relies upon, especially in the context of implantable medical devices.

The Regulator's reliance on information provided by international regulators or entities performing those functions, should be limited. Relying on certain international regulators potentially endangers New Zealand consumers. This is particularly the case with implantable medical devices, as international research has shown that medical devices are globally very poorly regulated (see The Critical Need to Properly Regulate Medical Devices page 17 and Appendix page 53). We should not be relying on the licencing or authorisation of products elsewhere unless those regulators have very robust and thorough process in place to ensure patient safety. Some regulators, such as the US FDA are subject to influence, conflict of interest/loading of licencing panels with people with strong industry/pharmaceutical ties, including consultants or advisors to the industry, and the US Government and FDA comes under heavy lobbying from the pharmaceutical industry (see page 16).

Of particular concern is the reliance of the Regulator on overseas regulators in the evaluation of implantable medical devices while the international the pre-market authorisation process of implantable medical devices is inadequate (see also Appendix page 53).

In the US, only 1% of implantable medical devices receive a full pre-market approval (PMA) and are entered onto the PMA database, which is publicly accessible and searchable. The vast majority (95-98%) rely on the lax 510(k) pathway, which allows manufacturers manufacturers to fast-track FDA approval, based no showing substantial equivalence without having to conduct expensive and time-consuming testing and randomised clinical trials, with the result that the devices have never been used on a single patient and have received little government scrutiny.[4]

The pre-market approval system in the EU, which included the UK until Brexit, is subject to a very similar flaw to the FDA's 510(k) process, but has the additional weaknesses of decentralisation and the use of private

4 IOM, 2011: *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*. Washington, DC: The National Academies Press

profit-driven companies called Notified Bodies as the backbone of the regulatory process.[5] So, the New Zealand regulator, being from a small country lacking the resources to conduct searching pre-market assessments itself, will almost always rely on overseas regulators' decisions, which are themselves seriously flawed. It is of major concern that the new Therapeutic Products Regulator will not have adequate data of safety (especially) and efficacy to make robust risk-benefit assessments. Yet the pre-market assessment process is crucial to the protection of patients, especially since it can be very difficult to discontinue their use if problems arise, unlike drugs. We have seen the impact of this in the difficulties of surgical mesh removal in New Zealand, with very few surgeons competent to do so, and women having to go to the US to have such surgery.

Section 332, subsection 1 (h) refers to participation in overseas organisations and forums relating to the regulation of therapeutic products. We believe that participation in such forums should focus on independent and not industry/ manufacturer/pharmaceutical sponsored forums.

There must be the means for complaints about the Regulator to be taken to an independent body for investigation and arbitration. Both applicants (sponsors, licence/permit seekers) and consumers should be able to lodge complaints about the performance of the Regulator to an independent body.

With regard to **Section 333 subsection 4**, we agree that the Regulator should have the capacity and capability to understand and give effect to the principles of te Tiriti o Waitangi/the Treaty of Waitangi; and to understand and take account of mātauranga Māori and Māori perspectives in relation to therapeutic products. This should be written into the secondary legislation for the Regulator, but as we have said previously we are disappointed that the intent to give effect to the principles of te Tiriti has not be signalled at the beginning of the TPB (see Te Tiriti o Waitangi and Te Ao Māori page 7).

Regarding **Section 334 Regulatory strategy for performance of functions and exercise of powers**, we strongly believe that this strategy should include engagement with consumers. Additionally, the regular reviews, not less than every three years, must include consultation with consumers. This is an important part of the checks and balances that, hopefully, will ensure protection of consumers and enable consumers to have a pathway to influence the activities of the Regulator. This would help to alleviate the situations such as New Zealand has experienced with surgical mesh, where mesh injured consumers have had to fight for over ten years to try to prevent more people being harmed, while the regulatory authorities have done very little to address the harm caused. The lack of action on the part of the Ministry of Health has reached the point where the continued harm can only be described as state sanctioned, and the Regulator will only be seen as being fit for purpose if has the power to prevent such situations in future.

It is vital that the Regulator is adequately resourced. While there should be recovery of costs (**Section 335**) built into the Regulatory process, and fees for authorisation of products, these costs should not be set so high as to financially disadvantage consumers through the passing on of such costs by the sponsor. To ensure consumer safety, it will likely be necessary for the Regulator to be funded by the Government to ensure independence from commercial entities and that public safety is paramount. Current underfunding of Medsafe ensures that it only carries out the bare minimum of evaluation of medical devices. The only requirement is that the manufacturer or importer list it electronically on Medsafe's WAND database within 30 days of it being first supplied. The Medicines Act contains no pre-market requirements for their assessment and approval whatsoever. Medsafe does not review any clinical or other information about a device, such as warnings or adverse event reports. With such a lax regulatory regime, it is hardly surprising

5 J McHale, 2018: Health law, Brexit and medical devices: A question of legal regulation and patient safety. Medical Law International 18(2-3);195.

that New Zealanders are subjected to faulty and dangerous medical devices that are insufficiently safety tested.

Thus, poor regulation, surveillance and reporting of harm in New Zealand to date is in part a function of insufficient resourcing, as well as a lack of political will and governing legislation. It is critical that the Regulator is sufficiently well resourced (financially and in terms of staffing and expertise) to ensure that a robust regulatory process is complied with and enforced, so that consumers are protected, and their health promoted.

With regard to **Section 336 Principles for cost recovery**, consumers and taxpayers should not have to pay for the regulation of products, particularly pharmaceutical products and implantable medical devices, from which massive multi-national companies and their shareholders make extortionate profits. On the other hand, the costs should not compromise the ability of small companies – particularly those producing/supplying low risk NHPs – to compete in the market. Nor should regulatory costs force the increase of retails costs out of the reach of many people doing their best to maintain their health and well-being without reliance on a health system already on its knees. We believe that fees should be paid by the applicant for authorisation, and fixed based on classification of the risk of the category, for example, risky implantable devices will need greater scrutiny and should require a much greater fee.

As with the three-yearly strategy review, the three-yearly review of cost recovery (**Section 342**) is an important opportunity for consumers to have their say on the fairness of costs and how that might be impacting costs and availability of all products, especially NHPs. Thus, consumers, not just the sponsors, should be consulted in the undertaking of this review. Ultimately, it is consumers who are most affected in terms of availability and/or affordability of therapeutic products.

The sharing of information (**Section 343**) is particularly important, and information sharing must be extended to our national entities (such as ACC and HDC) to ensure proper surveillance and monitoring of the safety of therapeutic products. Currently, various entities, particularly health and related entities such as ACC, Medsafe/MoH, and HDC are siloed and there is very limited sharing of information on harm and injury caused by medical/therapeutic products and procedures. AWHC has lodged a number of OIAs with HDC, ACC and Medsafe/MoH over recent years regarding treatment injury. It is clear from the gross disparities in information received, particularly actual numbers of reports of harm from each entity, that none of these agencies appear to share information, so there is no comprehensive understanding of the level of treatment injury.

Section 346 is a great concern to the AWHC. As discussed above regarding **Section 332**, the Regulator's reliance on information provided by international regulators or entities performing those functions, should be limited. Clearly New Zealand does not have the capacity to investigate every therapeutic product from scratch, but relying on certain international regulators potentially endangers New Zealand consumers. This is particularly the case with implantable medical devices, as international research has shown that medical devices are globally very poorly regulated (see The Critical Need to Properly Regulate Medical Devices). We should not be relying on the licencing or authorisation of products elsewhere unless those regulators have very robust and thorough processes in place that eliminates conflicts of interest.

Advisory committees (**Section 347**) must include consumer representatives with lived experience. Consumer representation on advisory committees would comply with the World Health Organisation's "Global Patient Safety Action Plan 2021-2030", the Code of Expectations for Health Entities' Engagement with Consumers and Whānau, and the Pae Ora (Healthy Futures) Act 2022. It is not good enough in 2023, under New Zealand health legislation that promised consumer involvement at ALL levels of the health system, for the Regulator

of all our therapeutic products to not include consumer representatives on ALL advisory committees. Given the scope and breadth of this legislation, and of the therapeutic products covered by it, consumers with lived experience must be appointed on an *ad hoc* basis to provide input. It might be necessary to have multiple consumers on any given advisory committee and/or at different times depending on the products that the Regulator requires advice on.

We are concerned about the possible use of automated systems and the blasé way in which the proposed legislation addresses this (**352 Use of automated systems** and **353 Effect of use of automated system**). It is not clear in the TPB what sort of evaluations an automated system would undertake. We believe it should only apply to very low-level applications, such as minor changes to medicines and devices, like packaging, data safety sheets, additional information, minor dosage changes, etc.

We are particularly concerned about **352 Subsection 2**: If the system carries out the action in a way that is clearly incomplete or wrong, the action may be completed or redone by the Regulator.

This must be reworded to read "the action **MUST** be completed or redone by the Regulator". It is completely unacceptable to say "***may*** be completed or redone by the Regulator". If something has clearly been done incorrectly by the automated system, if an automated system fails, it **MUST** be redone by the Regulator. Otherwise too much is left to chance and compromises the safety of consumers.

Additionally, any automated systems should be regularly audited to ensure that they are working properly and delivering the same or better outcomes as the Regulator.

It seems the Review of the Regulators decisions (**Section 357**) revolves entirely around applicants' (sponsors, licensees or permit holders) views that the decision not to authorise/licence/permit or to attach unwelcome conditions. There is no option under the legislation for a consumer group or any other stakeholder to seek a review. It is indefensible that the Regulator has such power over the authorisation, monitoring and surveillance of therapeutic goods, under legislation that states that the purpose of the Act is to protect, promote, and improve the health of all New Zealanders, yet only those who seek authorisations or licences or permits can apply for a review of decisions.

This review process is not focused on consumer safety, or promoting, improving and protecting the health of consumers. There is no mechanism by which consumers (individually or as a group) can oppose a decision to introduce a harmful device. Consumers are not listed as any of the people who can apply for a review of a Regulator's decision. This denies consumers the right to question authorisations that the Regulator may make for products that consumers have genuine concerns about regarding safety, where consumers believe that inadequate or insufficient evidence has been provided to the Regulator (e.g. the sponsor withholding important negative clinical trial results), or if they believe that the Regulator has placed undue emphasis and reliance on licensing/authorising of the product in other jurisdictions. While there are processes in place for monitoring safety or punishing infringements (e.g. misleading information on a product by a sponsor), an incorrectly approved product can cause significant harm between authorisation and when surveillance reveals harmful issues with the product.

Regarding **Section 358** (**Regulator to convene review panel**), it would be a conflict of interest for the regulator to appoint the panel reviewing its own decisions. As an alternative, the Health and Disability Commissioner, being concerned with the protection of consumer rights, and having the requisite knowledge in the field could appoint the review panel, or some other independent review body should be established.

Review panels must include consumer representatives. Again, under the health system overhaul that promised consumer involvement at ALL levels of the health system, for the Regulator of all our therapeutic

products to not include consumer representatives on ALL advisory committees and panels is inexcusable. Consumers with lived experience must be appointed to review panels!

We object to **Section 359**, where it is stated that the review panel can only review the merits of the original decision on the basis of information that was available to the Regulator when the original decision was made. This ignores the situation in which an applicant withheld material information or subsequent trials or research have revealed new information or understanding of a product. It must be possible for persons other than the product authorisation applicant to seek a review of a decision, and to present new information to support the claim that the decision was incorrect.

We also object to the provisions in **Section 361**, in which only the applicant for a review may appeal to the District Court against the Regulator's original decision. Consumers and/or other stakeholders must be able to seek a review of a decision or appeal to the District Court.

Patient Safety is of Paramount Importance

The AWHC believes that patient/consumer safety is of paramount importance in any legislation or regulatory regime that controls therapeutic products. The stated purpose of the Act is to protect, promote and improve the health of all New Zealanders. Whatever means the legislation sets out for achieving that purpose, consumer/patient safety must be paramount; all other considerations are secondary. No New Zealander should be worse off for the use of a therapeutic product. The needs and wants of health practitioners, sponsors, suppliers, the pharmaceutical industry and manufacturers must all be secondary to the health and well-being, and safety of health consumers.

There are conflicts in **Part 1 Preliminary Provisions** between **Section 3 Purpose** and **Section 4 Principles** that could compromises a focus on patient safety. Safety and risk-minimisation will have to be balanced with "timely availability" **(Section 4 (b) (i)**, since the attention of /pharmaceutical companies/manufacturers and their investors are increasingly focussed on "time to market", and pressure regulators to ever shorten the time it takes them to approve new products. We submit that all of the principles in **Section 4** are subject to the overall purpose in **Section 3**, so that timeliness MUST be consistent with safety.

Risk Versus Benefit

We understand that all therapeutic products carry risks and benefits. There is repeated statement in the TPB that the "likely benefits should outweigh the likely risks". This is a critical principle and how benefit and risk is balanced is crucial to whether or not the Bill protects consumers. However, a simple calculation that "benefits outweigh risks" is a low threshold and risks permitting products that are not harmful 51% of the time. Using such an inadequate measure, results in situations like the surgical mesh issue, where a therapeutic product could cause catastrophic harm for thousands of people, yet still be evaluated as having benefits, even with a lack of data or evidence of this.

Pharmaceutical drugs and implantable medical devices are both designed to be used inside the human body. Many such devices are designed to be permanent, but devices are much less rigorously examined before they are first marketed. Pharmaceutical medicines have to pass rigorous Phase I, II and III randomised controlled trials (RCTs) before being able to be sold on the market. However, it is most unusual to submit clinical trial data in support of submissions for pre-market approval of devices. For example, no clinical trials were required or carried out on surgical mesh in North America, Europe, Australia, or New Zealand before their introduction.

The term “proportionate” is also frequently used in the proposed legislation, with no definition of it in **Section 14 Interpretation**. That is because “proportionate” is a highly subjective measure, and one person’s idea of proportionate will be entirely different from another’s based on experience and perspective.

The subjective concept of having “regard for the likely benefits and risks” permits the sponsor and/or Regulator to ignore or dismiss harm that has not been thought likely or has not been considered at all.

Who determines what is appropriate and proportionate and who determines the likely benefits and risks? These are critical issues in the application of sections **119 Evaluation of medicine or medical device** and **120 Criteria for market authorisation of medicine or medical device**.

It is stated in the Explanatory note that “Risk can also arise because of a product’s manufacture, such as contamination or counterfeiting.” Risk also arises because there are already products on the market that should never have been licenced and brought to market, because they are inherently dangerous; far too many of them disproportionately harm women. This is especially true of implantable medical devices, widely recognised to be grossly under-regulated around the world.

Comment on Specific Sections with Regard to the Patient Safety

The legislation provides for therapeutic products to be regulated across their lifecycle (**Section 3**). We strongly support this provision, and it is particularly important for implantable devices and medicines for which there is limited pre-licensure safety data, especially long-term follow-up, and that may cause harm many years after implantation or prescribing (e.g. breast implants, surgical mesh, Cox 2 inhibitors, drugs like Primados and DES, among many others). We hope that there will be true life cycle regulation and that robust and ongoing surveillance will indeed protect consumers.

Section 121 sets out the criteria for being a sponsor and that includes that the sponsor be in New Zealand (resident here, incorporated here or a Crown organisation). While we understand the need for a sponsor to be based in New Zealand, we are concerned that this criteria is not used to limit the liability of a large overseas manufacturer or pharmaceutical company who might be better resourced to compensate consumers who have been harmed.

Regulations providing for and detailing what is involved in the sponsor’s surveillance and response system (**Section 142**) must be stringent. It is not sufficient to place the response to matters of safety in the hands of the sponsor, and a proper and prompt response to reports of harm must be undertaken by the Regulator. History has shown that if such responses are left up to the pharmaceutical company/manufacturer/ supplier/sponsor, products will remain on the market and reports of harm will be diminished and downplayed by those that have a vested financial interest.

How is the sponsor’s surveillance and response system monitored or enforced, and by whom? What mechanism is there to ensure that this happens? Is there any statutory reporting? Is evidence of an established surveillance and response system required before a product is authorised? At the very minimum, proof of a robust surveillance and response system MUST be required by the Regulator before a product is authorised and there MUST be a statutory reporting system in which the sponsor reports to the Regulator on their surveillance and monitoring.

Again, in this section, we have this subjective concept of having "regard for the likely benefits and risks"; this permits the sponsor and/or Regulator to ignore or dismiss harm that has not been thought likely or has not been considered at all.

In addition to the sponsor's surveillance and response system, under **Part 7 Regulatory matters, Subpart 1—Post-market surveillance and response, and compliance monitoring**, the Regulator must "have in place a post-market surveillance and response system for all therapeutic products with a market authorisation or that are otherwise lawfully in the supply chain."

It is absolutely vital that post-market surveillance and response, and compliance monitoring is done extremely well. For years, New Zealand has had lax surveillance and monitoring systems in place, particularly for implantable medical devices. We need robust and thorough surveillance that is well resourced. This must include a medical device register. While it is important to hold sponsors of therapeutic products accountable and ensure that they foot the bill for monitoring and collection of PROMs (patient reported outcome measures) and reports of harm, it is vital that we also have an independent system. In addition, it must not be a passive system in which it is often up to the harmed consumer to report adverse events/effects. It must be a requirement of practitioners to report adverse effects and harm when patients report it. All too often practitioners dismiss patient concerns and symptoms of an adverse effect or symptom of harm, because they cannot find any other record of such symptoms. This becomes a vicious cycle of patients not having harm and injury taken seriously, while escalating numbers of patients suffer. We have utterly inadequate systems for the reporting of harm and a non-existent, or lack-lustre and slow response, to reports of serious harm, that typically relies on injured consumers having to take on the role of red flag-raiser, whistle-blower, educator and lobbyist, to prevent further harm to more New Zealanders.

This surveillance system must include a relationship with, and information sharing between, the Regulator and other agencies including HQSC, HDC and ACC.

Additionally, the surveillance system must include the ability of consumers/patients or their whanau to report harm. Even with a compulsory notification of harm system, there will be practitioners who don't report harm, who simply don't believe their patients, and all too often attribute the patient's concerns to mental health issues, or somatic or functional disorders, especially for women.

In **Subsection 4** of **Section 203**, the Regulator must carry out surveillance of therapeutic products in accordance with the system; and when appropriate, respond to safety, quality, efficacy, or performance issues in accordance with the system.

Response must be swift and err on the side of caution. It is far easier to suspend use of a product and reinstate it, or issue a warning about its use, followed by a thorough investigation, than investigate while consumers continue to suffer harm and then withdraw/prohibit or limit use. Often the harm caused cannot be repaired and the quality of life not restored.

Section 346 (**Regulator may rely on decisions etc of recognised entities**) allows the Regulator, in evaluating a therapeutic product, to rely on reports, assessments, or decisions made by, or information received from, an overseas regulator or an overseas organisation.

We submit that the Regulator must do more than just a cursory review of a product's safety and efficacy relying largely on licencing elsewhere, particularly by the US FDA. It is widely known that the US FDA is subject to conflict of interest on its advisory panels[6, 7] and many of the "experts" on the FDA panels and committees also work for or are highly paid consultants to pharmaceutical companies. Additionally aggressive lobbying of Congress by the pharmaceutical industry, including expenditure of $233 million per

6 Lenzer J, 2006: Conflicts of interest are common at FDA, *BMJ*, vol. 332, 29 APRIL 2006; pp 991.

7 Pham-Kanter G, 2014: Revisiting Financial Conflicts of Interest in FDA Advisory Committees, *The Milbank Quarterly*, Vol. 92, No. 3, 2014 (pp. 446-470)

annum by the pharmaceutical industry at the federal level, influences the drafting of health care laws and referenda on drug pricing and regulation.[8]

New Zealander's deserve far more than to have the decisions of our Therapeutic Products Regulator influenced by over $230 million per annum of pharmaceutical industry lobbying in another country.

The Critical Need to Properly Regulate Medical Devices

In 2018, *The British Medical Journal's* Editor in Chief, Fiona Godlee, asked "Why aren't medical devices regulated like drugs?"[9] In her editorial she asked *BMJ* readers, predominantly practicing doctors and physicians, "How much do you know about the safety and effectiveness of the implanted devices your patients are offered? You may assume that pacemakers, neurostimulators, joint prostheses, and breast implants have been tested rigorously before being licensed for widespread use."

She went on to say "But this week a major international investigation, involving 59 organisations and including *The BMJ*, finds device regulation unfit to protect patients from harm."

That understated observation that "device regulation [is] unfit to protect patients from harm" doesn't begin to describe the catastrophic levels of harm inflicted upon health consumers including very many New Zealand citizens, because we too have had years of gross under-regulation of implantable medical devices.

In Europe, the major investigation referred to by Ms Godlee – the *Implant Files*[10] – that involved 250 journalists, and 59 organisations including *The BMJ,* and 8 million device related health records, found that "sources of harm to patients include a lung sealant that leaked, breast implants that went rancid, implanted pacemakers that stopped working, and deep brain stimulators that had to be removed." It was probably needless for her to also mention surgical mesh given the international coverage of the extraordinary harm that device has caused.

The website *Implant Files* is devoted to the first-ever global examination of the medical device industry, which has found that health authorities across the globe have failed to protect millions of patients from poorly tested implants.

The investigation found that when flaws are found in medical devices and safety alerts and recalls are triggered, all too often these warnings fail to reach doctors and patients. Recalls, withdrawals and bans on devices are not uniformly applied from country to country, causing confusion and raising risks to patients where insufficient action is taken.

The *Implant Files* state that "Doctors and manufacturers often fail to report adverse events, and when they do the information can be unverified and incomplete. And over large swaths of the planet, health authorities refuse to disclose information about harm to the public — or just never collect it in the first place."

New Zealand was one of the countries specifically mentioned. There is no escape from the fall out – New Zealand regulators facilitated significant harm to New Zealanders because they failed to do their jobs properly!

8 Wouters OJ, 2020: Lobbying Expenditures and Campaign Contributions by the Pharmaceutical and Health Product Industry in the United States, 1999-2018, *JAMA Intern Med*. 2020 May 1;180(5):688-697.

9 Godlee F, 2018: Why aren't medical devices regulated like drugs? *The BMJ* 2018;363:k5032.

10 ICIJ, 2018: Medical Devices Harm Patients Worldwide As Governments Fail On Safety, *The Implant Files*, International Consortium of Investigative Journalists.

The Therapeutic Products Bill represents not only the means by which our lawmakers can ensure that we have a regulatory regime that protects our citizens from dangerous implantable medical devices, but might place New Zealand in a position to lead the rest of the world to a better future for everyone who is recommended an implantable device by their health practitioner.

We have commented throughout this submission on the need for stringent regulations that ensure the safety of consumers particularly related to implantable medical devices. We have also commented throughout on the critical need for robust surveillance and monitoring, collecting and collating notifications of harm and PROMs, and the critical need for the Regulator to respond swiftly and err on the side of caution when it comes to protecting consumers from harm. Nowhere else is this more important than in the regulations for implantable medical devices.

We believe that we have made our concerns around the safety and regulation of implantable medical devices crystal clear in other parts of this submission.

However, we are extremely disappointed about the transitional provisions in this Bill that will ensure that New Zealanders have another six and a half years to wait before sponsors of implantable medical devices are held accountable for the lack of safety of their products. While the transitional provisions may well be acceptable for medicines that have always been subject to better and more robust regulation, it is unconscionable that New Zealanders have to wait another six and a half years to have any sort of confidence that our health regulators are going to take our safety and protection from harm from implantable medical devices seriously.

Section 10 of **Schedule 1 (Transitional, savings, and related provisions)** effectively gives health practitioners *carte blanche* to continue using harmful devices, such as surgical mesh, because such implantable devices will automatically be given a temporary market authorisation. This Bill may not come into force until the 1st of September 2026, to allow for time for the secondary legislation to be developed. Therefore, under clause **3 (d) (i) of Section 10**, the temporary market authorisation for a medical device that was a medical device under the 1981 Act, and under Medicines (Database of Medical Devices) Regulations 2003, will have up to three years before that temporary market authorisation expires. Thus, consumers will conceivably have to wait another six and a half years from now (March 2023) to see implantable medical devices sufficiently regulated to give some assurance of safety. The *status quo* on implantable medical devices effectively continues until September 2029!

The AWHC submit in the strongest possible terms that this provision MUST be amended! There MUST be recognition that implantable medical devices are already substantially improperly regulated and, as a result, inflict considerable harm on New Zealanders. There MUST be the enactment of stopgap or temporary legislation or regulation that covers those medical devices already identified as causing harm and provide for an immediate reassessment of their safety, quality and performance, or force them to be withdrawn until such time as they can undergo a full market authorisation under the new Act. All new devices MUST be subject to the more rigorous regulatory regime that will be introduced when the Therapeutic Products legislation is enacted.

Regulation of Natural Health Products

While we believe that natural health products (NHPs) should be regulated, we don't believe this Bill is the appropriate place to do it. NHPs are an entirely different class of therapeutic product and the regulations for NHPs in this Bill are far too heavy-handed and, in places, written in such a way that the Bill could have unintended consequences for consumers. The proposed legislation, as currently worded, has significant

implications for New Zealanders who grow and/or make their own natural "products" for therapeutic or medicinal purpose, as human beings have done for millennia.

This legislation has the potential to "capture" and regulate the activities of a person who does something as simple and everyday as making a lemon and honey drink to combat a sore throat or ease their recovery from a cold or the 'flu.

If NHPs are to remain in the Therapeutic Products Bill there needs to be some considerable alterations to the wording of the Bill to ensure that New Zealanders can continue to maintain their own health and well-being through foods and plants that also have therapeutic value, in the way in which such activities have been undertaken for thousands of years. The Bill should take account of the ages old adage that each of us should "let food be thy medicine, and let medicine be thy food."

We are pleased that the Bill acknowledges the generally lower risk of NHPs and that they "will be evaluated against different standards than those for medicines and medical devices." Many natural health products are based on traditional foods and herbs etc.; they also act in different ways. Controlling quality, and ensuring that a natural product contains what the label says it does, is important, but there must be different standards because NHPs don't work in the same way as pharmaceutical drugs.

We are very concerned that the wording of the legislation could allow the Regulator to reclassify an NHP as a medicine at the request of a sponsor, potentially someone who has a vested financial interest in such a reclassification that would then disadvantage many consumers who might use a plant, plant material or plant extract for therapeutic purposes. As discussed in our comments on **21 Changing or clarifying type of therapeutic product** in Specific Comments on the Therapeutic Products Bill**,** this may have significant and negative implications for natural health products that have effects similar to synthetic pharmaceutical drugs/medicines, e.g. St John's Wort and Prozac, and statins and red yeast rice.

Will **Section 21** enable pharmaceutical companies to lobby to have NHP reclassified as a medicine, effectively denying the NHP supplier the means to carry on business because it is now subject to unjustifiably rigorous licencing and regulation? Will this prevent consumers from using their own knowledge of traditional and natural health to maintain their own health and wellbeing, as discussed below.

48 Manufacture of NHP

To **manufacture** an NHP means to do any of the following:

(a) produce it:

(c) in relation to an NHP ingredient,—

(i) procure it (including removing it from its natural state so as to make it into a product (*see* **section 18**)):

(ii) prepare it by expression, extraction, distillation, purification, or a traditional preparation method:

The AWHC is very concerned that, under the proposed legislation, the Regulator could enact regulations (e.g. prohibiting a given activity) regarding the creation by individuals of products for their own therapeutic use; for example, grow plants and foods that they then turn into a therapeutic "substance" intended for a therapeutic purpose. A therapeutic product is defined as "a product that is intended for use in, on, or in relation to humans for a therapeutic purpose." To manufacture an NHP is to produce it, including removing it from its natural state or to prepare it by expression, extraction, distillation, purification or a traditional preparation method. So, if a person was to, for example, harvest calendula flowers and prepare an extract from them and make a healing cream from that extract using oils and beeswax, for the purpose of using the cream to heal wounds, or skin irritations; or to harvest kawakawa leaves and make a decoction to drink for a sore throat or bronchial inflammation or digestive upset, then they would be a manufacturer of a therapeutic

product. It would be possible under the wording of the legislation for the Regulator to make rules governing this and potentially prohibit people from making their own therapeutic products. Manufacturing is a controlled activity under this proposed legislation. A "Controlled activity is prohibited unless allowed by licence, permit."

Part 3 - Subpart 3 covers when controlled activities are allowed and under NHPs, "An NHP practitioner is allowed to manufacture an NHP that does not have a NZ authorisation" but an NHP practitioner must be an individual "who carries on a business or undertaking of providing personal consultations with clients to identify the client's health needs and to supply by non-wholesale supply or to administer NHPs to address those needs".

There is nothing that says a consumer manufacturing their own NHP is exempt from the controlled activities regulations, so that must mean that the Regulator could make rules to prohibit such activities. In theory, even a consumer making a lemon and honey drink for therapeutic purposes could be prohibited from doing so as it could be seen as a controlled activity.

Under **Section 55 Supply, subsection 1, clause (a)**, it appears that an individual consumer making a therapeutic product that is an NHP (as per the examples given for **Section 48** above) and who gives the home-made NHP to a family member or friend would be 'supplying' a therapeutic product. Therefore, they could be subject to regulations made by the Regulator. Again, this is an example of the regulatory creep enabled by the wording of this legislation. It could make consumers going about traditional activities that are part of taking personal responsibility for health and well-being, and alleviating demand on an in crisis and under-resourced health system, subject to ridiculous and heavy-handed regulation and legislative control. The power in this legislation to exert control on the everyday lives of New Zealanders is appalling and without any justification or merit.

61 Health benefit claim, permitted health benefit claim, and substantiating claims

Substantiation of health benefit claim

(4) A health benefit claim about an NHP may be substantiated by scientific evidence, evidence of traditional use, or both.

AWHC strongly supports the use of evidence of traditional use of NHPs for substantiating a health benefit claim. The efficacy of many NHPs cannot be measured by normal clinical standards, as they are prescribed by natural health practitioners on very personal basis having regard to a considerable amount of personal information (including how an individual reacts or feels, and very specific symptoms), not just based on a diagnosis of a set disease or condition. Also, unlike western medicine, natural health practitioners take a holistic view of the body, the different organ systems and their interaction, and the interaction and relationship between mental, physical and emotional health.

There is an increasing body of medical research into the health benefits of traditional medicines that, under this Bill, would be classified as NHPs. This research includes ongoing research into the compounds found in plants/plant materials and extracts. The evidence for the health benefits of plants and their extracts and the compounds found in them – NHPs under this legislation – is accumulating all the time. At any point in time, the absence of evidence for a health benefit for an NHP does not represent evidence of absence; it simply means that the appropriate research may not yet have been done.

In this legislation an inordinate amount of space is given to regulating the health benefit claims for NHPs, yet with "conventional" or pharmaceutical medicines and drugs that have been licensed or authorised, myriad claims are made about benefits that are either not true or exaggerated. For example, recent research found that there is little evidence that paracetamol works for a vast array of pain conditions that it is still frequently advertised for and recommended for by health practitioners.

For example, despite years of advertising and promoting paracetamol for alleviating multiple causes of pain, Sydney researchers revealed in 2021 that, for most conditions, evidence regarding the effectiveness of paracetamol is insufficient for drawing firm conclusions.[11] While there was moderate to strong evidence for its efficacy in only four conditions (more efficacious than placebo, but the effect sizes were very small for knee or hip osteoarthritis, early post-partum perineal pain and episodic tension-type headache) there was also strong evidence that paracetamol is ***not*** effective for other conditions it is regularly recommended/ prescribed for. There was high quality evidence that paracetamol was *no better than placebo* for treating acute low back pain. In addition, there is poor evidence that paracetamol was effective for 11 painful conditions (dental procedures, major surgery including gynaecological and orthopaedic surgery; acute migraine in adults, otitis media in children, orbital surgery, renal colic, metastatic breast cancer, common cold-related headache, cataract surgery, and abdominal pain).

Worst of all, there was inconclusive or no evidence that paracetamol was effective for alleviating chronic low back pain, post-caesarean delivery pain, knee and hip arthroplasty, rheumatoid arthritis, bariatric surgery, and cardiac surgery among others.

Not only is paracetamol not as effective as is advertised or believed to be by health practitioners, there is a fine line between a therapeutic dose and toxic dose. Starship advise that "Paracetamol is the most common single agent involved in poisonous ingestions in young children"[12], and Sheen *et al*., concluded that paracetamol – freely available in supermarkets – is now the most common drug in self-poisoning, with a high rate of morbidity and mortality.[13]

The proposed legislation has a significant and unjustifiable imbalance of focus on the health benefit claims of NHPs, acknowledged to present a very low risk of harm, while (at least some) pharmaceutical medicines are not subject to the same scrutiny yet pose far greater risk of harm.

67 Market authorisation required to import, supply, or export

This has implications – as discussed in **Section 48** regarding the manufacture of NHPs – for consumers making their own NHPs, and that may provide such NHPs to family and friends, but not as a natural health practitioner and not as a business or for financial gain. As it currently reads in the Bill, consumers as described above, could conceivably be required to obtain a market authorisation, which is patently ridiculous and an example of the sort of regulatory creep that we find most disturbing in this Bill (see Regulations that are Contradictory, Vague, Poorly Worded page 23).

112 Personalised NHPs

(1) This section applies for the purposes of **sections 67 and 69(1) and (2)(d)(i) and (ii)**.

(2) An NHP practitioner is allowed to manufacture an NHP that does not have a NZ authorisation if—

…

(5) In this section, **NHP practitioner** means an individual (regardless of the title or description they use) who—

(a) carries on a business or undertaking of providing personal consultations with clients to identify the client's health needs and to supply by non-wholesale supply or to administer NHPs to address those needs; or

(b) the rules say is an NHP practitioner.

11 Shaheed AC, *et al*.,2021: The efficacy and safety of paracetamol for pain relief: an overview of systematic reviews. *Med J Aust*. 2021 Apr;214(7):324-331.

12 Paracetamol Poisoning, Starship, 2 may 2022.

13 Sheen CL, et al., 2002: Paracetamol toxicity: epidemiology, prevention and costs to the health-care system. QJM: An International Journal of Medicine. 2002 Sep;95(9):609-19.

As discussed previously an NHP practitioner can manufacture NHPs without an authorisation as long as the ingredients are recognised NHP ingredients, and the person carries on a business or undertaking of providing personal consultations with clients to identify the client's health needs and to supply by non-wholesale supply or to administer NHPs to address those needs. Together with other clauses it appears possible for the regulator to prohibit individual consumers from making their own NHP products.

Definition of a Natural Health Practitioner

It is bizarre that registered naturopaths, medical herbalists and homoeopaths are not included as health practitioners under the Health Practitioners Competence Assurance Act 2003, nor are they recognised as experts in natural health products in this Bill. In contrast pharmacists are recognised in the Bill and sell natural products although they are not trained as experts in this field. If natural health practitioners are not health practitioners under the HPCA Act, then one has to wonder why NHPs are included in this Bill at all.

Naturopaths, medical herbalists and homoeopaths are also not considered to be providers of health and disability services under the Health and Disability Services (Safety) Act 2001.

With regard to the definition of practitioner, the HDC Act is contradictory. In one place it says a health practitioner has the same meaning as in section 5(1) of the Health Practitioners Competence Assurance Act 2003 (a person who is, or is deemed to be, registered with an authority as a practitioner of a particular health profession – those authorities do not include naturopaths, medical herbalists or homoeopaths). In another it says that a health care provider is among other things, any other person who provides, or holds himself or herself or itself out as providing, health services to the public or to any section of the public, whether or not any charge is made for those services.

Direct to Consumer Advertising

The AWHC is extremely disappointed that direct to consumer advertising (DTCA) has been retained. We remain strongly opposed to DTCA and, in our submission on the 2018 Therapeutics Regulatory Scheme consultation document, urged the Government to put an end to this practice. This new legislation is the ideal opportunity for the Government to take note of the widespread opposition to DTCA and ban this practice. DTCA of prescription medicines is legal only in the USA and New Zealand; the growth in this form of drug promotion has been spectacular and has rarely been in the best interests of consumers or the New Zealand health system.

It is clear that research demonstrating harm from DTCA,[14, 15, 16] and opposition from much of the medical fraternity[17, 18, 19] and the majority of New Zealanders,[20] has failed to counter what can only be the lobbying of those with a vested financial interest in seeing the continuation of DTCA, most notably the pharmaceutical

14 Every-Palmer S, *et al.*, 2014: Direct-to-consumer advertising of prescription medication in New Zealand. *New Zealand Medical Journal*; 127:102–10.

15 Zadeh N, *et al*., 2017: 'At-risk' individuals' responses to direct to consumer advertising of prescription drugs: a nationally representative cross-sectional study. *BMJ Open*; 7:017865.

16 Zadeh N, *et al*.,2019: Lifestyle determinants of behavioural outcomes triggered by direct-to-consumer advertising of prescription medicines: a cross-section study. *Australian and New Zealand Journal of Public Health*; Apr;43(2):190-196.

17 CMC, 2016: Direct to consumer advertising in New Zealand, Statement by the Council of Medical Colleges in New Zealand.

18 NZMA, 2018: Direct-to-Consumer Advertising of Prescription Medicines, New Zealand Medical Association Position Statement.

19 RNZCGP, 2017: Prohibition of direct-to-consumer advertising of prescription medications, The Royal New Zealand College of General Practitioners Position Statement.

20 A Consumer survey published in 2019 found that 57% of New Zealanders supported banning DTCA, while on 15% supported it's continuation, and that 59% had a negative opinion of the information such advertisements provide, and believed that they did not provide had a negative opinion of the information these ads provide.

industry. It is alarming that policy makers, advisors and/or those writing the Therapeutic Products Bill seem to have been unduly influenced by those vested interests.

The pharmaceutical industry plays a role in the introduction, promotion and use of medicines in New Zealand through the use of DTCA and through the influence it is able to exert on patient groups. DTCA has had a significant impact on the demand for specific drugs. The need for unbiased, credible and reliable information for consumers about therapeutic products remains a priority gap that needs to be filled.

An example of harmful direct to consumer advertising is provided by Bayer Pharmaceuticals' promotion of Elevit. Direct to consumer advertising of Elevit is inappropriate especially for women already pregnant and/or women on low incomes who cannot afford the product. The statement that the product reduces the risk of neural tube defects by 92% gives no weight to the fact that the same benefits may be available through adequate diet or affordable supplements prescribed by a midwife or GP. Elevit was subject to an unsuccessful complaint to the Advertising Standards Authority in 2012. Similarly, advertising of Vioxx® and Reductil® led to far more New Zealanders being harmed by these harmful drugs before they were withdrawn from the market.[21]

DTCA clearly influences consumer demand; "in New Zealand, expenditure on DTCA has been estimated to be in the tens of millions of dollars annually"[14] and pharmaceutical companies would not be continuing to spend that amount of money if advertising did not achieve their goals of increased profit through increased sales of their drugs.

Khalil Zadeh *et al.*, found in their New Zealand study that 'at-risk' (i.e. with poorer self-reported health status, older, less educated, lower income and ethnic minorities), may be more vulnerable to drug advertising and may make uninformed decisions accordingly.[15] They reported that "nearly half of all participants believe[ed] that only drugs that are completely safe could be advertised. Similarly, a substantial proportion thought that only drugs that are extremely effective could be advertised."[15]

DTCA: oversells benefits while minimising or suppressing well known harm; prompts consumers to request drugs they don't need[17, 19]; increases demand for new, branded medicines with a premium price tag thus increasing pharmaceutical expenditure within the health system; [17, 18, 19] and detrimentally affects the patient-doctor relationship.[17]

The AWHC strongly advocates the banning of direct to consumer advertising of prescription pharmaceutical medicines, and submits that the Therapeutic Products legislation is the ideal opportunity for Parliament to take note of the significant opposition to DTCA in New Zealand.

Regulations that are Contradictory, Vague, Poorly Worded

The AWHC understands the need to make the legislation flexible enough to account for new therapeutic products, for a changing medical and therapeutic landscape; to effectively future-proof the legislation to ensure it is fit for purpose and has longevity.

However, the proposed legislation is, in part, unnecessarily vague, in places contradictory, and in many cases untenably permissible enabling the Regulator to make rules on an *ad hoc* basis and as it pleases, often to the detriment of consumers. The legislation is riddled with wording that will ultimately lead to unwelcome

21 Toop L, 2019: Statement from New Zealand public health experts on direct-to-consumer advertising of prescription drugs, University of Otago Media Release, *New Zealand Doctor*, 7 August 2019.

regulatory creep: a process by which regulation is developed or enforced in a less than transparent way, and leads to rules and regulation that give rise to unintended consequences.

For example:

> **31 Low concentration NHP**
> (3) However, a product is not a low concentration NHP under subsection (2) if the rules say it is not.

These clauses (and there are many of them) that state that something is a specific thing until the rules says it is not, that it is something else altogether, are concerning. It is like saying "this small domestic creature that has four legs and fur and eats meat and purrs is a cat, until I say it is not a cat"; it is a regulatory version of having a bet each way.

We are concerned that the regulations are all functional and reasonable until someone (e.g. a sponsor) says they don't like the rules and they should be changed to reclassify something at their convenience. Historically, that usually means 'patch protection' and changes to their advantage and in their financial best interests.

Similarly:

> **34 Reportable products and critical needs products**
> (1) A medicine or medical device with a NZ authorisation is a reportable product if the rules say it is.

Such a definition is ridiculously vague and open to whatever interpretation the Regulator feels like applying. In **Part 2 Interpretation**, the definition says a "**reportable product** has the meaning set out in section 34", but in **Section 34** it says a device or medicine is a "**reportable product** if the rules say it is". There is no actual definition, simply a circular argument, and leaves the reader to ***assume***, on the basis of the following clauses and subclauses that, in this case, such a product is so important that the supplier has to report any shortages or cessation to supply.

There are numerous instances of what can only be described colloquially as a "get out of jail free card". For example:

> **115 Regulations may allow controlled activities to be carried on by other persons**
> (1) This section applies for the purposes of sections 45(1)(a) and 67 to 71.
> (2) A person is allowed to carry on a controlled activity or do something that would otherwise contravene any of those sections if—
> (a) they are in a class of persons the regulations say may carry on the activity or do the thing; and
> (b) they comply with any requirements in the rules about doing so.

In other words, the regulations can be "infringed" if the regulations say so. Regulations may be made to get around existing regulations and legislation without having to amend the legislation. While this may be beneficial in some cases, it can also be harmful and relies entirely on the rigour and robustness and attitude of the Regulator.

Then there is the use of highly subjective language: appropriate and proportionate; likely benefits and risks:

> **375 Regulations**
> (3) The Minister must not recommend that regulations be made unless satisfied on reasonable grounds that they are appropriate and proportionate having regard to the likely benefits of, and risks associated with, the therapeutic products in relation to which they apply.

We have discussed this in more detail in Risk Versus Benefit on page 14 under Patient Safety is of Paramount Importance, as this has significant implications in terms of protecting consumers from harm from therapeutic products.

"Appropriate and proportionate" and "likely benefits of and risks associated with, the therapeutic products" will almost entirely be a matter of perspective. What a pharmaceutical company or device manufacturer thinks will be vastly different from what a consumer harmed by a drug or device thinks. The Regulator must err on the side of caution, with the safety and protection of the consumer of the utmost importance.

The "vagueness" of the language around the making of regulations and rules enables necessary scope for a very wide range of decisions and activities that must be undertaken by the Regulator, and for products that don't even exist yet, and in order to future-proof the legislation and ensure it is not constantly having to be amended. However, the flip side of this is that the "vagueness" of the language around the making of regulations and rules allows for the making of rules and regulations that may be disadvantageous to people and entities/organisations – consumers and sponsors. The language is sufficiently vague that it largely relies on the Regulator to "do the right thing" and that will depend on their independence, impartiality, and commitment to doing what is necessary to protect, promote, and improve the health of all New Zealanders rather than facilitate the desires of those with vested financial interests.

As a result, the AWHC believe that secondary legislation and subsequent rules and regulations must be open to public consultation; and earlier still, developed and written with consumers having a seat at the table. Consumers must have an opportunity to be involved in the development of the rules and regulations to ensure that the rules and regulations do, in fact, protect, promote, and improve the health of all New Zealanders.

Specific Comments on the Therapeutic Products Bill

2 Commencement

… this Act comes into force on 1 September 2026.

The AWHC believes this is a worryingly distant time for the legislation to come into force. We understand that a huge amount of work is required to be undertaken, including the consideration of thousands of written submission, hearing of oral submissions, work on updating the legislation to reflect those submissions and further debate in Parliament, not to mention the writing of secondary legislation. However, three and a half years is a long time to wait for better protection for New Zealanders against grossly under-regulated medical devices (as we discuss in detail above), particularly as women are disproportionately harmed by dangerous, under-tested devices.

Part 1
Preliminary provisions
3 Purpose

It is critical that the primary purpose of this Act is for the protection, promotion and improvement of health – the consumer must come first in all aspects of this bill (including engagement/ participation/consultation regarding the making of rules and regulations and the appointment and duties of the Regulator), and the concerns of sponsors, suppliers, pharmaceutical companies and device manufacturers must be secondary. This is particularly important for implantable medical devices and medicines that, despite short term safety studies and follow-up, may cause harm many years after implantation or prescribing (e.g. devices such as breast implants and surgical mesh; and drugs such as Cox 2 inhibitors, Primados and Diethylstilbestrol (DES), among many others).

4 Principles guiding exercise of powers under Act

(a) the likely benefits of therapeutic products should outweigh the likely risks associated with them, and their regulation should be proportionate to those benefits and risks:

This is a critical principle and how benefit and risk is balanced is crucial to whether or not the Bill protects consumers. A simple comparison of "benefits outweigh risks" is a low threshold and risks permitting products that are not harmful 51% of the time. On such a measure, products could cause catastrophic harm for thousands of people (e.g. surgical mesh) but still be evaluated as having benefits that outweigh risks because fewer than 50% of those in whom surgical mesh is implanted have reported harm.

(b) regulation of therapeutic products should support— …

(ii) open and well-functioning markets for those products;

(iv) choice of, and equity of access to, therapeutic products for Māori and other population groups:

There are significant indications that despite the stated purpose of the Act being to "to protect, promote, and improve the health of all New Zealanders" this Bill is focussed on giving pharmaceutical companies, manufacturers and suppliers, and any other profit driven entity access to consumers. It is clear that the Bill is market-focussed, favouring corporates within the medico-pharmaceutical industrial complex, rather than being truly focussed on benefit to the health consumer.

Medicine is not a one-size-fits-all proposition and choice is a vital principle that must be applied. Many individual medicines are not efficacious in all people (in fact, for some medicines only relatively small cohorts) and side-effects/adverse effects occur in some people but not others. Choice, particularly in medicines and NHPs is vital to ensure that all New Zealanders can access medicines that suit their needs and individual constitutions. For example, Tramadol can cause violent nausea and vomiting in up to 50% of people who have been prescribed it, yet can provide good relief for severe pain for those who tolerate it. Alternative effective relief for severe pain must be available.

(c) there should be co-operation with overseas regulators and, if appropriate, alignment with international standards and practice.

While this principle is admirable it should be with considerable caution that New Zealand looks to overseas regulators in some matters. Medical devices are grossly under-regulated internationally, and if our new Regulator is as effective as is hoped, we may set a new international standard for regulating medical devices. Regarding pharmaceutical medicines, some regulators (e.g. the US FDA) are subject to vigorous lobbying by the pharmaceutical industry, and many conflicts of interest among those that advise or sit on the licencing panels. We should seek to make decisions with as much independent advice as possible, irrespective the licensure of therapeutic products elsewhere, and rely on clinical trials data that has been gathered in the most transparent and ethical manner possible.

We believe that a further principle should be included in **Section 4**: a statement that the Act should be administered "in an open, transparent and inclusive manner."

10 Controlled activities

(2) The controlled activities, which are listed in **section 69**, include the following:

(e) administering medicines and using medical devices:

(f) conducting clinical trials:

(g) carrying on a pharmacy business.

Regarding clause (e), the AWHC is concerned that medical practitioners/surgeons who implant medical devices be required to prove competency in doing so. One of the significant issues with surgical mesh is the lack of competence of surgeons in implanting it (see The Critical Need to Properly Regulate Medical Devices,

page 17). There must be strict provisions for the competence of surgeons/practitioners implanting medical devices; they must be credentialled to do so and there must be a valid education and training pathway to ensure that competence that includes mentoring, proctoring and oversight by an experienced and competent practitioner.

Regarding clause (f), clinical trials need to be better regulated than currently, particularly around requirements regarding transparency of clinical trials and reporting of results, and this should be legislated for in the TPB. TranspariMED, a global campaign that works to end evidence distortion in medicine, has expressed concern that the TPB "falls significantly short of global best practices in clinical trial transparency set out by the World Health Organisation (WHO) and endorsed by numerous other stakeholders. Failure to register and fully report clinical trials harms patients, wastes taxpayers' money, and slows down the development of new treatments, vaccines and cures."[22]

In July 2020, the Ministry of Health advised that the WHO had added New Zealand's Health Research Council as a signatory to *Joint statement on public disclosure of results from clinical trials*.[23] However, "while there appears to be reasonably good registration of clinical trials, not all are registered prospectively, and there is no mandating of reporting on results." TranspariMED report "huge transparency gaps in New Zealand clinical trials." Compliance has not been well monitored and lack of compliance has not been sanctioned."[24]

The use of incompetent participants in clinical trials must also be addressed as this issue has not yet been resolved by the Health and Disability Commissioner. In 2017, there was a public consultation – Health and disability research involving adult participants who are unable to provide informed consent. In November 2019, then HDC Anthony Hill released a report[25] with recommendations to the then Minister of Health (David Clark) that "would provide more clarity about when health and disability research involving people who cannot give informed consent to participate could occur. The changes would also, with robust safeguards in place, allow some research to occur that is not currently permitted."

It appears that nothing has happened since then but AWHC hopes that this issue will be revisited in current HDC, Morag McDowell's review of the HDC Act and Code of Rights this year.

Regarding clause (g), it is entirely bizarre to have carrying on a pharmacy business as a controlled activity in the TPB, for the TPB to regulate all pharmacy and prescription medicines and pharmacy activity and business (including **sections 50-52**, and **76-81**), for the TPB to replace the Medicines Act 1981, and yet not transfer the entire legislation regarding pharmacy ownership and operation to the TPB. It seems unnecessarily complicated – ludicrous, in fact – to retain a 42 year old piece of legislation, that will be renamed just for one issue, pharmacy ownership. Surely there is a mechanism by which that entire piece of legislation can be written into the new Therapeutic Products Act, as many other issues relating to pharmacy and supply of medicines is held in this new Act, rather than spend time amending and renaming a completely outdated piece of legislation to regulate a single issue.

13 Administration of regulatory scheme

(3) The Regulator carries out surveillance of therapeutic products with a market authorisation (or that are otherwise lawfully in the supply chain) to collect and evaluate information about—

(a) the safety, quality, and efficacy of medicines; and

22 Brukner T, 2019: Comments on the Therapeutic Products Bill (New Zealand), TranspariMED, 28 May 2019.

23 WHO: Joint statement on public disclosure of results from clinical trials.

24 Korte C and Haggie J, 2022: Clinical Trial Transparency, press release, Transparency International New Zealand 8 August 2022.

25 HDC, 2019: Health and disability research with adult participants who are unable to provide informed consent, the Health and Disability Commissioner.

(b) the safety, quality, and performance of medical devices; and
(c) the safety and quality of NHPs.

This surveillance must be robust, must include mandatory reporting of harm and patient reported outcome measures (PROMs), and include sharing of information on harm from therapeutic products between ACC (treatment injury), HDC and HQSC. Currently these agencies are siloed and one agency may hold information on treatment/product harm that is currently not shared with other relevant agencies, such as Medsafe. There are numerous instances in which ACC have data on harm caused by medical devices, while there have been no reports on harm from the same devices/same patient to Medsafe, who are the current regulators and collectors of reports of harm.

(5) The Regulator can make various kinds of regulatory orders if there are problems that create unacceptable risks to personal health or public health. These include recall orders, advertising remediation orders, and product moratorium orders.

The Regulator must be proactive and take a highly precautionary approach. The Regulator needs to issue suspensions and warnings with a lower threshold of harm than has been the case under Medsafe. Consumer safety must be paramount and the Regulator needs to act swiftly and with the power to enforce cessation of use/prescription or sales until adequate investigation of harm can be undertaken.

Part 2
Interpretation
Subpart 1—General
14 Interpretation

We note that there is no definition of a natural health practitioner. Notwithstanding our belief (see Regulation of Natural Health Products page 18) that natural health products do not belong in this Bill at all, and should be regulated under their own legislation, it is entirely inconsistent not to provide a definition of natural health practitioner and to essentially ignore natural health practitioners when they are integrally connected with the promotion and "prescribing" of natural health products to consumers.

Subpart 2—Therapeutic products
21 Changing or clarifying type of therapeutic product
(5) The Regulator may, by Regulator's notice, say that a specific NHP is a medicine if—
(a) the sponsor of the NHP (or if there is no sponsor, a person who meets the criteria in **section 125** for being a sponsor) applies for the notice to be made; and
(b) the Regulator is satisfied on reasonable grounds that it is appropriate for the product to be regulated as a medicine.

The AWHC has concerns regarding the implications of **Section 21, Subsection (5) clauses a & b**. The power of the Regulator to say that an NHP is a medicine if a person who meets the criteria for being a sponsor applies, or the Regulator is satisfied (no criteria provided) that it is appropriate, could potentially allow foods with medicinal uses/benefits to be regulated as a medicine.

This is reminiscent of what has occurred in the US where the FDA banned the sale of the traditional Chinese food, red yeast rice (RYR), because it contains a naturally occurring statin monocolin K, chemically identical to lovastatin. "Because of its functional similarity to lovastatin, monacolin K is considered an unapproved drug by the US FDA, and as such all RYR products that contain a specific amount of monacolin K are prohibited."[26]

The wording of the TPB effectively allows for a similar situation to occur in New Zealand.

26 Nguyen T, *et al*., 2017: Red Yeast Rice, *Foods*; 2017 Mar 1;6(3):19.

In the New Zealand context, could these clauses prohibit consumers from growing and using kawakawa for medicinal purposes? Recent research has found that kawakawa has more than 60 biologically active compounds in its leaves.[27, 28] For example:

- pellitorine has a key role in chemical pathways in the body that reduce inflammation.
- yangambin, has been shown in earlier human trials to have potent anti-inflammatory effects on the cardiovascular system;
- dopamine has known health effects on the digestive system, and provides a mechanism by which the consumption of kawakawa tea soothes upset stomachs and other gastrointestinal complaints. It can also help people metabolise sugar and regulate insulin response.[27]

Researchers at the Liggins Institute are running trials testing the possibility that kawakawa could reduce inflammation and improve the health of those who have conditions like heart disease and diabetes.[27]

It is conceivable that, as worded, these regulations may allow plants used traditionally for therapeutic benefit such as kawakawa, being classed as medicines and use prohibited in the community and by individuals, because a pharmaceutical company lobbies to have a plant such as kawakawa, and its constituents and extracts, regulated as medicines (as per the definition of a medicine in **Section 22, subsections 1 and 2**).

22 Medicine

(3) However, a product referred to in **subsection (1)** is not a medicine if—
(a) it is an NHP; or

This appears to contradict **Section 21 Changing or clarifying type of therapeutic product** (above), which clearly states that an NHP can be a medicine if a sponsor applies for a notice that says an NHP is a medicine or if the Regulator says it's appropriate.

27 Supply-restricted devices and use-restricted devices

The AWHC would like to see this section used to proactively protect consumers from harm from implantable medical devices.

(3) Supply or use restrictions may (without limitation) relate to any of the following:
(a) the persons who are allowed to supply or use the device:
(b) the circumstances in which the device is allowed to be supplied or used:
(c) how the device is allowed to be supplied or used.

For example, there is clear evidence that a large part of the problem of injury from surgical mesh is that many surgeons do not have the competence to use it for pelvic organ prolapse and stress urinary incontinence, and that many of the women who have suffered mesh injury have had mesh implanted by inadequately trained surgeons. Hence, the very belated credentialling of surgeons who call themselves uro-gynaecologists. If implantable devices were use-restricted in terms of the training and competence of surgeons (**Subsection 3, clause a**), or if mesh had been prevented from being used in some procedures (**Subsection 3, clauses b and c**) there may be far fewer women living with chronic pain and disability.

In the recent hearing of evidence by the Health Select Committee on Sally Walker's petition to suspend the use of surgical mesh for stress urinary incontinence, Dr Eva Fong[29]submitted that surgeons in New Zealand were not competent to implant mesh safely. Dr Fong has treated over 300 New Zealand women with mesh

27 UoA, 2023: Scientists explore kawakawa's healing properties, Liggins Institute, Faculty of Science, 20 January 2023.

28 Ramya Jayaprakash R, *et al.*, 2022: Exploring the Chemical Space of Kawakawa Leaf (Piper excelsum), *Nutrients*; 2022 Dec 5;14(23):5168.

29 Dr Eva Fong, urologist, current Chair of the Female Urology Special Advisory Group of the Urological Society of Australia and New Zealand, member of the Mesh Complications Committee of the International Incontinence Society.

complications from 76 implanting surgeons, including New Zealand's most "experienced" surgeons.[30] In a paper published in the journal *Urology* in 2022, Dr Fong and Dr Hazel Ecclestone found that there were significant short-comings in diagnosis and follow-up in patients who had mesh sling surgery in New Zealand, and that surgeons often fail to recognise and diagnose problems when they occur.[31]

It is imperative that surgeons implanting medical devices are properly trained, proctored and mentored for device surgery, and are not permitted to rely on their original surgical training for new devices. **Section 27, subsection 3** should be applied to ensure the safety of consumers and that all medical device implanting surgeons are competent and credentialled to undertake implantation surgery and provide the required follow-up.

29 NHP

(3) However, a product referred to in subsection (2) is not an NHP if—

(a) it is intended to be administered by injection or parenteral infusion; or

There is a lack of clarity in **Section 29, subsection 3 (a)**. Does that make an injectable NHP a medicine, and would it have to be classified as a medicine first? For example, vitamin C is an NHP, but it is also used intravenously. What about IM B12 injections or iron infusions. All meet the definition of NHPs in Section 30 (below).

30 NHP ingredient, recognised NHP ingredient, and additive or formulation aid

(1) Each of the following is an NHP ingredient:

(a) a plant, plant material, an alga, a fungus, or non-human animal material:

(b) a substance or mixture of substances that—

(i) is obtained by expressions, extraction, distillation, purification, or a traditional preparation of anything referred to in paragraph (a); and

(ii) is not subject to any other process involving chemical transformation other than hydrolysis or electrolysis:

(c) a vitamin or provitamin, including salts and other compounds, of the following types:

(i) biotin:

(ii) choline:

(iii) folate:

(iv) vitamin A, B1, B2, B3, B5, B6, B12, C, D, E, or K:

(d) a mineral or mineral compound:…

The definition of an NHP is extraordinarily broad and includes foods that have a therapeutic value, such as herbal teas and foods such as garlic, or for example, Brazil nuts that people consume specifically to ensure sufficient selenium in their diets. Combined with **Section 15, clause (h) supporting or sustaining human life**, which effectively determines that all foods have a therapeutic purpose as they sustain life, plant foods could be defined as NHPs and therefore could be regulated as NHPs. A further, presumably unintended, consequence is that under **Section 21 Changing or clarifying type of therapeutic product**, a food once classified as an NHP, could be then reclassified and regulated as a medicine. This type of regulatory creep is of great concern, and has the potential for consumers to be prevented from using food, as it has been for millennia, therapeutically to maintain an individual's health and well-being. In this manner, the proposed legislation has the ability to allow the Regulator to make future rules and regulations that would prevent consumers from "self-medicating" using "NHP" ingredients that they have grown, gathered or acquired from someone who has grown or gathered these ingredients for non-commercial purposes. The AWHC is vehemently opposed to any legislation or regulation that would permit such control.

30 Oral submission of Dr Eva Fong to the Health Select Committee on the petition of Sally Walker to suspend the use of surgical mesh for stress urinary incontinence, as in video of the hearings (at 41 minutes). 15 February 2023.

31 Fong E and Ecclestone H, 2022: Quality of Pre-operative Assessment for Mid Urethral Slings in Women Who Present With Mesh Complications. Urology. 2022 Oct;168:90-95

33 Prohibited product

(2) The Minister must not recommend that regulations be made about a product for subsection (1) unless satisfied on reasonable grounds that—

(a) the product directly or indirectly exposes any individual to a risk of death, serious injury, or serious illness; and

(b) the risk cannot be adequately managed by the exercise of the Regulator's powers under this Act.

Section 33, subsection 2 is critical in ensuring patient safety, and the regulations regarding this must be robust and place paramount importance on patient safety. It is important that, where the risk of harm is great or that harm is severe, consumers who will still derive significant benefit may be able to access the product under strictly controlled circumstance despite the risk of harm. However, the regulation and management of such high-risk products must be exercised with the safety of the majority uppermost. Regulations regarding use of harmful products must be stringent, and warnings substantial and communicated extremely clearly to both practitioners and consumers.

63 Product standards

…

(2) The product standards may (without limitation) relate to any of the following:

…

(f) product information and consumer information for the products.

(3) However, a provision of a product standard does not apply to a therapeutic product with a market authorisation—

(a) if the authorisation says it does not apply; or

(b) to the extent that meeting the standard would cause the product to not conform to the market authorisation.

AWHC strongly submit that product standards must prioritise consumer safety over any other factor.

With regard to **subsection 2 (f)**, consumer information must be thorough and complete and include all safety data. Where a product, particularly a pharmaceutical medicine/drug has not been tested on pregnant and breastfeeding women, this should be highlighted. It was years before there was any recognition of the harm caused by anti-convulsant medication (and that recognition was brought about through consumer advocacy by affected consumers), leading to many New Zealand babies born with foetal anti-convulsant syndrome. Many other medications either cause harm, or the safety of use during pregnancy has never been assessed.

Product information – for practitioners and consumers – must be updated regularly, particularly to amend for contraindications, drug interactions and adverse effects/events. For drugs and devices, product information should err on the side of caution and the Regulator should issue comprehensive and timely warnings about adverse effects and enforce clear warnings on packaging and to prescribers (medicines) and surgeons (implantable devices) and their regulating bodies (medical colleges and vocational associations). Too often the latter do not update information to their members (e.g. the New Zealand Association of Plastic Surgeons have still not updated their website regarding the safety of breast implants and BIA-ALCL despite a letter from Medsafe and the manufacturer about safety issues, and despite having this brought to their attention by AWHC). The Regulator must include updated consumer information, in particular safety warnings, on their website and make it easily accessible to consumers.

AWHC is very concerned about the wording in, and reasoning behind **subsection 3 (a and b).** Under what circumstances would a product standard not apply to a therapeutic product with a market authorisation, and what are the criteria? If meeting a product standard means it cannot conform to the market authorisation then why has the product been given a market authorisation? These clauses appear to be a "get out of jail free card" to allow sub-standard products to be marketed/prescribed/recommended to consumers. It cannot be overstated: **safety of consumers is paramount**, and no consumer can make an informed decision if the

reasons why a product has a market authorisation but does not meet the standard for such a product, are not made known.

65 Special case requirement

We support this section if it would be beneficial for people with rare diseases or conditions, or for those facing a disabling or life-threatening disease, conditions or symptoms, where their situation is so dire that the risk of using a device or drug not available in New Zealand is outweighed by the use of an experimental product or product that does not have New Zealand authorisation.

Part 3
Dealing with therapeutic products
Subpart 2— Controlled activities and supply chain activities
69 Controlled activity prohibited unless allowed by licence, permit, or subpart 3

…
(1) Each of the following is a controlled activity:
…
(b) in relation to medical devices,—

We fail to understand why dispensing, prescribing, administering and possessing a prescription medicine is a controlled activity, but implanting an implantable medical device is not a controlled activity? Implanting a medical device is the corollary of prescribing or administering a prescription medicine and should be subject to the same level of regulations and controls. As it is currently in the Bill, the only way that implanting an implantable medical device is a controlled activity is if under **Section 27 (2)** the rules say it is a use-restricted device. Thus, consumers are reliant on secondary legislation and the rules made by the Regulator to state that each implantable device is use-restricted, and further, who the persons are who are allowed to use/implant the device and the circumstances and how the device is to be used. The regulation of medical devices and the safety of consumers in relation to those devices is entirely reliant on the strength of regulations yet to be made by a Regulator that doesn't exist yet, under a regulatory system that is subject to secondary legislation that has yet to be written and enacted, and may not be until as late as 2029. The proposed legislation around implantable medical devices is weak, insubstantial; it does little to nothing to protect consumers from harm from currently grossly under-regulated devices.

(d) in relation to NHPs,—
(i) manufacturing in the course of a business or undertaking:

A business or undertaking is described as "a business, professional practice, or other undertaking, whether or not carried on for gain or reward". This is potentially problematic for consumers making their own NHPs and under this section would appear to be a controlled activity not excluded in **Subpart 3 section 112**.

71 Administering NHP by injection or parenteral infusion
A person must not administer an NHP to a person by injection or parenteral infusion.

As with **Section 29, subsection 3 (a)**, this section must be better defined. Currently the "list" of NHP ingredients provided in **Section 30** is very broad. The explanatory note states that "The rules will list a subset of NHP ingredients as recognised NHP ingredients." However, the rules do not exist yet, so it is impossible to know from the legislation if things like IV vitamin C, IM B12 and iron infusions will be permitted; are they NHPs or are they medicines, and if they are NHPs how is it possible for them to be administered under this legislation?

72 Person in supply chain must comply with rules
(1) A person in the supply chain must comply with any requirements in the rules about any of the following:
(b) product information and consumer information:

(c) identification and labelling:
(h) tracing and recall (*see* **subsection (3)**):
(i) post-market surveillance and response:
(j) record-keeping and auditing:
(k) giving information to the Regulator:
(l) giving information and other assistance to sponsors to enable them to comply with their obligations under this Act:

This is critically important for patient safety and reporting of harm/adverse events/adverse effects.

Product information and consumer information, and identification and labelling are significant issues for patient safety. Many people who are frequent consumers of health care live with disabilities. Consumers with low vision can struggle to read the instructions and consumer information on medicines. People for whom NZSL (New Zealand Sign Language) is their first language have a lower reading age, and many New Zealanders are migrants and refugees, and English is their second language. It is vital that product and consumer information is accessible for them. These are considerations that must be incorporated in the rules for sponsors.

In addition, when a different quantity of prescription medication is prescribed than the quantity that comes in the proprietary packaging, the prescribed amount is put by the pharmacist into plain packaging, such as a plain white box, with only the prescription/dosage information on the outside. No consumer information, including warnings about contraindications or interactions is provided, as would be the case with the original manufacturers box. The rules must include the need for pharmacists to supply all original information and warnings with repackaged medicines.

Health practitioners prescribing or administering medicines, or implanting medical devices or using medical devices (e.g imaging devices) are persons in the supply chain and therefore MUST comply with any rules including post-market surveillance, record-keeping, and providing information to the Regulator or sponsor. Therefore, the rules must be rigorous about the reporting of harm arising from the use of therapeutic products and the Regulator MUST be given the power to enforce them and ensure that ALL reports of harm are made.

(2) Rules made for subsection (1)(h) may (without limitation) relate to any of the following:
(a) having in place procedures for tracing and recalling therapeutic products:
(c) implementing those procedures to trace or recall therapeutic products:
(d) responding to recall orders:
(e) how recalled products are dealt with.

These are all vital aspects of ensuring patient safety, and the rules must be robust and stringent, and the Regulator must enforce such rules, and there must be adequate penalties for non-compliance. It is unconscionable that we still have a passive reporting system for notifications of harm and that there is still no adequate or enforceable means to require practitioners to report harm from medicines and medical devices, nor any follow-up with practitioners or their vocational organisations when warnings are issued.

Tracing and recalling therapeutic products is vital in ensuring patient safety and a prompt response to reports of harm. How effectively these clauses contribute to patient safety and prevention of further harm is entirely reliant on the Regulator having the power and will to properly set regulations and rules, and to enforce them.

73 Person in supply chain must comply with qualification, training, and competency requirements
(1) A person in the supply chain,—
(a) if they are an individual, must not carry on a qualifying activity unless they meet the qualification, training, and competency requirements for the activity; and
(b) must ensure that no-one working for them carries on a qualifying activity unless the

person meets the qualification, training, and competency requirements for the activity.

(2) An activity that is, or is part of, a supply chain activity is a qualifying activity if the regulations say it may be carried on only by a person who meets qualification, training, and competency requirements in the regulations.

Section 73 suggest that rules will be made regarding who can use medical devices (among other therapeutic products) and such rules MUST include competency and training (credentialing) of surgeons implanting medical devices.

AWHC submits that there MUST be more stringent qualification, training and competency requirements for implantable medical devices. The surgical mesh crisis has shown us how poorly regulated this aspect of medicine is, as there are many surgeons in New Zealand not competent to implant mesh, yet continue to do so years after the harm from surgical mesh was brought to light. Women continue to be harmed, the grossly belated credentialing process for surgeons is just window dressing, and surgeons are calling themselves uro-gynaecologists even though there is no such vocational group in New Zealand.

In the recent hearing of evidence by the Health Select Committee on Sally Walker's petition to suspend the use of surgical mesh for stress urinary incontinence, Dr Eva Fong, urologist and chair of the submitted that surgeons in New Zealand were not competent to implant mesh safely. Dr Fong has treated over 300 New Zealand women with mesh complications from 76 implanting surgeons including New Zealand's most "experienced" surgeons.[30] In a paper published in the journal *Urology* in 2022, Dr Fong and Dr Hazel Ecclestone found that there were significant short-comings in diagnosis and follow-up in patients who had mesh sling surgery in New Zealand, and that surgeons often fail to recognise and diagnose problems when they occur.[31]

This is the case with just one of many medical devices, before considering issues with Essure, breast implants, hip replacements, pacemakers, among others. It is clear that the current regulation and control over implantable medical devices is grossly inadequate. It is only a matter of time before another implantable medical device wreaks the same level of harm upon another cohort of New Zealanders as a result of our lax regulations regarding medical devices and who can implant them.

75 Vending machines for medicine only if expressly allowed

The AWHC do not agree with vending machines for dispensing medicines and believe that this option should be removed entirely from the legislation or expressly banned in the legislation.

Subpart 3—When activities are allowed

Personal use imports

105 Patient or carer importing medicine for personal use

(2) An individual (person A) is allowed to import a medicine (whether or not it has a NZ authorisation) if they comply with the personal use import conditions.

The AWHC supports this section as an important option for patients who are not well catered to by medicines available in New Zealand but who could significantly benefit from medicines available overseas, and who may derive a significant survival or quality of life benefit when suffering from certain serious diseases and conditions.

As in **Section 65 Special Case requirement**, there are benefits to this clause when there are no other options left for people with rare or terminal conditions and new medicines are available overseas that may make a difference to their survival or quality of life.

Cessation of market authorisation

113 Stock in supply chain if market authorisation ceases

…

(4) A person is allowed to carry on any activity with product A if—

(a) they would be allowed to do so if product A's market authorisation were still in force; and

(b) the specific product with which they carry on the activity is current stock.

It is unclear how this section applies if an authorisation is cancelled for patient safety/risk of harm reasons. If the authorisation has been cancelled for safety reasons the remaining stock MUST be prohibited from being used, and it should be recalled. **Subsection 4 (a & b)** MUST NOT apply to therapeutic products whose authorisation has been cancelled for patient safety reasons. It is patently ridiculous to permit stock to be used if under clause (a) "they would be allowed to do so if product A's market authorisation were still in force", if the reason for cancellation is because the product causes harm.

116 Emergency arrangements

While we understand the need for emergency arrangements, patient safety is paramount.

Part 4 Market authorisations for medicines, medical devices, and NHPs

Subpart 1—Market authorisations

117 Kinds of market authorisations

(1) There are 3 kinds of market authorisation—

(b) a **provisional authorisation**, which authorises a medicine or medical device for import, supply, and export when the Regulator is not able to determine whether the product meets the criteria for a standard authorisation (for example, because there is insufficient information available) but is satisfied that it is nevertheless appropriate to authorise it on a limited basis:

The AWHC are concerned that the provisional authorisation clause may be a means to give authorisation to unsafe products. Such a provisional authorisation MUST only be used in extenuating circumstances, as there is a considerably greater risk of harm to consumers from a product that may not meet all safety and efficacy requirements for standard authorisation. This MUST not be a pathway to rapidly bring products to market for the financial benefit of the manufacturer and enable them to derive financial and market benefit before having undertaken adequate safety and efficacy studies/clinical trials. Such provisional authorisation must only be permitted when the perceived benefit to consumers is extraordinarily high and the risk is low. Post-authorisation surveillance must be extremely rigorous, and submission of reports of harm notifications must be mandatory, and there should be active and effective collection of PROMs to ensure consumer safety and the Regulator must move immediately to suspend authorisation upon reports of harm.

118 Application and issue of market authorisation for medicine or medical

(3) However, if the application is for a standard authorisation, the Regulator may instead issue a provisional authorisation for the product.

In evaluating applications, the Regulator **must place the utmost importance on patient safety.**

Subsection 3 appears to allow a provisional authorisation because an application for a standard authorisation does not meet the criteria. Again, **patient safety is paramount**. The AWHC is concerned that this clause will permit products to be authorised when the sponsor hasn't done enough work to ascertain the safety, quality and efficacy/performance of a product. Unless there are compelling factors, such as emergency use of a critical nature, applications should be denied until such time as the sponsor can provide more than adequate data on the safety, quality and efficacy/performance of a product. Given the international history of medical devices being grossly under-regulated this "work around" for inadequately evidence-based authorisation applications is worrying.

In addition, consumers MUST be fully informed of the provisional status and why the product does not have standard authorisation. In order to comply with the Code of Health and Disability Services Consumers' Rights, consumers must be advised of the provisional status and reasons for it in order to make an informed decision.

119 Evaluation of medicine or medical device

(3) In evaluating the product, the Regulator may (without limitation) have regard the following:

The wording of **Subsection 3** must be amended to read:

"In evaluating the product, the Regulator MUST (without limitation) have regard for the following…"

The use of the word "may" means that the Regulator could legitimately issue an authorisation without having regard to issues such as safety.

Guidance note

The Regulator may rely on reports, assessments, or decisions made by, or information received from, a recognised entity (*see* section 346).

This permits the Regulator to consider the decisions made by international regulators that may not be as rigorous as we would wish them to be regarding patient safety, or regulators that are subject to lobbying by pharmaceutical companies/manufacturers and conflict of interest. This is especially concerning given the gross under-regulation of medical devices globally.

143 Sponsor must comply with rules

(1) The sponsor of a therapeutic product must comply with any requirements in the rules about any of the following:

(a) the safety, quality, and efficacy of medicines:
(b) the safety, quality, and performance of medical devices:
(c) the safety and quality of NHPs:
(d) product information and consumer information:
…
(i) tracing and recall:
(j) record-keeping and auditing:

It is vital for patient safety that the clauses in **Subsection (1)**, especially **a, b, and i**, are stringent and enforced. With regard to **clause d**, it is important that product and consumer information is kept up to date and complete, especially any warnings, changes or information on safety and efficacy, interactions and contraindications from post-marketing surveillance, in order to comply with the patient rights to make informed decisions.

Sponsors must also be cognisant of the fact that many people who are frequent consumers of health care live with disabilities. Consumers with low vision can struggle to read the instructions and consumer information on medicines. People for whom NZSL (New Zealand Sign Language) is their first language have a lower reading age, and many New Zealanders are migrants and refugees and English is their second language. It is vital that product and consumer information is accessible for them. These are considerations that must be incorporated in the rules for sponsors.

(2) However, the sponsor is not required to comply with a requirement set out in the rules—

(a) if the product's market authorisation says it does not apply; or
(b) to the extent that compliance with it would be contrary to the market authorisation.

The AWHC is concerned that **Subsection 2** (above) is yet another "get out of jail free card", enabling the making up of rules, *ad hoc*, to suit the sponsor. This is another example of the apparent market-focus of the legislation.

145 Sponsor of reportable product must notify Regulator of likely shortage
146 Sponsor of reportable product must notify decision to stop supplying product

For critical and or common usage medicines, **Sections 145** and **146** are very important, and such regulations must be strictly enforced. During the Covid-19 pandemic, New Zealand ran short of some drugs, such as paracetamol, and purchase was restricted in retail outlets, especially supermarkets. Notwithstanding the issues we have raised regarding paracetamol in our response to **Section 61**, regarding medicines required for life threatening conditions, such as asthma medication, epipens or other medications required for anaphylactic reactions, and many other medications, the health and well-being of New Zealanders is paramount, and cost and market forces are secondary, as shortages of critical medicines may lead to deaths.

Subpart 3—Protection of active ingredient information about innovative medicines
149 Periods when protected active ingredient information may not normally be disclosed or used

It is understandable from a commercial point of view, that pharmaceutical companies want to protect their R&D, especially with new or innovative medicines. There is also the need to both inform and protect consumers. This Subpart appears to attempt to balance the commercial needs of manufacturers/ pharmaceutical companies/patent holders with consumer rights and protection. However, this only applies to new medicines applying for market authorisation with the new Regulator. For existing medicines there is an automatic rolling over of what used to be a standard consent to a standard authorisation:

"Transitional provisions in the Bill provide that products that are currently consented under the Medicines Act 1981 will automatically receive a market authorisation under the Bill."

In terms of the protection period, there is evidence that information on some currently consented medicines has been closed for 50 years meaning that for some consumers, information on active ingredients is inaccessible for the remainder of their lives.

It is unfair on both consumers and suppliers to have different rules, and previously consented medicines should be subject to the same rules as new medicines under the new regime, including the periods of protection.

Part 6
Other prohibited conduct
Tampering
187 Tampering with therapeutic product

(3) To **tamper with** a therapeutic product means—
(a) to interfere with any of the following:
(i) the product itself:
(ii) its manufacturing process:
(iii) its performance:
(iv) its identification or labelling:
(v) its package:
(vi) its product information or consumer information; and

The AWHC has been made aware by a consumer/patient advocate that when medication is taken from the original packaging put into a plain white box by a pharmacist (for example, Epilim, an anti-convulsant that causes significant *in utero* harm to babies when the drug is taken by the mother) the warnings are not carried over to the plain packaging. The repackaging of prescription medication by the pharmacists can occur when

a different quantity is prescribed than the quantity that comes in the proprietary packaging; the prescribed amount is put into plain packaging, such as a plain white box, with only the prescription/dosage information on the outside. No consumer information, including warnings about contraindications or interactions is provided, as would be the case with the original manufacturers box. Although this is not tampering in the sense intended in **Section 187**, the practice essentially deprives consumers/patients of critical safety information. All warnings regarding pregnancy, lactation, contraindications and drug interactions that is on a branded box must be carried over to plain packaging.

195 Improper inducement to health practitioner or veterinarian

(1) A relevant person must not give a benefit, or offer or agree to give a benefit, to a health practitioner or veterinarian with the intention of—

(a) inducing the practitioner or veterinarian to make a favourable clinical decision about a therapeutic product; or

(b) rewarding the practitioner or veterinarian for making such a decision.

(2) A health practitioner or veterinarian must not accept, or ask for, a benefit that would contravene **subsection (1)**.

(3) A health practitioner or veterinarian makes a **favourable clinical decision** about a therapeutic product if they make a clinical decision that the product is appropriate for a patient or give favourable advice about the product to a patient.

Improper inducements within medical practice and health care is a decades old (if not centuries old) problem, and continues with all manner of perks offered to doctors to recommend or prescribe particular drugs/medicines, procedures and implantable devices. As with DTCA (see our submission on Direct to Consumer Advertising page 22) these practices benefit pharmaceutical companies and manufacturers not consumers/patients and the evidence is that they cost our health system more.

The regulations governing inducements, perks, gifts – any activity that influences non-evidence based recommendations and prescribing by health practitioners – should be stringent and rigorously enforced, and infringements should attract penalties that function as sufficient deterrent to stamp out these practices.

The experience of the AWHC is that some medical practitioners have a limited grasp of what a conflict of interest actually means as it pertains to their own relationships and interests, and the direct and indirect benefits they derive from those relationships and interests. For example, we have been in meetings where surgeons deny having any potential conflicts of interest, yet derive a substantial income from a performing procedures that are the subject of the meeting.

Overall, we believe that gifts, offers and inducements are highly problematic and this aspect of the relationship between medical practitioners and health-related commercial organisations should **completely cease**. There is ample evidence in the medical literature regarding the pervasiveness of this type of "marketing" to medical professionals by commercial organisations, the negative impact that it has on patient care, and the inability of doctors to avoid unconscious bias in their prescribing behaviour as a result.

Goupil *et al*. wrote that evidence writes that doctors' exposure to marketing and promotional activities of pharmaceutical companies, including gifts to doctors, has a negative impact on the quality and quantity of drugs they prescribe, resulting in lower quality of care, unjustified risks to patients, and more costly prescriptions. They concluded in their research that "GPs who do not receive gifts from pharmaceutical companies have better drug prescription efficiency indicators and less costly drug prescriptions than GPs who receive gifts."[32]

32 Goupil B, *et al*., 2019: Association between gifts from pharmaceutical companies to French general practitioners and their drug prescribing patterns in 2016: retrospective study using the French Transparency in Healthcare and National Health Data System databases. *BMJ*. 2019 Nov 5;367:l6015.

Lee and Begley found that "the vast majority of physicians receive industry gifts in various forms, and the receipt of gifts is associated with lower perceived quality of patient care. There is also an inverse relationship between the frequency of received gifts and the perceived quality of care."[33]

King and Bearman write that "The pharmaceutical industry spends roughly 15 billion dollars annually on detailing – providing gifts, information, samples, trips, honoraria and other inducements – to physicians in order to encourage them to prescribe their drugs", and they found "that **policies banning or limiting gifts** from pharmaceutical representatives to doctors are likely to be more effective than disclosure policies alone."[34] [our emphasis]

Sah and Fugh-Berman found that "Physicians fail to recognize their vulnerability to commercial influences due to self-serving bias, rationalization, and cognitive dissonance. Professionalism offers little protection; even the most conscious and genuine commitment to ethical behavior cannot eliminate unintentional, subconscious bias."[35] They went on to conclude that "In addition to educating faculty and students about the social psychology underlying sophisticated but potentially manipulative marketing and about how to resist it, academic medical institutions should develop strong organizational policies to counteract the medical profession's improper dependence on industry."

209 Special requirements at certain places

(3) When at a treatment room or consulting room while a patient or client is present, the inspector must take account of the patient's or client's privacy and well-being so far as practicable in the circumstances.

We hope that such action would be very rare, and the circumstances of having to do so extraordinary and absolutely unable to be delayed, and a matter of life and death. To subject patients, particularly those who may be vulnerable or suffer anxiety or PTSD or other mental health issues, to such a serious situation must meet the highest threshold of justification, and the safety and well-being of consumers/patients must be the foremost consideration. We believe that this part of the legislation should be actively reviewed to ensure that harm is not caused to patients, and any instances where such action was deemed necessary subjected to rigorous scrutiny.

210 Inspector's powers having entered place

(2) The inspector may do any of the following:

(e) take samples of any of the following:

(i) any therapeutic products found at the place:

(ii) the output of any medical devices found at the place (such as an x-ray from an x-ray machine):

(g) make records or recordings of things at or being done at the place:

(h) copy documents or otherwise make copies of information produced under **subsection (3)**.

We have serious concerns regarding the privacy of consumers/patients in the circumstance that output from imaging devices are taken by an inspector or that documents are copied. There is no reference at all in this section to the Privacy Act 2020, or consumer rights. There is nothing in this section to suggest that documents pertaining to and images of specific patients/consumers are excluded from the items that may be taken under this section, so we can only assume that documents pertaining to and images of specific

33 Lee D and Begley CE, 2016: Physician report of industry gifts and quality of care, *Health Care Manage Rev*. 2016 Jul-Sep;41(3):275-83.

34 King M and Bearman PS, 2017: Gifts and influence: Conflict of interest policies and prescribing of psychotropic medications in the United States, *Soc Sci Med*, 2017 Jan;172:153-162.

35 Sah S and Fugh-Berman A, 2013: Physicians under the influence: social psychology and industry marketing strategies, *J Law Med Ethics*; 2013 Fall;41(3):665-72.

patients/consumers may be taken by an inspector. There MUST be protection of patient/consumer rights and privacy, and this MUST be explicit in the legislation.

Subpart 3—Regulatory orders

213 Recall order

(1) The Regulator may make a recall order for a therapeutic product if satisfied on reasonable grounds that the continued availability of the product directly or indirectly creates or increases a significant risk to personal health or public health.

What is "reasonable grounds" to one person may look very different to another. The Regulator should take a precautionary approach and err on the side of caution and to protect patients' health and well-being. A suspension or warning should be issued **before** an investigation into the need for a recall, to ensure the least possible harm to consumers. The severity of possible harm to an individual should be a major consideration even if the majority of recipients of the product are unharmed (e.g. surgical mesh).

218 Advertising remediation order

This section should only apply to non-prescription therapeutic products, as DTCA of prescription medicines should be prohibited (see Direct to Consumer Advertising page 22).

220 Directions order

(1) The Regulator may make a directions order in relation to a therapeutic product if satisfied on reasonable grounds that—

(a) the product directly or indirectly exposes any individual to a risk of death, serious injury, or serious illness; and

(b) making the order is a necessary or desirable way to address that risk; and

(c) the extent of the order is not broader than is reasonably necessary to address that risk.

There may be cases in which, for some individuals, the benefits of a harmful product (e.g. Vioxx and other Cox 2 inhibitors) outweighs the risk of harm, even if that risk of harm is high. For example, a consumer may make an educated, informed choice to sacrifice longevity for a substantially increased quality of life, knowing full well the risks of the product. Health practitioners MUST fully discuss with individuals the entire range of risk versus benefit of any therapeutic product, including alternatives and a do nothing approach, before obtaining informed consent. There should also be orders that prohibit use of a product in a particular cohort of consumers (e.g. an anti-convulsant during pregnancy) as it is clear that many practitioners are unaware of the dangers of some products in some normal, everyday life circumstances. Additionally, black box warnings/label warnings should be mandatory in some instances of reported harm.

222 Product moratorium order

We believe this is a vital clause that, if properly applied, would prevent the use of products that are incredibly harmful in certain circumstances; for example, surgical mesh banned for stress urinary incontinence and pelvic organ prolapse, but suitable for hernia repair. Similarly, thalidomide is catastrophic in pregnancy but now has many beneficial uses, including for multiple myeloma and leprosy.

Clauses in this section allow a cessation or suspension of use while a thorough investigation is undertaken; if used properly, freely and with consumer protection in mind, they should enable a system in which patient safety is far better prioritised.

223 Compliance with product moratorium order

This section MUST be supported with adequate regulations regarding educating practitioners about compliance and follow-up, and enforcement to ensure that practitioners (for example, private practitioners

who often make considerable amounts of money from implantable devices and procedures in private practice), are aware of and adhere to the moratorium, especially if they retain stock of the product. Vocational organisations must also be required to inform their members – see our earlier comment on the New Zealand Association of Plastic Surgeons and risk of BIA-ALCL in our submission on **Section 63 Product standards.**

232 Regulatory orders to be publicly available

(1) The Regulator must make a regulatory order publicly available.

(2) However, a failure to do so does not affect the validity of the order.

It is very difficult to have any confidence that the proposed legislation will have adequate power to enforce the regulations that will be made. In this section, in the first statement the Regulator MUST make regulatory orders publicly available, but the second assumes that the Regulator won't or won't always do so. If the Regulator must "make a regulatory order publicly available" it MUST do so, and therefore there will not be a need for the second statement. What this section tells consumers is that doesn't really matter if the public is informed or can access it or not. These two clauses are contradictory - the Regulator must do something but there are no consequences if they don't!

236 Public safety announcements

(1) For the purpose of protecting, promoting, or improving personal health or public health, the Regulator may make a statement relating to any of the following:

The power of this clause depends entirely on the Regulator having the will and fortitude to ensure that public safety is the most important factor. Such a power in the case of surgical mesh may have alerted many women to the risks and given them confidence to question recommendations to consent to mesh procedures. However, many mesh injured women were not told that their procedure would include mesh, or a different name for the device was used (e.g. tape or sling). Had such a public safety announcement been made a decade ago, the toll on New Zealand women may have been far less.

Historically, consumers would have had greater protection from many harmful drugs, such as Primodos and DES, or specific dangers from drugs such as anti-convulsants during pregnancy, had such a regulation existed or been complied with, with consumer safety as the paramount concern.

Part 8 Enforcement

Subpart 2—Offences involving knowledge or recklessness

247 Significant risk to personal health or public health—level 1 penalty

(1) A person commits an offence if—

(a) they contravene a provision listed in **subsection (3)**; and

(b) in doing so, they create or increase a significant risk to personal health or public health; and

(c) they know that, or are reckless as to whether, their conduct has that effect.

The AWHC is pleased to see that there are meaningful penalties for non-compliance with the Act, but it remains to be seen if how well these penalties will be applied for non-compliance, and how non-compliance will be established in some cases. Will these penalties apply to individual practitioner versus consumer cases, and will the balance of power still reside with practitioners as is currently the case with complaints to the HDC, where the word of the practitioner carries far more weight than that of the consumer?

We want to see practitioners charged with an offence when they recklessly prescribe medicines or implant medical devices or use non-implantable medical devices (e.g. imaging devices), or do so with insufficient training, skill or competence. Increasing complaints to the HDC and claims of avoidable treatment injury to ACC, and documentation of preventable treatment injury in New Zealand show that, in many cases,

practitioners have recklessly endangered the health of consumers/patients. The HDC complaints system is clearly not reducing or slowing this problem. This legislation and the new Regulator have an opportunity to provide a "fence at the top of the cliff" and ensure accountability and reduce reckless behaviour among practitioners, rather than relying on a complaints system as a deterrent to such behaviour.

250 Offences for misrepresentation about therapeutic product

A practitioner not adequately informing consumers/patients about the risks and benefits, alternatives and side-effects/adverse impacts of a product is tantamount to misrepresentation. Failure to properly inform consumers/patients must be considered misrepresentation. Up until the TPB is enacted and implantable medical devices are forced to obtain market authorisations that impose on them the same standards as medicines, regulation of implantable medical devices remains grossly inadequate. We hope that the inclusion of medical devices in this Bill will ensure that practitioners take more care when recommending devices to patients, particularly regarding risks, benefits and alternatives, and obtaining informed consent. This is equally as important with regard to medicines, but there has historically been far better regulation. However, there are still many individual cases in which the benefits and risks of drugs/medicines have been misrepresented by both practitioners and pharmaceutical companies; consumers might be more willing report such misrepresentation if they knew that there was some penalty for practitioners and suppliers.

272 Considerations for determining amount of civil penalty

In determining the amount of a civil penalty to be imposed on a person, the court must take into account all relevant matters, which may include any of the following:

(a) the nature and extent of—

(b) any loss or damage suffered by any other person because of the contravention:

We are disappointed that if an individual consumer/patient has suffered harm as a result of civil penalty contravention, there is no reparation to the consumer/patient from the payable penalty in a conviction, all of which appears to go to the Crown!

(c) the nature and extent of—

(ii) any loss or damage suffered by any other person because of the contravention:

In **clause (c) (ii)** loss or damage suffered by another person because of the contravention is considered in determining the penalty, but the penalty still goes to the Crown and there are no reparations to the injured consumer/patient.

275 Civil penalty payable to Crown

(1) A civil penalty is payable to the Crown.

(2) However, the court making the civil penalty order may order all or part of it to be paid to the Regulator.

The Regulator gets the money and again no reparations to the injured consumer/patient! While we understand that New Zealand's no fault Accident Compensation Scheme should cover treatment injury, claimants are not always adequately compensated and compensation is often limited. There are many costs involved in responding to and recovering from the many types of harm and/or injury that consumers suffer. Where actions by a practitioner are reckless (for example, breach of consumer rights to information and making informed decisions, misrepresentation of a product) there should be the ability to pay reparations to a consumer as a result of financial penalties imposed upon the person/entity that committed the offence/infringement of the Regulations.

Subpart 7—Enforceable undertakings

289 Regulator may accept undertaking

(1) The Regulator may, on application, accept an undertaking given by a person in connection with an alleged contravention of a provision of this Act (the alleged contravention).
(2) Without limiting what an undertaking may relate to, an undertaking may include undertakings to do any of the following:
(a) pay compensation to any person:
(d) pay to the Regulator the reasonable costs they have incurred doing either or both of the following:
(i) in investigating the alleged contravention

Clause (a) appears to be the only provision in the TPB for compensation to an injured/harmed consumer although that is not explicit, and we do not think this is adequate.

(5) Giving an undertaking is not an admission that the person giving it has committed the alleged contravention.

The AWHC fails to see the rationale for **subsection (5)**. Giving an undertaking as per **subsection (1)** is effectively an admission of having contravened the legislation/regulations, yet **subsection (5)** determines that giving an undertaking is not an admission. Why would a person give an undertaking if they had not contravened the regulations? For example, if a person had not committed a contravention, why would they offer to pay costs to the Regulator for an offence or infringement that they didn't commit.

Part 10
Administrative matters
Subpart 1—Therapeutic products register
363 Therapeutic products register
(1) The Regulator must maintain a therapeutic products register.
(2) The register must include—
(a) all therapeutic products—

The AWHC strongly supports the introduction and implementation of therapeutic products registers. However, it is illogical and unworkable to have a single register for all products – medicines, devices, APIs and NHPs. It would be too large and too unwieldy, and there is no logic in having a single register as the information that would need to be held in each varies significantly for each class of product. There must be separate registers for all four classes of products, and separate registers for implantable and non-implantable medical devices. While all medical devices are in a single class in the TPB, the difference between implantable and non-implantable devices is substantial and very significant in terms of potential for harm and injury.

Consumer advocates who have been working for over a decade to address a range of issues arising from devastating harm caused to New Zealanders by surgical mesh have been calling for a mesh registry for many years. Surgical mesh injury perfectly illustrates the need for an implantable medical device registry.

A 2016 Health Select Committee report, on a petition for an independent inquiry into safety issues regarding surgical mesh, recommended investigating options for establishing and maintaining a centralised surgical mesh registry.[36] The MoH commissioned a benefit:cost analysis for the establishment and maintenance of a clinical quality register (CQR) for surgical mesh. The proposed register would continually monitor and improve surgical outcomes, resulting in lower treatment cost, mortality and morbidity, and had a benefit to cost ration of 3:1.[36]

Surgical mesh is not the only implantable medical device to inflict devastating harm upon health consumers; others include the Essure contraceptive device, breast implants, lung sealant, deep brain stimulators, hip

36 DAE, 2018: Surgical Mesh Registry: Cost Benefit Analysis, Deloitte Access Economics, commissioned by the Ministry of Health, 24 September 2018.

joint replacements, among many others.[37] The is clear evidence that a register for implantable medical devices is critical to ensuring patient safety. In 2018, the UK Royal College of Surgeons said that there must be a compulsory registry of all new implantable medical devices.[38]

There must be the facility in the implantable devices register to enter data for every single device implanted (redacting or anonymising patient data for all but the Regulator). Various device crises and debacles have shown the critical importance of a register that tracks every device and PROMs and notifications of harm.

(3) For each product, licence, permit, or thing, the register must include the information required by the regulations.
(4) The register may include any other information that the Regulator thinks is appropriate (including information about a product or thing that is not required to be included in the register).

These regulations must be robust and thorough, and development of the register and regulations about the information required to be included, must involve consumers from the start. Past regulations on medical devices (Medicines (Database of Medical Devices) Regulations 2003) were woefully inadequate and in part contributed to the surgical mesh crisis, and no doubt have contributed to harm caused by other devices such as Essure and breast implants, among others. The implantable medical devices register must include data on the patient/consumer (redactable/anonymised for all but the Regulator), implanting surgeon/health practitioner, serial numbers, etc. as well as follow-up notes and facility to include PROMs and adverse events/effects related to the device.

(5) The Regulator must make the register publicly available.

We strongly support the registers being publicly available and that availability makes it even more important for there to be separate registers for ease of access and use by the public.

Subpart 2—Applications, notices, etc

Applications

Guidance note

One of the grounds for cancelling a market authorisation, licence, or permit is that the application for it included misleading information. Because of this section, that extends to all information that the applicant gives to the Regulator in relation to the application.

369 Regulator may reject non-complying application

The Regulator may reject the application without considering its merits if—

(c) the Regulator is satisfied on reasonable grounds that any information in the application is misleading information.

Misleading information must be considered to include the omission of material information such as negative findings in clinical trials.

Similarly, grounds for cancelling a market authorisation (see **Guidance Note** above) should include omission of material information, such as negative findings in clinical trials that often is not published in journals, despite attempts by the major journals to stamp out such lack of transparency in clinical trials.

373 Making document or information publicly available

(1) If the Regulator is required under this Act to make a document or other information publicly available, they must publish it—

37 Godlee F, 2018: Why aren't medical devices regulated like drugs? *BMJ* 2018;363:k5032.

38 Coombes R, 2018: Surgeons call for compulsory registers of all new medical devices, *BMJ*; 2018 Nov 26;363:k5010.

The AWHC strongly supports transparency of all activities and functions of the Regulator and particularly supports making documents and information publicly available. Access must be as easy and user friendly as possible and information and documents must be loaded to the Regulators website promptly. The Regulator's website must include a highly functional and comprehensive search facility. The website must be easy to navigate and must be well maintained to ensure that internal links work.

380 Consultation

(1) The Regulator must comply with **subsection (3)** before—
- (a) recommending that the Minister recommend that regulations be made; or
- (b) making any other instrument.

(2) The Minister must not recommend that regulations be made unless satisfied on reasonable grounds that the Regulator has complied with subsection (3).

(3) The Regulator must—
- (a) consult the persons who the Regulator thinks—
  - (i) are likely to be substantially affected by the instrument; or
  - (ii) have knowledge, skills, and experience of any mātauranga Māori that is relevant to the instrument; and
- (b) give them an opportunity to comment.

The AWHC are consumer advocates and advocates of consumer engagement. We strongly believe that ALL consumers have an inalienable right to be involved at ALL levels of the health system, in line with the Pae Ora (Healthy Futures) Act 2022, and promises made by the New Zealand Government that the "new" health system would be a people-centred one.

We advocate that approach in the Therapeutic Products legislation as it will affect every New Zealander over the course of their lives.

The wording of **Section 380 Consultation** is concerning because it relies on the Regulator determining who will be affected by any regulations rather than taking the standpoint that ALL New Zealander may be affected and are entitled to be consulted. Limiting consultation is contradictory to the intent of the Pae Ora (Healthy Futures) Act 2022. It is not consumer-centred to have any Government agency, including the new Regulator, decide who should or should not be consulted. Ideally consumers should be involved in developing the rules and regulations to ensure that consumer safety is paramount. At the very least, in the same manner this proposed legislation is currently open to public consultation and feedback, it is vital that the secondary legislation and regulations and rules are too.

(5) However, the Regulator need not comply with subsection (3) if satisfied on reasonable grounds that making the instrument without consultation is necessary because of a risk to any individual of death, serious injury, or serious illness.

It is difficult to see how **subsection 5** could apply. We can only see this applying in instances of an emergency response, and even then a level of consumer consultation or engagement through consumer representatives should be undertake if at all possible.

Subpart 4—Review of Act

382 Minister must review Act

We strongly agree with a regular review of the Act and believe that consumer engagement is vital in these reviews. Consumer groups/key consumer stakeholders should be invited to participate in the review and to provide feedback.

Subpart 2—Amendments to Health Practitioners Competence Assurance Act 2003

If the Therapeutic Products Act is to cover NHPs then registered naturopaths, medical herbalists and homoeopaths should be listed as health practitioners under the Health Practitioners Competence Assurance Act 2003, and recognised as experts in natural health products in both the Therapeutic Products Act and Health Practitioners Competence Assurance Act. It is completely illogical to exclude those trained practitioners who are experts in NHPs, and who prescribe/recommend them to their clients. This Bill recognises and defines pharmacists, who may sell NHPs without any NHP training, yet natural health practitioners are effectively ignored. They are essentially only mentioned once in the context of personalised NHPs (**Section 112**) yet the products that are an integral part of their practice are heavily regulated in this Bill.

Subpart 3—Medicines Act 1981

397 Long Title repealed

Repeal the Long Title.

398 Section 1 amended (Short Title and commencement)

In section 1(1), replace "Medicines" with "Pharmacy Ownership".

As we have stated previously (see General Support for the Therapeutic Products Bill starting on page 5), we believe it is ludicrous to repeal almost the entirety of the Medicines Act 1981 because it will be superseded by the Therapeutic Products Act, then rename it and retain only the parts relating to Pharmacy Ownership, while all the legislation relating to the medicines and NPS that pharmacies dispense and sell is contained in the Therapeutic Products Act. It makes no sense at all and the legislation relating to Pharmacy Ownership should be shifted to the Therapeutic Products Act.

Schedule 1

Transitional, savings, and related provisions

Subpart 1—Market authorisations

Consents under 1981 Act

2 Standard consent becomes standard authorisation

(1) This clause applies to a therapeutic product that was a medicine under the 1981 Act and is a medicine under this Act.

(2) If the medicine has an existing standard consent, on commencement it becomes a standard authorisation for the medicine.

(3) If a new standard consent is given for the medicine, it becomes a standard authorisation for the medicine immediately after the consent is given or taken to have been given.

(4) A standard authorisation created by this clause,—

(a) applies to the medicine as described in the consent; and

(b) authorises the medicine for the purposes or indications described in the consent; and

(c) is taken to have been issued to the applicant for the consent (who is therefore the sponsor of the medicine); and

(d) has the same expiry date (if any) as the consent had (or, for a new standard consent, would have had) under the 1981 Act ; and

(e) is subject to all of the conditions (whether relating to the medicine or the sponsor) to which the consent was (or, for a new standard consent, would have been) subject under the 1981 Act.

We are concerned about the situation if the regulations for a standard authorisation are more stringent than the original standard consent. For the protection of consumers, we expect that sponsors of medicines must comply with the new regulations and there would be a "sunset" period during which all consents are made provisional or temporary authorisations and must be reviewed and standard authorisations issued only if they comply. If they did not comply within the "sunset" period then provisional or temporary authorisation would be cancelled and no authorisation given until they did comply.

10 Medical devices listed under 1981 Act: temporary market authorisation created

We are very concerned about this section of the Bill. This provision offers little to no protection to consumers from harmful devices; it in effect ensures that harmful devices continue to have authorisation for use for some time (perhaps years). It is well known that, both in New Zealand and internationally, implantable medical devices are grossly under-regulated and not subject to the same standards of safety, quality and performance as medicines (see The Critical Need to Properly Regulate Medical Devices, page 17).

The transition period allowed by this Bill effectively gives health practitioners *carte blanche* to continue using harmful devices, such as surgical mesh, because such implantable devices will automatically be given a temporary market authorisation. This Bill may not come into force until the 1st of September 2026, to allow for time for the secondary legislation to be developed. Therefore, under clause **3 (d) (i) of Section 10**, the temporary market authorisation for a medical device that was a medical device under the 1981 Act, and under Medicines (Database of Medical Devices) Regulations 2003, will have up to three years before that temporary market authorisation expires. Thus, consumers will conceivably have to wait another six and a half years from now (March 2023) to see implantable medical devices that are sufficiently regulated to give some assurance of safety. The *status quo* on implantable medical devices effectively continues until September 2029!

The AWHC submit in the strongest possible terms that this provision MUST be amended! There MUST be recognition that implantable medical devices are already substantially improperly regulated and, as a result, inflict considerable harm on New Zealander. There MUST be the enactment of stopgap or temporary legislation or regulation that covers those medical devices already identified as causing harm and provide for an immediate reassessment of their safety, quality and performance, or force them to be withdrawn until such time as they can undergo a full market authorisation under the new Act.

Summary of Recommendations

Key Considerations

1. That the therapeutic Products Act honours and empowers Te Tiriti o Waitangi and the articles of Te Tiriti as is the case in much recent legislation and health agency and Government documents. This should be included in **Part 1 Preliminary Provisions.**

2. That medicinal cannabis products are treated like any other therapeutic product and are included in the Therapeutic Products legislation either as NHPs or medicines and that they are removed from the Misuse of Drugs Act 1975 Psychoactive Substances Act 2013.

3. That the Medicines Act 1981 is completely replaced by the Therapeutic Products Act with the inclusion of legislation and regulation to do with pharmacy ownership together with the legislation relating to pharmacy and supply of medicines already in the TPB.

Consumer Rights and Consumer Representation

4. That the secondary legislation be made available for public consultation and feedback as it is developed and written.

5. That the new Therapeutic Products Regulator be required to be a signatory to, and act in accordance with, the Code of Expectations for health entities' engagement with consumers and whānau, as required by other health entities under sections 59 and 60 of the Pae Ora (Healthy Futures) Act 2022, and report annually on how it has given effect to the code.

6. That the new Therapeutic Products Regulator be required to engage with and consult with consumers where any consultation is required, including in reviews of the Act, the strategy and recovery of costs.

7. That the Code of Health and Disability Services Consumers' Rights (under the Health and Disability Commissioner Act 1994), be acknowledged in the Therapeutic Products Act, particularly when it comes to issues such as the provision of information about therapeutic products to enable consumers to make informed decisions, and participation in clinical trials.

The Therapeutic Products Regulator

8. That the new Therapeutic Products Regulator, as an independent health entity, be required to present an annual report to Parliament and to the New Zealand public/consumers, as is the case with other such agencies, such as the Health and Disability Commissioner.

9. That there be the establishment of an independent body for the investigation and arbitration of complaints about the Regulator and that both applicants (sponsors, licence/permit seekers) and consumers should be able to lodge complaints about the performance of the Regulator to this body.

10. That regular reviews of the Therapeutic Products Act, the strategy for performance of functions and exercise of powers of the Regulator, and of the recovery of costs, include engagement and consultation with consumers.

11. That the Regulator is adequately resourced (financially and in terms of staffing and expertise), beyond recovery of costs to ensure independence from commercial entities and that public safety is paramount.

12. That the Therapeutic Products Regulator and existing health entities and entities involved with collecting information on patient safety and treatment injury, including but not limited to ACC, HQSC, MoH, and HDC be required to share information, including notifications of harm and PROMs, to ensure proper surveillance and monitoring of the safety of therapeutic products.

13. That Advisory committees (**Section 347**) include consumer representations with lived experience, including multiple consumers on any given advisory committee and/or at different times depending on the products that the Regulator requires advice on.

14. We are concerned about the possible use of automated systems and the blasé way in which the proposed legislation addresses this (**352 Use of automated systems** and **353 Effect of use of automated system**). It is not clear in the TPB what sort of evaluations an automated system would undertake. We believe it should only apply to very low-level applications, such as minor changes to medicines and devices, like packaging, data safety sheets, additional information, minor dosage changes, etc.

15. That **352 Subsection 2** be rewritten to read "If the system carries out the action in a way that is clearly incomplete or wrong, the action MUST be completed or redone by the Regulator.

16. That any automated systems are regularly audited to ensure that they are working properly and delivering the same or better outcomes as the Regulator.

17. That consumers, consumer groups or other stakeholder be able to seek a review of the Regulators decisions (**Section 357**) including an appeal to the District Court (**Section 361**).

18. That an independent person or body appoint the review panel **(Section 358**) to avoid conflict of interest, and that review panels include consumer representatives.

19. That the review panel may consider all material information (**Section 359)**, including new information or information withheld in the original application when undertaking a review of decision made by the Regulator.

Patient Safety

20. That proof of a sponsor's robust surveillance and response system MUST be required by the Regulator before a product is authorised and there MUST be a statutory reporting system in which the sponsor reports to the Regulator on their surveillance and monitoring.

21. That the Regulator's surveillance and monitoring system is well resourced to ensure that it is robust, effective and thorough, and collects notifications of harm and PROMs (patient reported outcome measures).

22. That we have a compulsory reporting system that requires of practitioners to report adverse effects and harm when patients report it.

23. The surveillance and monitoring system must include a relationship with, and information sharing between, the Regulator and other agencies including HQSC, HDC and ACC.

24. That consumers/patients or their whanau can report harm to the surveillance system.

25. That the Regulator's response to notifications of harm is swift and errs on the side of caution, and that regulations enable the Regulator to quickly and easily suspend use of a product followed by a thorough investigation of a product's safety before a decision on continued use or prohibition of a product is made.

Regulating Medical Devices

26. That there are stringent regulations that ensure the safety of implantable medical devices, including robust surveillance and monitoring, collecting and collating notifications of harm and PROMs, and the ability of the Regulator to respond swiftly and err on the side of caution to protect consumers from harm.

27. That **Section 10** of **Schedule 1 (Transitional, savings, and related provisions)** be substantially rewritten for implantable medical devices, to enact stopgap or temporary legislation or regulation that covers those medical devices already identified as causing harm and provides for an immediate reassessment of their safety, quality and performance, or withdraw them from the market until such time as they can undergo a full market authorisation under the new Act.

28. That that medical practitioners/surgeons who implant medical devices be required to prove competency in doing so. There must be a valid education and training pathway to ensure that competence, which includes mentoring, proctoring and oversight by an experienced and competent practitioner, before credentialling for specific procedures.

Regulation of Natural Health Products

29. That natural health products (NHPs) be removed from this Bill and be regulated through a new Bill.

30. That if NHPs remain in the Therapeutic Products Bill, a natural health practitioner is defined and recognised.

31. That if NHPs remain in the Therapeutic Products Bill that the wording of many of the sections, subsections and clause be rewritten to ensure that New Zealanders can continue to maintain their own health and

well-being through foods and plants that also have therapeutic value, in the way in which such activities have been undertaken for thousands of years.

32. That if NHPs remain in the Therapeutic Products Bill that regulations explicitly exclude consumers making their own natural therapeutic products for their own use and the use of family/whānau and friends in a manner that does not constitute carrying on a business, being considered as manufacturing an NHP or carrying out a controlled activity, or any activity that would might require a authorisation, licence or permit for the purposes of the legislation.

33. That the Health Practitioners Competence Assurance Act 2003 be amended to recognise registered naturopaths, medical herbalists and homoeopaths as health practitioners.

34. That the Health and Disability Services (Safety) Act 2001 be amended to recognise registered naturopaths, medical herbalists and homoeopaths as providers of health and disability services.

Direct to Consumer Advertising

35. That direct-to-consumer advertising of prescription medicines is prohibited.

Regulations that are Contradictory, Vague, Poorly Worded

36. That the TPB is amended to remove unnecessarily vague (or circular in nature) and contradictory language, as far as possible removes language that is highly subjective, and as far as possible removes language that would permit regulation to be developed or enforced in a less than transparent way, or that leads to rules and regulation that give rise to unintended consequences.

Specific Recommendations Section by Section (not covered above)

37. That a further principle should be included in **Section 4 Principles guiding exercise of powers under Act**: a statement that the Act should be administered "in an open, transparent and inclusive manner."

38. That clinical trials **Section 10 Controlled activities** are better regulated than currently, particularly around requirements regarding transparency of clinical trials and reporting of results, with monitoring of compliance.

39. That **Section 29 NHP** be clarified regarding therapeutic products that are currently administered by injection or parenteral infusion, such as IV vitamin C IM B12 injections and iron infusions. All meet the definition of NHPs but are administered by injection or parenteral infusion (also clarify **Section 71**).

40. That **Section 30 NHP ingredient, recognised NHP ingredient**… be clarified to explicitly exclude foods that have a therapeutic value, such as herbal teas and foods such as garlic, Brazil nuts, etc. that people consume for both dietary and therapeutic purposes.

41. That with regard to Section 63 **Product standards, subsection 2 (f)**, the regulations ensure that consumer information is thorough and complete and include all safety data; that product information for practitioners and consumers be updated regularly, particularly to amend for contraindications, drug interactions and adverse effects/events; for drugs and devices, product information errs on the side of caution and the Regulator issues comprehensive and timely warnings about adverse effects and enforces clear warnings on packaging and to prescribers (medicines) and surgeons (implantable devices) and their regulating bodies (medical colleges and vocational associations).

42. That implanting an implantable medical device is included as a controlled activity in **Section 63** in the same way that prescribing, dispensing, administering and possessing a prescription medicine is a controlled activity.

43. That regulations around product information consumer information, identification and labelling of therapeutic products (**Section 72 (1) b & c**) take account of people living with disabilities, such as low vision or those for whom English is a second language.

44. That when prescription medication repackaged by a pharmacist into plain packaging, that pharmacists to supply all original consumer information and warnings (**Section 72 (1) c**).

45. That **Section 73** include competency and training (credentialing) of surgeons implanting medical devices.

46. That vending machines dispensing medicines (**Section 75**) be removed entirely from the legislation or expressly banned in the legislation.

47. That if a market authorisation is ceased (**Section 113**) for patient safety/risk of harm reasons the remaining stock is prohibited from being used, and it is recalled.

48. That provisional authorisation (**Section 117**) is only used in extenuating circumstances; that post-authorisation surveillance is extremely rigorous; submission of reports of harm notifications is mandatory; there is active and effective collection of PROMs to ensure consumer safety; and the Regulator moves immediately to suspend authorisation upon reports of harm. In addition, consumers MUST be fully informed of the provisional status and why the product does not have standard authorisation.

49. That the wording of Section **119 Evaluation of medicine or medical device Subsection 3** is amended to read: "In evaluating the product, the Regulator MUST (without limitation) have regard for the following…"

50. That giving of gifts, offers and inducements (**Section 195**) by a health-related commercial entity to health practitioners is entirely prohibited; that all gifts, offers and inducements are considered improper.

51. That the provisions in **Section 209** permitting inspectors to enter a treatment room or consulting room while a patient or client is present, is actively reviewed to ensure that harm is not caused to patients, and any instances where such action was deemed necessary subjected to rigorous scrutiny.

52. That **Section 210** be rewritten to explicitly include reference to and compliance with the Privacy Act 2020.

53. That **Section 223 Compliance with product moratorium order**, be supported with adequate regulations regarding educating practitioners about compliance and follow-up, and enforcement to ensure that practitioners are aware of and adhere to the moratorium, especially if they retain stock of the product.

54. That a practitioner not adequately informing consumers/patients about the risks and benefits, alternatives and side-effects/adverse impacts of a product is considered as misrepresentation (**Section 250**) and regarded as an offence.

55. That consumers/patients that have suffered harm as a result of civil penalty contravention, are entitled to reparations where financial penalties are imposed (**Sections 272 & 275**).

56. That there be a separate register for each class of therapeutic product, and a separate register for implantable and non-implantable medical devices (**Section 363**).

57. That the register (**Section 363**) for implantable medical devices include data on the patient/consumer (redactable/ anonymised for all but the Regulator), implanting surgeon/health practitioner, serial numbers, etc. as well as follow-up notes and facility to include PROMs and adverse events/effects related to the device.

58. That the definition of misleading information (**Section 369**) includes the omission of material information such as negative findings in clinical trials.

Appendix

One of the Auckland Women's Health Council's greatest concerns regarding new legislation to govern and regulate therapeutic products is that implantable medical devices are finally robustly regulated in New Zealand and that the risk of harm to New Zealanders is significantly reduced.

Over the last five years we have written and published a number of articles about surgical mesh specifically and implantable medical devices generally. The surgical mesh crisis in this country, in which thousands of New Zealanders, predominantly women, have been harmed, many absolutely catastrophically rendering them disabled, has been a concern that never been far from front of mind and we have played an active role in advocating for mesh injured and in effecting change that would prevent such a crisis occurring again in New Zealand.

The importance of what has happened with surgical mesh cannot be underestimated in the context of the therapeutic Products Bill. Our current utterly inadequate regulatory regime for implantable medical devices means that another medical device disaster like surgical mesh is just waiting to happen.

We have cited the international research on the laxity of medical device regulation globally (see The Critical Need to Properly Regulate Medical Devices page 17). Additionally, we provide this appendix on the international regulation of medical devices to provide background. We have expressed our significant concern that the Therapeutic Products Regulator will place any reliance at all on devices regulated overseas because the regulation of devices elsewhere is as bad, if not worse than the current regulation of devices in New Zealand. It is vital that the inadequate regulation of devices is understood so as to ensure we do not continue to make the same mistakes under the new Therapeutic Products Act and new Therapeutic Products Regulator. We MUST have a system that protects New Zealanders from harm. Understanding why the current regulation of implantable medical devices does not and cannot do that is critical to implementing a better regulatory regime here now.

The text below is reprinted, with permission, from an as yet unpublished paper by Professor Joanna Manning, Professor of Law at the University of Auckland and who specialises in medical ethics.

Regulation of medical devices

International,

A. Inadequate pre-market and post-market Regulation of medical devices worldwide, especially in NZ FDA and EU pre-marketing – equivalence

Pharmaceutical drugs and implantable MDs are both designed to be used inside the human body. Many such devices are designed to be permanent. Further it can be very difficult to discontinue their use if problems arise, unlike drugs. But devices are much less rigorously examined before they are first marketed. Pharmaceutical medicines have to pass rigorous Phase I, II and III randomised controlled trials (RCTs) before being able to be sold on the market. It is, however, most unusual to submit clinical trial data in support of submissions for pre-market approval of devices. No clinical trials were required or carried out on surgical mesh in North America, Europe, Australia, or New Zealand before their introduction. This makes post-market surveillance more important in detecting problems, but that system too is inadequate.

FDA 510(k) clearance

There are two main avenues for MDs to be sold on the market legally in the US, "approval" and "clearance."[39] Some classes of device have to be approved, rather than cleared. Under the first, a manufacturer applies for Pre-market Approval (PMA) by submitting detailed information of the results of laboratory studies and "clinical investigations involving human subjects" i.e. randomised clinical trials, as well as manufacturing processes.[40] The FDA assesses its safety and effectiveness in terms of the statutory requirements ("reasonable assurance of its safe and effective performance").[41] It is applicable to class III devices, which pose the highest risk. Only approx 1 percent of MDs receive a PMA. MDs with PMA are entered onto the PMA database, which is publicly accessible and searchable.

The other route is the 510(k) pathway, which allows manufacturers to fast-track FDA approval without having to conduct expensive and time-consuming testing and randomised clinical trials. The FDA's commitment is that the product will be "cleared" for sale within 90 days of application. The basis for clearance is the manufacturer demonstrating "substantial equivalence" of the new device to that of an already legally marketed ("predicate") device for the same intended use. The purpose of the 510(k) process is not to assess safety and effectiveness, but simply to determine whether the FDA agrees with the manufacturer's claim that the device is substantially similar to a predicate device already on the market. Technically the 510(k) process is intended for moderate-risk (class II) devices, but some risky class III devices are determined to be class II because the manufacturer is able to demonstrate substantial equivalence. The vast majority (between 95 and 98 percent) of medical devices used on patients on sale in the US received clearance through the 510(k) process with the result that they have never been used on a single patient and have received little government scrutiny.

In 1997 the FDA cleared Boston Scientific's ProteGen Sling via the 510(k) pathway, as the first polypropylene transvaginal mesh device for the treatment of SUI. It did not undergo any clinical trials, but was based on a 90-day animal study on rats and to the fact that the mesh was already being used for cardiovascular grafting. Boston Scientific nominated five nominated predicate devices, four of which were not made of polypropylene and all of which had been used only for abdominal hernia repair, a different surgery performed on tissues with different characteristics.[42] In 1999 Boston Scientific recalled the ProteGen because "catastrophic" injuries: high rates of vaginal erosion, bleeding ulcers, pain and infection.[43] But before its recall, the FDA cleared several other mesh products based on it as a predicate device, including Johnson and Johnson's TVT device. Its recall did not prompt the FDA to review those decisions.

Thus, from 1998 gynaecologists started implanting transvaginal placed mesh to repair SUI and then POP without evidence from clinical trials of its safety and effectiveness, on the assumption that it was safe and probably more effective than traditional native tissue repair. It was only a matter of **months** before this assumption was shown to be disastrously wrong. Gynaecologists began reporting adverse events with the

39 Low risk Class I devices, such a bedpans and tongue depressors, are generally exempt from the regulatory process and can be marketed without receiving FDA clearance. Manufacturers of class I devices must register them and list their generic products with the FDA.

40 See Title 21 of the Code of Federal Regulations, part 814.20(v)(B)

41 Food, Drugs and Cosmetic Act, s 514(2)(A).

42 Boston Scientific Corp, 510(k) Summary of Safety & Effectiveness (Aug 12, 1996).

43 K Kobashi et al, "Erosion of woven polyester pubovaginal sling" (1999) 162:6 *J Urol* 2070; L Lewis Wall & D Brown, "The perils of commercially driven surgical innovation" (2010) 202:1 *Am J Obstet & Gyne* 30.

placement of transvaginal mesh to the FDA soon after clearance. These included erosion into the vagina, severe vaginal pain, dyspareunia (decreased sexual interest). As expert commentators stated in JAMA:[44]

> The approval of surgical mesh through [the 510(k)] pathway for the transvaginal repair of POP is an excellent case study of the adverse consequences of requiring only proof of substantial equivalence for the marketing of medical or surgical devices.

Pre-market certification in the EU

At the heart of EU regulation of medical products is a tension between facilitation of trade and the needs of the internal market, and achieving product safety.[45] Europe is said to have some of the lightest regulations on MDs in the developed world. Even though US manufacturers dominate the industry worldwide, and the US is the largest market for sales, many companies choose to trial their new devices first in Europe.[46] One reason for its attractiveness is that MDs are approved for use on the market on average three years before they are in the US.[47]

The pre-market approval system in the EU, which included the UK until Brexit, is subject to a very similar flaw to the FDA's 510(k) process, but has the additional weaknesses of decentralisation and the use of private profit-driven companies called Notified Bodies (NBs) as the backbone of the regulatory process. The regulation of MDs started in June 1998, later than for pharmaceutical drugs. The process is more decentralised than that for drugs, which is overseen by a centralised authority, the European Medicines Agency (EMA). Until recently MDs were regulated by three directives, which were enacted into each member's national law. The Medical Devices Directive (93/42/EEC) governed surgical mesh products. (In 2017 a new Medical Devices Regulation, in effect from …, replaced the Directives).

MDs are not licensed, but are instead "certified" by means of a "CE mark" to show conformity with "essential requirements" set out in the Directives that apply to every medical device whatever its class. These essential requirements are a set of safety and quality standards for how a device must perform and be produced, designed to protect the health and safety of patients. If a device meets the essential requirements, it can be CE Marked by the manufacturer and distributed in any member state without further barriers to trade.

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44 V Jacoby & L Subak, "The FDA and the vaginal mesh controversy — Further impetus to change the 510(k) pathway for medical device approval" *JAMA*, 2016: 176:2, 277.

45 See C Hodges, "Do we need a European Medical Devices Agency?" (2004) 12:3 *Med L Rev* p 268.

46 S Bowers, "How Lobbying Blocked European Safety Checks For Dangerous Medical Implants" International Consortium of Investigative Journalists (ICIJ), Nov 25, 2018, reporting on the key findings of a year long A year-long investigation by the ICIJ and 58 news organizations in 36 countries, known as the Implant Files: https://www.icij.org/investigations/implant-files/how-lobbying-blocked-european-safety-checks-for-dangerous-medical-implants/

47 Although the 3 year time difference compared MDs approved the FDA's PPMA pathway (not the 510(k)) pathway, and devices approved first in the EU were associated with a 2.9-fold greater rate of safety alerts and recalls than devices approved first in the US, see T Hwang et al. "Comparison of rates of safety issues and reporting of trial outcomes for medical devices approved in the European Union and United States: cohort study" *BMJ*. 2016;353:i3323. Available from: http://www.bmj.com/content/353/bmj.i3323

It is a "risk-based classification scheme," in that the essential requirements differ according to the risk posed by the device. Risk is determined by its use, whether it is invasive, and the length of time it is in contact with the body. Devices are classified into one of four classes: lowest risk (Class I), which do not interact with the body and can be self-certified by the manufacturer, for example, plasters, bedpans. The other three classes require a certificate of conformity from what is called a "notified body." These are medium risk (Class IIa), devices which interact with natural orifices, e.g. hearing aids; medium risk but with potential for high risk (Class IIb), which includes most surgically active devices, either partially or fully implantable, e.g. ventilators and mesh products; and high risk (Class III), which include devices which support/sustain life, significantly prevent health impairment or have high potential to cause illness/injury, e.g. heart valves, breast implants.

Each state designates a "competent authority", the official government regulator, which oversee operation of the Directives and the accreditation and designation of the NBs, to whom the role of performing the conformity assessments is delegated. The critical point about these is that they are not state regulators, but third-party private companies. Though NBs must be independent of manufacturers, they have a contractual relationship with the manufacturer that submits an application to and pays for it. NBs compete with each another in that a manufacturer can submit an application to any accredited NB in any member state. The involvement of NBs has long been highly controversial, with concerns about insufficient medical knowledge; inconsistency in the standards applied, permitting unscrupulous manufacturers to "forum shop" for a less stringent NB; variable oversight by CEs; and NBs improperly assisting manufacturers to achieve approvals.[48] For example, in 2015 a Dutch undercover journalist and an Oxford University expert in evidence based medicine, exposed the laxity of the regulation of MDs when they received tacit approval from an Austrian NB of a fake application to market mesh netting normally used in bags for mandarins as an implantable medical device.[49]

Under the Directive MDs could be certified in two ways: either by "clinical investigations," which are full pre-market scientific and clinical testing to establish safety and performance ("full quality assurance"); or in a similar pathway to the FDA's 510(k), by "clinical evaluation reports," which consists only of a review of the published literature on clinical experience with the device or a similar device already in use. If the latter, the report contains a statement as to how the device is "equivalent" to the predicate device. "Equivalent" was undefined in the Directive and is left to the NB and the manufacturer to determine. As a result certification could be based on minimal clinical evidence.

The 510(k) route has been subject to much criticism. In 2011 an Institute of Medicine report described the 501(k) pathway as "flawed" so long as it was premised on substantial equivalence.[50] Less than 1 percent of 510(k) applications submit clinical data to support substantial equivalence claims.[51] The 510(k) process determines only the substantial equivalence of a new device to a previously cleared device, which can be built on a chain of predicates dating back to devices already on the market in 1976 before the FDA's existence, not the new device's safety and effectiveness or whether it is innovative.[52] While the most frequently used pathway and despite a very high frequency of findings of substantial equivalence (approx. 90 percent),[53]

48 C Hodges, "The regulation of medicinal products and devices' in J Laing & J McHale, *Principles of Medical Law* (OUP, 4th ed 2017), pp 889-950; J McHale, "Health law, Brexit and medical devices: A question of legal regulation and patient safety" (2018) 18 *Med L Int'l* 195, p 201.

49 L Rogers, "Scandal of fruit mesh 'approved as surgical implant'" *The Sunday Times*, 11 January 2015.

50 Institute of Medicine report, Conclusion 7-1, p 5: https://doi.org/10.17226/13150 See also ICIJ egs of ….

51 Huerta S, Varshney A, Patel PM, Mayo HG, Livingston E, "Biological Mesh Implants for Abdominal Hernia Repair: US Food and Drug Administration Approval Process and Systematic Review of Its Efficacy" *JAMA Surg*. 2016 Apr; 151(4):374-81.

52 Institute of Medicine report, Findings 4-1 & 4-2, p 91.

53 Institute of Medicine, *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years* (Washington, DC: The National Academies Press, 2011): https://doi.org/10.17226/13150, p 86.

devices cleared via the 510(k) process are 11.5 times more likely to to be recalled than the 1 percent of devices subject to the PMA process.[54]

The following criticisms of pre-market approval based on equivalence apply to both the US and EU systems:[55]

- Unpublished safety issues with the predicate device. One of the most controversial weaknesses, as the ProteGen Sling case shows, is that substantial equivalence can be based on a predicate device known to have design flaws or to be associated with patient injuries until the predicate is removed from the market.
- Lack of incentive for the manufacturer to explore safety issues with the predicate device, when a new device does not require a new approval but can be based on equivalence;
- No or minimal level of safety and efficacy data necessary or evaluated for clearance/certification, compared markedly with the type and extent of clinical trial data required for new drugs;
- Equivalence claimed to device when the new device is made from a different material or is implanted in a different manner or used in a different part of the body;[56]
- No requirement that the predicate device be CE marked or sold in the EU;[57]
- "Product creep" i.e. a chain of devices certified based on equivalence to the previous one, so that after several years, the approved device bears little resemblance to the to the original one;
- No automatic recall or review of a subsequent equivalent device when a predicate device has been withdrawn from the market for safety reasons.
- Regulators find it very difficult to judge if a device is "equivalent" to another on the market

In a 2012 report the House of Commons Science and Technology Select Committee concluded that as a result of these flaws, the system of "equivalence'" and the acceptance of studies of other devices reported in the scientific literature were "one of the main drivers of poor quality under-researched devices on the market today."[58] The implications of this for patients (and their surgeons) were starkly spelled out by two US physicians writing around the same time, "we are operating under 'a rule of caveat emptor:' Let the buyer beware, rather than the kind of careful scientific scrutiny that the public health demands."[59]

Post-market surveillance in the US and EU

Because, it is said, pre-market RCTs are not feasible or possible for MDs, robust post-market surveillance is essential to monitor device safety. Safety issues come to light more often only once the device is being used in patients. But here too systems are insufficiently rigorous. Experts have said that the essential elements of post-market surveillance are "early warning systems, gathering of data and registries" to track devices and patients[60] Against this standard, the latter were and remain non-existent, and the other two systems confer insufficient protection.

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54 Drugwatch, FDA 510(k) Clearance Process

55 *First Do No Harm: The report of the Independent Medicines and Medical Devices Safety Review* (2020), paras 5 & Annex H, para 3.14.5; J McHale, "Health law, Brexit and medical devices: A question of legal regulation and patient safety" (2018) 18 *Med L Int'l* 195, pp 200-201.

56 The TV T-O is implanted differently to the TVT; yet was certified as equivalent to it.

57 For example, Ethicon's TVT certification was based on equivalence to Boston Scientific's ProteGen sling, despite the fact that the latter was not CE marked nor sold in the EU, and was later recalled in the US, see First Do No Harm, para 5.114.

58 House of Commons Science and Technology Select Committee, *Regulation of Medical Implants in the EU and the UK* (5th Report of Session, 2012, HC 163), para 26.

59 L Lewis Wall & D Brown, "The perils of commercially driven surgical innovation" (2010) 202:1 *Am J Obstet & Gyne* 30.

60 Head of the British Standards Institute, quoted in House of Commons Science SC, p 27.

No record of devices used in a patient, and so when a recall is issued or problems arise, limited ability to trace patients

The FDA relies largely on passive surveillance of reports to a publicly accessible and searchable database of adverse events (deaths and serious injury) and device malfunctions reported to it called MAUDE. Manufacturers must report adverse events ("vigilance reports") and facilities like hospitals must report deaths, but reporting is voluntary by surgeons and patients. Although often critical in bringing problems to light, reported adverse events are estimated to be a small fraction of total actual adverse events. And, until the practice was stopped in June 2019 due to criticism, some serious injuries and malfunctions could be reported by manufacturers via a non-public reporting system called Alternative Summary Reporting, although deaths and unusual adverse events had to be reported to MAUDE. The IOM found many problems dogged the reporting system, such as insufficient information and investigation by manufacturers, and delayed FDA review. IOM found substantial weakness in the FDA's post-marketing surveillance of medical devices with a resulting lack of useful, consistent, and reliable data which made it impossible to confidently draw broad conclusions about the safety and effectiveness of products on the market.[61] The FDA has a wide variety of active tools available, such as device tracking and requiring manufacturers to carry out clinical surveillance studies. But the IOM found that where it discovered violations of the law or products that pose unacceptable risks to consumers, it used these "sparingly" to remedy the situation and to sanction the violators. [62]

In the EU there is a lack of transparency of information relating to both pre-market approval and post-market surveillance. Reporting of serious adverse events, similarly mandatory for manufacturers and voluntary for health professionals and patients, is described as "undertaken with variable rigour."63 Importantly, there is no central device registration and reporting database across the EU comparable to MAUDE. Each member state's regulator is currently responsible for their own. None are publicly accessible. It is up to manufacturers to decide what information is released to the public. NBs cannot make information public. In 2012 the MRHA stated that:[64]

> Very little information is available about a medical device throughout its lifetime – clinical evaluations, conformity assessment, adverse incidents and post-market surveillance plans, for example, are generally not published.

It is therefore very difficult for clinicians and patients in the UK and EU to get reliable information on a device. The EUDAMED database, long delayed and now due for launch in mid-2022, is being developed as a central devices registry to remedy this. It will record the evaluations by notified bodies and vigilance data: serious incidents and the manufacturer's analysis of them, its corrective actions, and trend reporting of increased frequency or severity of incidents. The MHRA pressed for this information to be in the public domain, but the new Regulation only allows for "appropriate levels of access to the electronic system" by health professional and the public. [65] The European Commission has admitted that adverse event and malfunction reports are likely to be kept confidential, because of manufacturers' commercial sensitivity, exactly as lobbied for by the industry.[66]

61 IOM report, Finding 5-2, p 129.

62 IOM report, Finding 5-4, p 133.

63 House of Commons Science SC, p 28.

64 House of Commons, para 37.

65 First Do No Harm, para 5.111; Article 92, para 3 of the EU Regulation 2017.

66 S Bowers, ICIJ

International Reform

For example, a growing number of scandals (PiP silicone breast implants, the metal-on-metal hip implant, surgical mesh), rejections and product withdrawals from the market led to a new EU Regulation, which require greater clinical evaluation and stricter pre-market review of higher risk devices such as Class III implantable devices than previously occurred under the applicable Directives.