Auckland Women's Health Council

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

The Auckland Women's Health Council wishes to register its opposition to the Repeal of the Therapeutic Products Act, in the strongest possible terms.

The passing of the Therapeutic Products Act 2023 (TPA) into legislation was accompanied by the hopes and dreams of health consumers that we would have a system that would both keep us all safer from the harms that come with medical care, plus access to the best that the pharmaco-medical industry has to offer.

Repealing the TPA in its entirety is shortsighted and tantamount to "throwing the baby out with the bath water". It would have been possible to amend the TPA and, after widespread consultation, remove those parts of the Act that the coalition Government still did not believe were fit for purpose. This would have enabled retention of the important parts of the TPA that would have offered New Zealanders better protection from harmful products, and replaced the 43-year-old Medicines Act 1981 to ensure that significant developments in medical technology and practice were covered.

While there were many failures and inadequacies in the Act that was finally passed, it did represent a step towards an improved regulatory environment that would ultimately improve patient safety.

We are most concerned with the complete lack of regulation of implantable medical devices. Lifecycle regulation of implantable medical devices is critical given short term safety studies and follow-up, as they may, and often do, cause harm many years after implantation.

Implantable Medical Devices

One of two greatest concerns with the TPA as it was enacted, was the transitional provisions in the Bill that ensured that we would have to wait another six and a half years from when the Act was passed in Parliament before sponsors of implantable medical devices were held accountable for the lack of safety of their products. In our submission on the Therapeutic Products Bill, we said that it was vital that we have temporary legislation or regulation that covered those medical devices already identified as causing harm, and provision for an immediate reassessment of their safety, quality and performance, or force them to be withdrawn until such time as they can undergo a full market authorisation under the new Act.

However, in the TPA at least we had a piece of legislation that had the potential to offer improved regulation of implantable medical devices, albeit one we had to wait some time for. With the repeal of the TPA, New Zealanders are back to square one with a system that allows defective, faulty, poorly studied implantable medical devices to be registered on the WAND database and implanted in people that believe that the Government and its health agencies ensure their safety from harm. It may take years to develop and

enact new legislation to replace the Medicines Act 1981, meanwhile New Zealanders continue to be harmed by medical devices that have been inadequately regulated around the world.

Under our current legislation and regulations, Aotearoa New Zealand substantially accepts implantable medical devices based on approval by the FDA. Here, Medsafe only carries out the bare minimum of evaluation of medical devices. The only requirement is that the manufacturer or importer lists it electronically on Medsafe's WAND (Web Assisted Notification of Devices) 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. There is no formal requirement for adverse events involving medical devices to be reported.

We are substantially reliant on FDA approval of medical devices through the flawed 510K process. We include an explanation of Medical Device regulation in the US, written by Prof. Joanna Manning, Professor of Law at the University of Auckland (see page 3). One of the major issues with the 510K process is the reliance on predicate devices, which results in a "daisy chain"; new devices are approved if they are substantially similar to an existing approved device, even if that predicate device has actually been recalled from the market because it has failed or is dangerous.

This is the appallingly defective regulatory system that Aoteroa New Zealand relies on for many of the implantable medical devices registered and used here.

We have seen harm caused in Aotearoa New Zealand by faulty pacemakers, metal-on-metal artificial joints, contraceptive implants including Essure, breast implants, and surgical mesh. The devastating harm caused by these, and other implantable medical devices, will continue without proper and robust regulation and post marketing surveillance.

International research has found that globally, implantable medical device regulation is unfit to protect patients from harm. In Aotearoa New Zealand, as in many other countries, grossly inadequate regulation of medical devices has led to catastrophic levels of harm being inflicted upon health consumers, for example, surgical mesh.

The *Implant Files* investigation[1] was the first-ever global examination of the medical device industry, and it 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; the current situation in Aoteroa New Zealand with the Essure contraceptive device is a perfect example of how pitifully inadequate our recall processes are. 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."[1]

Aotearoa New Zealand was one of the countries specifically mentioned. Our current regulators facilitated significant harm to New Zealanders because they failed to do their jobs properly!

[1] ICIJ, 2018: Medical Devices Harm Patients Worldwide as Governments Fail on Safety, *The Implant Files*, International Consortium of Investigative Journalists.

The Therapeutic Products Act represented not only the means by which our lawmakers might ensure that we have a regulatory regime that protects our citizens from dangerous implantable medical devices, but could also have put Aotearoa 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.

In repealing the Therapeutic Products Act 2023, the Coalition Government has placed New Zealanders in harm's way for the foreseeable future, and in the time it will take to pass legislation and implement a new regulatory system that adequately regulates implantable medical devices, that many hundreds more people will suffer life changing injury.

Medical Device Regulation in the US

By Prof. Joanna Manning, Professor of Law at the University of Auckland

Originally included in the AWHC Submission on the Therapeutic Products Bill with permission from Prof Manning.

There are two main avenues for medical devices to be sold on the market legally in the US, "approval" and "clearance." 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. The FDA assesses its safety and effectiveness in terms of the statutory requirements ("reasonable assurance of its safe and effective performance"). It is applicable to class III devices, which pose the highest risk. Only approximately one percent of medical devices receive a PMA. Medical devices 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.

Health Consumer Involvement in the Development of New Legislation to Replace the Medicines Act 1981

It is clear that repealing the TPA is a 'done deal' and that this opportunity for New Zealanders to make submissions is paying lip service to the concept of public consultation.

The Background Material and Policy Information in the Departmental Disclosure Statement makes it clear that the Coalition Government has not sought any review, evaluation or opinion on their proposed repeal of the TPA outside the Coalition members. There has been no:

- publicly available inquiry, review or evaluation reports that have informed, or are relevant to, the policy to be given effect by this Bill;
- regulatory impact statements provided to inform the policy decisions that led to this Bill;
- analysis available on the size of the potential costs and benefits;
- external consultation on the policy to be given effect by this Bill, or on a draft of this Bill.

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.

We submit that health consumers should be consulted during the development of the new legislation that will replace the repealed TPA and the Medicines Act 1981. Of critical importance is the safety of New Zealanders from therapeutic products that cause harm. New Zealanders must have timely access to quality therapeutic products, but safety must come before all other considerations. Patient/consumer safety is of paramount importance in any legislation or regulatory regime that controls therapeutic products. 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.

Whatever regulatory regime is put in place, the regulator must be independent of the MoH and DGoH, and must have the appropriate legislative power and resourcing to act on cases of patient harm, and must be accountable to consumers as well as Parliament. Consumers must have an engagement and consultation role and consumers with relevant lived experience must be consulted.

Background to the Auckland Women's Health Council

The Auckland Women's Health Council was founded 36 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 Therapeutic Products Bill consultation 2023; *Therapeutics Regulatory Scheme* consultation document 2018; the Medicines Amendment Bill 2012; and the Ministry of Health's 2006 consultation.