Submissions on the Therapeutic Products Bill

5 March 2023

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Voices For Freedom thanks the Health Committee for the opportunity offered to review and make comment upon the Therapeutic Products Bill.

Voices For Freedom

1. **VFF is a grassroots, not-for-profit, community advocacy organisation**. It is focused on raising awareness of the human issues associated with the Government's response to Covid-19 and other matters impacting the rights and freedoms of New Zealanders.[1]

2. VFF was founded by three Kiwi mothers; passionate women with professional backgrounds in law and education as well as running online communities in the health, wellbeing, and arts arenas.[2] We have a strong and clear vision for our future.[3]

3. **Our audience exceeds well over 100,000 supporters spread throughout the country with over 40,000 members active and engaged in local community groups.** Our supporters are diverse in nature and span all ages, ethnicities, socio-economic groups, religious and political beliefs, and abilities.

4. **We advocate for the open discussion and debate** of important issues, information, research, and data affecting New Zealanders, particularly as a result of the Government's response to COVID-19 including their public messaging, unethical and coercive policies, and rushed legislation. We operate according to our Code Of Conduct.

5. When tens of thousands of upstanding Kiwis were forced out of their jobs and homes, as a result of Government policy, VFF was there to assist them with resources, advice, and supportive community networks. **We cared at a time when the Government and media turned their backs**, instead using their power to encourage and create a two-tier society in New Zealand.

6. **We have over 500 hours of interviews recorded, including many many hours of interviews with experts recognised as world leaders in their respective**

[1] https://www.voicesforfreedom.co.nz/about-us

[2] https://www.voicesforfreedom.co.nz/our-founders

[3] https://www.voicesforfreedom.co.nz/our-vision

fields. To see our key podcasts we refer you to our website and we recommend the interviews with Professor Mattias Desmet, Dr Ryan Cole as introduction.

7. **It is a testament to the quality of our guests and the information we share on our interviews that we have experienced huge Live audiences on these broadcasts**. During the height of Covid measures our Live calls regularly had over 8,000 attendees, with thousands more on replay, and on one occasion hitting 12,000 Live attendees. This is extraordinary and acknowledged as such by the provider to have been the largest call in Australasia during this time.

8. At the outset, we do wish to bring to the Select Committee's attention that pursuant to an Official Information Act request we have been provided a document that suggests that Voices For Freedom, and their members, will be ones that are particularly active in opposing the Therapeutic Products Bill. While this is certainly an accurate suggestion, it is phrased in such a derogatory way which highlights a concern that there is no open and free dialogue on such important matters - that the government does not wish to hear from all sides. This suggests not only a self-righteous imperious attitude, it also infers that issues are predetermined and if anyone opposes the narrative or ideology, then it will be disregarded and if heard at all, couched as conspiracy theories and/or dis- mis-information.

9. We trust that this Select Committee considering this bill does so with an open mind, clearly hearing all sides - this is such an important bill, it is the health of our nation and the freedom to be able to choose!

10. Finally, we note for the record that we requested an extension to the date for this response for the 250,000 people in the East Cape, Napier, Hastings who have been dealing with the clean up following Gabrielle. We are aware from many members in the area an interest and desire to be heard, but that request was denied.

Therapeutic Products Bill

11. The Therapeutic Products Bill (**Bill**) proposes:

    11.1. to replace the Medicines Act 1981 and the Dietary Supplements Regulations 1985 to regulate therapeutic products, such as medicines, medical devices, natural health products, and active pharmaceutical ingredients;

    11.2. introduces a new regulator within the Ministry of Health, headed by an independent statutory officer, with a wider remit than the medicines regulator Medsafe.

12. The purpose of the Bill is to protect, promote, and improve the health of all New Zealanders by providing for the:

    12.1. Acceptable safety, quality, and efficacy or performance of medicines, medical devices, and active pharmaceutical ingredients across their life-cycle; and

    12.2. Acceptable safety and quality of natural health products across their life-cycle.

13. The significant change in the Bill is the inclusion of natural health products (**NHPs**) as well as natural health therapies (**Natural Health Therapies**) (together **Natural Therapies**). NHPs are currently regulated by the Dietary Supplements Regulations 1985 under the Food Act 2014, Natural Health Therapies are currently regulated by their relevant authority or body.

14. We say that the status quo should remain, and that the Bill should relate solely to medicines and products currently covered by the Medicines Act 1981.

15. This is not the first time in recent years that attempts have been made to modernise the Natural Therapies regime. The first attempt in recent times was 2011 through the Natural Health Products Bill. That Bill failed to gain enough support in Parliament, and the Government revisited natural health product regulations again in 2015. Following public consultation on the draft of a new Bill in 2019, the Government decided to include regulation of natural health products in what is now the Therapeutic Products Bill.

16. For all New Zealanders, it is imperative that we are given every opportunity to take control of and be responsible for our own health (if we wish) to be able to make choices appropriate to our individual situation. Natural Therapies are a large part of self care that promotes health and well being. As opposed to curing disease and a problem, Natural Therapies are at the top of the cliff, whereas medicines are the ambulance at the bottom.

17. It is estimated that at least 50% of New Zealanders use natural products (67% of patients at a medical centre[4]) - a number which is no doubt far greater following Covid-19, where vitamin D, a natural therapy, was for primary prevention or as an adjunctive treatment of Covid-19.[5]

18. VFF's submissions focus on:

- Risk-Benefit analysis
- No or negligible risks of Natural Therapies therefore no need to regulate
- Natural Therapies
- Medicines - provisional consent
- Role of new regulator re natural therapies

19. We look forward to the opportunity to speak to the Select Committee regarding these submissions and welcome any questions the members have.

20. **Risk-Benefit analysis**

20.1. In respect to medicines, Medsafe[6] undertakes a risk-benefit analysis and *approves medicines based on a favourable balance of benefit to risk of harm for the intended treatment population.*

20.2. For Medsafe, the:

20.2.1. **benefit** of *a medicine is the sum of its efficacy and the context of use*, with respect to certain considerations;

[4] Taylor M. Patients' and general practitioners' attitudes towards complementary medicine in Wanganui, New Zealand. New Zealand Fam Physician. 2003;30:102–7. As cited at footnote 3 in Liu, L (et al) Complementary and alternative medicine - practice, attitudes, and knowledge among healthcare professionals in New Zealand: an integrative review BMC Complementary Medicine and Therapies (2021) 21:63

[5] Charoenngam, C (et al) (March 2021), Vitamin D and Its Potential Benefit for the COVID-19 Pandemic, NIH National Library of Medicine. Endocr Pract. 2021 May;27(5):484-493. doi: 10.1016/j.eprac.2021.03.006. Epub 2021 Mar 17. PMID: 33744444; PMCID: PMC7965847.

[6] The Medsafe Files – Episode 12: Benefit-risk (of harm) review, 6 December 2019.

20.2.2. **risk** of a medicine is *assessing the risk of harm both the frequency and severity of the harm are considered*.

20.3. In considering a medicine for approval, Medsafe undertakes a detailed analysis of the material submitted by the relevant sponsor with its application (including all trial information), applies its knowledge and understanding of medicines including any paper printed in a medical journal (as this is deemed knowledge imputed on a regulator) and weighs up of the benefits against the risk before considering whether to grant consent to a medicine.

20.4. This is all done because there is a risk with all medicines - using medicines is never completely safe.[7]

20.5. Both VFF and our members have reached out to local Members of Parliament regarding concerns about the regulation of natural therapies proposed in the Bill. Many of the emails we have received back are that there is a need to regulate Natural Therapies because of the risk Natural Therapies impose (see Schedule 1, email from National MP Nicola Griggs). Interestingly, no evidence is given in support of these broad and wide-ranging statements.

20.6. Furthermore, if Medsafe is to take over the regulation of Natural Therapies, Medsafe should really have its house in order with medicines before branching out and regulating a whole new area. A parallel example is councils stepping outside their areas of responsibility with respect to roads, rubbish and water into equality. Given the road craters you no doubt dodged on the way to work this morning, councils are not even getting their current remit right!

21. Natural Therapies - All Benefit - Nil or Negligible Risk therefore no need to regulate

21.1. The Bill already acknowledges that NHPs, by their nature have a nil to negligible risk. In this regard, their benefit alone could be nil, a placebo or even psychosomatic - the fact they are nil to negligible risk means there is no need to regulate them - the inclusion of them into the Bill is simply not necessary and so is the proposed regulation of potentially hundreds if not thousands of products, items and foods.

21.2. Just how little a risk are NHPs?

[7] Health.gov.au

21.3. A recent EU study found that natural health products are 45,000 times safer than pharmaceutical drugs[8].

21.4. But we do not need to take European analysis for gospel, in 2016, Dr Wallace Bain, Acting Chair of the New Zealand Coroners' Council, released a report of an investigation into deaths caused by natural health medicines in New Zealand. That report titled *Complementary Medicines, Natural Products, Traditional Products, Supplements, Vitamins etc*.

21.5. Dr Bain's detailed, broad and considered report found *"no death or incident involving any of these natural products"*. He did however, find significant adverse events and identified reports outlining the resultant costs of medicines.

21.6. Dr Bain concluded his report:

The Coronial and literature searches in so far as natural products etc are concerned and linkages to public safety and risk can be described legally as De minimis non curat lex. That is of minimal risk importance. The law (regulations etc) does not and should not concern itself with trifles.

21.7. Dr Bain's report:

21.7.1. Reviewed:

Coronial records re the above products together with prescription and other drugs, to identify if they have been involved in Coronial Inquests and deaths.

21.7.2. Stated:

A Health Risk Expert, recognised by the MOH, has advised of conducting extensive medical literature research throughout the world for incidents with these products. There has also been considerable communication with professors around the world seeking to identify any incidents. The result as advised is overwhelming lack of evidence identifying fatalities/incidents involving natural products.

[8] Juderon Associates, Individual Risk Relative to the Use of Food Supplements in EU-27 Countries, prepared for Natural Health Alliance, UK, 2012.

21.7.3. Undertook further inquiries:

Subsequently all Coroners, other pathologists and Crown Prosecutors have been emailed to provide their best guess of drug induced / involved deaths. A broad brush percentage was requested. There have been a number of inquests relating to suicides / risk taking in respect of prescription drugs. Party pills are included. Responses have indicated a best guess percentage of 5% of deaths. That is approximately 200 deaths per annum. Contrast this to Natural products etc which has nil deaths per annum. These figures are considered very much on the light side due to the way the Coronial database records are recorded.

21.7.4. With respect to natural therapies, did identify two possible natural therapies, which were inconclusive:

21.7.4.1. A possible under dosing of folic acid during a woman's third pregnancy - where during the 5 month scan it was identified that the foetus had spina bifida (the previous two children having no reported difficulties);

21.7.4.2. An Indian herbal product K4, which contained 25-30 herbal products advertised for prostate cancer, was bought by direct mail. A coronial inquest found no case to answer with respect to K4 but left open a verdict on non-viral hepatitis of 'unknown origin'. With respect to K4, in 1996, Medsafe issued Adverse Reaction Newsletter 1996:4 in respect to K4, following an increase in CARM reports.

21.7.5. With respect to medicines, identified:

21.7.5.1. *A recent published study of the deaths in New Zealand with a base year 1998 shows the number of deaths from adverse drug reaction to be 1524 and from highly preventable adverse drug reaction 669. That does not include deaths from suicide relating to drugs.*

21.7.5.2. *A recent Australian study shows that 1 in 10 patients presenting to a GP had an adverse drug event in the*

preceding 6 months with 50% being in the moderate to severe range and 8% hospitalised.

21.7.5.3. Both of which were clearly undertaken before the role out of the Covid-19 vaccines, which has seen a 5,207% increase in adverse event reports in New Zealand alone.

21.7.6. Referenced overseas concerns with medicines:

…international studies point to the huge cost from drug-related patient injury and death. In the United States this cost is put at billions of dollars. One study puts complications resulting from medication errors in US hospitals at 1.5 billion every year. Studies also show that prescription drug errors double a person's risk of dying in hospital and cost an estimated 2 billion a year. Another study put the cost of a single adverse drug event to a hospital in the US at $2,500. The estimate of costs incurred by US hospitals as a result of drug-related injury or death was put at 76.6 billion which was three times the cost of all diabetes care.

21.7.7. And more local concerns with medicines:

A recent analysis done of patients being admitted to a major hospital in the Auckland area shows that nearly 50% of patients who come to hospital with more than 5 medicines are admitted with problems relating to ascertaining a way of getting an accurate list of their medicines in a timely manner. In other words 50% of patients are admitted with an error on their charts. Another 50% were estimated as being non-compliant – i.e. they got an element of their medicine taking wrong. The US estimates put a figure of every $1 spent on medicines, another $1 is spent on sorting the problems that arise out of them.

21.7.8. And concluded:

What is ironic here is that what is being held out as a justification for high regulation and compliance in the area of Complementary Medicines, Natural Products, Traditional Products, Supplements, Vitamins etc, is public safety and risk. Despite a diligent search of Coronial records and the literature, no instances have been found

to demonstrate that in fact with these products in NZ there is any serious public health issue or risk to the public. The problem is clearly with prescription and other drugs and no demonstrable risk at all with these natural products.

22. Dr Bain's report clearly identified that there is nil to negligible risk with respect to Natural Therapies, making the very regulation of them not only unnecessary, but down right nonsensical.

23. We respectfully submit that the only possible basis for regulation is some nefarious commercial interest that is not for the benefit of New Zealanders.

24. **Natural Health Products**

24.1. NHPs are significantly safer than the other therapeutics being regulated alongside them in the Bill, such as novel mRNA gene therapies, biologics, biotech, tissue therapies and transplants, medical devices and implants, and pharmaceuticals.

24.2. That is not to say Natural Therapies are risk-free but the risks are nil to negligible compared with pharmaceutical medicines.

24.3. Importantly, the issue of whether Natural Therapies should be included in legislation alongside medicines has already been considered by this Government within the last few years.

24.4. In a December 2018, Cabinet Social Wellbeing Committee government paper re Therapeutic Products Regulatory Scheme: Overview and Consultation on Bill Exposure Draft, the Social and Wellbeing Committee recommended that NHPs remain out of the Therapeutic Products legislation:

*"**Natural health products***

*16 **noted** the non-reinstatement of the Natural Products Bill would have the unintended consequence of bringing natural health products within the ambit of the Therapeutic Products Bill if appropriate steps to mitigate this are not undertaken;*

*17 **agreed**, in order to not unduly further delay the Therapeutic Products Bill and to allow due process in respect of the ongoing work on the regulation of natural health products, that natural health products be excluded from the Therapeutic Products Bill as far as is possible;*

*18 **agreed** that the consultation document to be released with the exposure draft of the Bill make clear that the government is to consider options for the regulation of natural health products and that it will therefore exclude them from the Therapeutic Products Bill as far as is possible;*

19 ***noted*** *that the natural health product exclusion will be drafted and included in the Bill that is introduced to the House of Representatives;*

20 ***noted*** *that this issue will attract considerable attention during the consultation process and during the Select Committee stages of the Bill;"*

24.5. A position confirmed again a couple of days later (18 December 2018) in Confidence paper from the Chair, Cabinet Social Wellbeing Committee to the Office of the Minister of Health (obtained under and OIA request):

"1 A Therapeutic Products Bill to replace the Medicines Act 1981 …[REDACTED s9(2)(f)(iv)].... This paper provides an overview of the proposed new regulatory scheme for therapeutic products, and

…

7.3 Natural health products (NHPs) – under the previous administration these products were to have been regulated by the Natural Health Products Bill. That Bill was not reinstated by this Government and this has had the unintended consequence of bringing NHPs within the ambit of the Therapeutic Products Bill. In order that the Government can consider how it wishes to regulate NHPs into the future, this paper recommends that NHPs are, as far as is possible, excluded from the Therapeutic Products Bill. The consultation document would make it clear that the intention is to develop an exclusion for NHPs before the Bill is introduced."

(emphasis added)

24.6. Subsequent meetings across the country were held where officials promised that Natural Health Products would **not** be included in the proposed law.

24.7. Less than 5 years later, we now find in the Bill a renewed attempt to include Natural Therapies in the Therapeutic Products Bill - yet another broken promise by Labour!

25. Natural Health Therapies under the Bill

What is a natural therapy under the Bill?

25.1. We don't know! But all of them are to be regulated!

25.2. The Bill defines natural health product as:

a product that contains one or more NHP ingredients (along with permitted additives or formulation aids), so long as it is not administered by injection or parenteral infusion and has not been classified as a different product by the regulator.

25.3. The Bill regulates all NHPs alongside medicines and medical devices - natural form products such as spirulina, turmeric, barley grass will be considered by the Ministry of Health alongside medicines as opposed to where they appropriately belong, beside or as food.

25.4. The Bill is vague, and where it is not vague, it is absent any information whatsoever, instead indicating matters will be:

25.4.1. Dealt with in regulations - secondary legislation - driving the rules down into regulations means the public has no say and the regulator has all the power; and

25.4.2. Lists in terms of what natural health products and ingredients will be available - all to be determined at the discretion of the new regulator.

25.5. While previous lists are available from earlier attempts at the Bill[9], what is on those lists is very limiting and concerning, for example Labour's 2017 list of 300 prohibited NHT's specified many key foods used safely in everyday meals, such as:

The More Well-Known Among the 300 Herbs Whose Traditional Use Is Being Restricted

Neem	Aloe Vera	Tamarind	Valerian
Belladonna	Comfrey	Lungwort	Senna
Camphor	Manjishta	Rauwolfia	Quinine
Nux Vomica	Guggulu	Mustard	Hibiscus
Ipecac	Ipomoea	Betel Nut	Castor
Worm Wood	Cardamom	Shatavari	Coconut
Sida Cordifolia	Eggplant	Grapeseed	Tea Leaf
Cinnamon	Snowdrop	Juniper	Cedar
Embelia Ribes	Jasmine	Almond	Bala

25.6. It appears from the Bill that if an ingredient is not approved, then any products based on that will be gone. For example, if lecithin is banned for internal use in supplements, as Dr Guy Hatchard points out happened in the 2016 legislation, anything including it will be gone too, including liposomal forms of supplements.

[9] NHSP Permitted Ingredients List V1.xlsx

How will Natural Therapies be regulated?

25.7. This too lacks any real specificity in the Bill!

25.8. For example, if a practitioner wished to promote natural health benefits of a product, then under the Bill, all NHPs are required to have a market authorisation before it can be imported, supplied, or exported (clause 67 of the Bill). Notably, that practitioner would be the sponsor of the NHP, which is the same as a sponsor of medicines and devices (clause 125 of the Bill), with similar criteria as for medicines, the exception being that there is no requirement to establish the efficacy of the NHP. There is, however, a requirement that any proposed health benefit claims are substantiated (clause 124 of the Bill).

25.9. The Oxford Dictionary defines ***substantiate*** to mean *"provide information or evidence to prove something is true."* Which with respect to therapeutics, sounds very much like ***efficacy*** which means *"the ability to produce a desired or intended result."* 'Doublespeak' at its best!

25.10. In order to prove the benefits, medical grade clinical trials will need to be conducted, for assessment by the new regulator. This cost to obtain authorisation, will be prohibitive for any one that is not a large, well resourced company. For example, small businesses producing quality herbal and natural products will not be able to meet the enormous costs of registering products and the red tape involved in getting them to market - the costs of compliance with this Bill will push many out of business and make it unattainable for all but the biggest to operate. The Bill makes no provision to exclude existing small businesses either - they are not exempt from this enormously costly and unnecessary legislation.

25.11. The inclusion of NHPs in the Bill will only create increased costs of living and is counter to the cost of living crisis currently gripping New Zealand.

Who and how can they practise?

25.12. We can't tell from the Bill!

25.13. There are no clear definitions provided for what constitutes a natural health practitioner, or traditional medicine and traditional practice (Western herbalism, rongoa Maori, TCM, Ayurveda, other traditional medicine systems should all be included in that, but the question is – will they be?). Nor are there any assurances

that qualified members of the Natural Therapies community will be on the advisory panels, as they should be if this Bill goes ahead.

25.14. The herbal medicine list has not yet been supplied at this stage, but based on prior attempts as an indication, a significant number will be lost.

25.15. Natural Therapies practitioners will be silenced, their right to freedom of speech, their ability to inform us about the healing properties of virtually anything is at risk if a therapeutic claim is made (or even implied, eg garlic lowering heart disease risk). If these were not on the approved list (not yet available), then practitioners face a $200,000 fine and/or up to five years in prison. This denies access to good information to inform our health decisions.

The intended (or unintended) consequences of regulation

25.16. Inclusion of Natural Therapies alongside medicines will have the very real consequence that Kiwis will not be able to access a wide range of high-quality natural products at reasonable prices.

26. The new NHT regulator

26.1. The Bill proposes a new regulator. That regulator will have the power to make decisions over what products New Zealanders can access as consumers and as Natural Therapies health professionals. That is putting the decision making of potentially thousands of products into the hands of one man (or woman), who is unlikely to have any actual knowledge of natural health products. While the suggestion is that that regulator will be independent - they will not actually be independent because:

"the regulator will be a public servant appointed by the Director-General of Health on the basis of their relevant knowledge and expertise. The Regulator will exercise their powers under the Bill independently of the Director General of Health and the Minister of Health, but may be subject to general policy directions issued by the Minister."

This is the antithesis of independence.

26.2. Further, the Bill fails to specify that the new regulator must have the appropriate skills or expertise (such as natural health professionals, naturopaths, or medical herbalists). Expertise, which may fall to public servants or bureaucrats within the

natural product regulatory team, yet the Bill also fails to mention that those individuals need to be appropriately skilled and have the necessary expertise.

26.3. Furthermore, there is no obvious requirement for the new regulator (or members of their office) to disclose affiliations, associations, or benefits (either past or promised). That is, there is no obligation specified in the Bill for the new regulator to disclose all or any possible conflicts and/or affiliations, which should have to be published annually, at least.

26.4. Improper inducement is a recognised issue that has been identified in the Bill - see clause 195 of the Bill *Improper inducements to health practitioners or veterinarians* - yet this does not flow through all levels of the regulatory organisation. It needs to!

26.5. The Bill simply concentrates too much discretionary power in a new regulator, along with expectations that will be very difficult for them to exercise practically and effectively.

27. Medicines

Provisional consent

27.1. A special type of consent allowed for a new class of gene based therapy products to be designed, made and supplied to most of the populations in first world countries in less than a year.[10]

27.2. In New Zealand, this type of consent is called provisional consent and is set out in section 23 of the Medicines Act 1981. It allowed Medsafe to approve the Covid-19 products, where there was a "clear and immediate need" for it, but "it was not possible to go through a full consent process because all the information necessary to establish its safety was not available."[11]

27.3. The consequence being that an entirely new class of drug, having never been through any comparable set of full trials, or for which any regulator had knowledge or experience, nor had undergone the ordinary typical rigorous testing pharmaceuticals go through before even being considered for approval, the Covid-19 products were provisionally consented to in New Zealand while the products were still in stage III clinical trials (there are VI stages ordinarily). In fact,

[10] Report of expert in pharma regulation, Dr Phillip Altman filed in the High Court.

[11] *Nga Kaitiaki Tuku IHO Medical Action Society Incorporated v Minister of Health* [2021] NZHC 1107

the trials are not due to be completed until May 2023 (this year)[12], with data being made available a further 24 months thereafter (May 2025[13] at this stage).

27.4. That means, that these products were approved before any medium and long term safety data was available - that is still not available given the limited time since the stage III clinical trials were concluded.[14]

27.5. There is however, short-term data including Pfizer's own post marketing six month report following up on the 44,000 in the first clinical trial. That data, in a report dated February 2021, not made publicly available until November 2021, indicated significant and concerning levels and types of adverse events including death, neurological conditions, aut-immune issues, cardiac issues, the list goes on.

27.6. There is also New Zealand's own data, reports to CARM following Covid-19 injection increased 5,207% compared to other, traditional, vaccines.[15] Similarly in Australia, which has a much larger population, the Therapeutic Goods Administration (**TGA**) database of adverse events (DAEN) reported more adverse events in the first year of Covid-19 vaccines (2021), than from all vaccines in the 50 years the TGA operated its adverse events reporting system.[16]

27.7. These products were then mandated to the majority of the public sector workforce, and where they were not mandated, they were required by the implementation of vaccine policies, and employer discretionary policies. Such that allegedly 95% of New Zealand's eligible population allegedly received the primary doses of Covid-19 injections.

27.8. These products were rolled out to the majority of New Zealanders despite the fact that they had only received provisional consent pursuant to s 23 of the Medicines Act 1981, which had to be subsequently amended to remove the subsection that specified provisional consent was limited to products where it would only be supplied to "a limited number of patients", which was clearly "more limited than all New Zealanders".[17]

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[12] See Pfizer's information about the "Landmark Trial"

[13] Being 24 months from the "primary study completion date" https://www.pfizer.com/science/clinical-trials/trial-data-and-results/data-requests

[14] Report of expert in pharma regulation, Dr Phillip Altman filed in the High Court.

[15] Report of expert statistician Lisa Mitchell filed in the High Court.

[16] Therapeutic Goods Association, Database of Adverse Events Notifications.

[17] Ibid 9.

27.9. More recently, and concerningly, on 22 December 2022, Medsafe granted provisional consent for the Bivalent Covid-19 injections - it is unclear what "clear and immediate need" there was for this product given the majority of New Zealanders received their primary doses, the majority of people have also had Covid-19, some even twice, the majority of the mandates were dropped September 2022, and at the same time, the state of emergency was also downgraded at the same time with the removal of the traffic light system. None of which highlights a "clear and immediate need".

27.10. Allowing these products to be granted the special type of consent, without restricting or limiting the situations, or upholding the limitation or restrictions that were in place has led to these gene based therapies creating the largest iatrogenic catastrophe in human history. All of which could have been avoided had proper pharma-vigilance had been adopted and the law followed.

Advertising of medicines

27.11. The Medicines Act 1981 clearly articulated advertising for medicines, those provisions were such that New Zealand's Prime Minister and both former and current COVID-19 Health Response and Minister of Health, would be held in breach of the Medicines Act advertising for stating the Covid-19 products as "safe and effective". Based on "expert advice", healthy teenagers should be vaccinated, and the dosing interval to be reduced from 8 weeks to 3 weeks. All of which was not true:

27.11.1. The products were not "safe and effective";

27.11.2. The Government had ignored their own expert advice about the risks of myocarditis and intentionally concealed the risk from the public;

27.11.3. The Government ignored the dosing interval risk and there was a last minute about face when it came to injecting healthy teenagers.[18]

27.12. The Bill needs to clearly set out and articulate that such misleading and deceptive behaviour cannot be allowed to happen again.

[18] See Cranmer's recent expose Part 1 and Part 2:

Conclusion

28. It is imperative that we are given every opportunity to take control and be responsible for our own health (if we wish) to be able to make choices appropriate to our individual situation. Natural Therapies are a large part of self care that promote health and well being.

29. Natural Therapies should not be included alongside or treated as medicines - the risk profile of them makes this unnecessary and nonsensical.

Voices for Freedom
5 March 2023

Schedule 1

From: Nicola Grigg MP <Nicola.GriggMP@parliament.govt.nz>
Subject: Reply: Therapeutic Products Bill
Date: 19 January 2023 at 1:20:36 PM NZDT

Thank you for your email to Nicola which she has seen and read. I am replying on her behalf.

It is important that New Zealanders have a modern set of regulations for all our medicines. Accordingly, the Bill is intended to replace the Medicines Act 1981 and the Dietary Supplements Regulations 1985 and to regulate therapeutic products - like medicines, medical devices, natural health products, and active pharmaceutical ingredients.

The Bill is wide ranging in its scope and will regulate how products are manufactured, tested, imported, promoted, supplied, and exported. Natural health products are included under the Bill to ensure consumers have the information they need to make informed decisions about the products they use and have access to safe and high-quality products.

Natural health products are not risk-free. They are generally lower risk products than medicines and higher risk than foods with similar ingredients. Regulations can help ensure:

- products contain safe ingredients at a safe dose
- high quality manufacturing processes are in place to provide assurance that products are not contaminated
- product information is clear on the use and recommended dose
- health claims are based on evidence
- New Zealand producers are in a positive position in the global marketplace.

The Therapeutic Products Bill takes on board sector feedback to consultation undertaken in recent years, the work underway on the health and disability system reforms, as well as new health technology changes and also lessons from COVID-19. It is the result of more than a decade of policy work, much of it led by previous National governments, so you won't be surprised that National supported the first reading of this Bill when it was introduced to the House on 30 November 2022.

However, the Bill has now reached the Select Committee stage, and the call has gone out for people to have their say and make a submission. There will also be further opportunities to have your say, during the consultation stage on the subsequent regulations.

The link below will take you to the page on the Parliament website where, you can make your submission, and I encourage you to do that.

https://www.parliament.nz/en/pb/sc/make-a-submission/document/53SCHE_SCF_BILL_130084/therapeutic-products-bill

Kind regards
Helen
Helen Gibbs | Senior MP Support
Office of Nicola Grigg MP | Member of Parliament for Selwyn
Associate Spokesperson for Agriculture | Spokesperson for Rural Communities, Animal Welfare, Land Information & Women
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