PSGR

Physicians & Scientists for Global Responsibility

February 25, 2023.

Submission

Therapeutic Products Bill

Submitted to the:

Health Select Committee (Chair Tangi Utikere)

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PSGR would welcome an opportunity to speak to this submission.

Physicians and Scientists for Global Responsibility Charitable Trust (PSGR) work to educate the public on issues of science, medicine, technology (SMT). PSGR work to encourage scientists and physicians to engage in debate on issues of SMT, particularly involving genetics and public and environmental health.

AT A GLANCE.

The Bill is unfit for purpose and must be discarded. The principles and rules in the omnibus bill fail to entrench democratic norms of accountability and transparency that prevent misconduct and abuse of power. The Bill is not structured adequately to:

- Recognise much greater risk from medical interventions over the product lifecycle.
- Take account of financial bias (conflicts of interest) by Sponsors and overseas institutions.
- Provide obligations and resourcing at high level to assist the Regulator with independent scrutiny, as drug and device safety and efficacy claims cannot be accepted at first glance.
- Demand that the Sponsor and Regulator transparently discloses information sources and data.
- Demand that the Regulator takes account of non-industry data throughout the product life cycle and that these requirements are structured at high level in the bill.
- Make clear accountability and transparency requirements for market authorisation.
- Make clear principles and rules for post-market surveillance and adverse event monitoring.
- Steward off-label use in the public interest (appropriate to long-understood safety signals).

The Therapeutic Products Bill is an unsuitable regulatory instrument for dietary and nutritional products:

- The Regulatory Impact Statement and the Bill's content demonstrate that there is no scientific expertise regarding the benefits of nutrients and human physiology in the bill's drafting.
- The documents suggest that risk benefit considerations will and cannot take account of dosage and prescribing differences between clinical drugs with toxicological action and dietary and nutritional supplements with largely known toxicities. For example, nutrient intake not only concerns tolerance, but involves an intention to redress nutrient deficiencies.
- The absence of feedback loops between nutritional scientists and between practitioners of nutrition and herbal medicines demonstrate an authoritarian and non-consultative approach.
- The absence of scientific expertise implies that there is no capacity to recognise the potential for nutrients to redress large inequities experienced by Māori relating to health and disease.
- Due to this technical and scientific ignorance, it is likely that increased regulation will increase barriers to nutrition by restricting supply and by increasing cost.
- This may breach the Treaty of Waitangi principle of active protection.

Regulators are in place to ensure the safety of citizens and promote trust.

- The purpose of this Bill is to protect personal and community health.
- Regulation is in place to prevent abuse of power, i.e., limit the political and financial influence of the regulated industry.
- Medical/biotechnological/pharmaceutical industries are markedly more powerful and more resourced than New Zealand regulators, and regulatory capture is a key risk.
- Decision-making must be in the public interest and not unduly biased (subservient) to industry.

This omnibus bill focuses disproportionately on food and dietary supplements, and on end stage use by practitioners. It fails to put in safeguards to prevent regulatory capture. The risk of capture increases when a regulator depends on information sourced from large powerful interests, in this case, the medical, pharmaceutical and biotechnological industry.

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Therapeutic Products Bill

3 Purpose

The purpose of this Act is to protect personal and community health by—

(a) ensuring acceptable safety, quality, and efficacy or performance of therapeutic products across their lifecycle; and

(b) regulating the manufacture, import, promotion, supply, and administration or use of therapeutic products.

INTRODUCTION

The Physicians and Scientists for Global Responsibility (PSGR) welcome the opportunity to respond to the public consultation on the Therapeutic Products Bill.[1] The PSGR object to the Bill and consider that:

1. The 238-page Therapeutic Products Bill is poorly designed, overly complex, and promotes extensive uncertainty. The legislative scaffolding does not impose accountability and transparency mechanisms concerning decision-making processes, and relatedly, networks of power and information flow.

2. The Regulatory Impact Statement (RIS) is unfit for purpose as the *Problem Definition* exclusively focuses on 'Regulating Natural Health Products' (NHPs) yet medical regulation is central to the bill.[2]

3. Insufficient transparency obligations concerning decision-making processes (such as for market authorisation), and regulation of medical drugs and devices, of the Regulator, to promote public trust in the regulated products and in public-facing practitioners.

4. Food and dietary supplements should remain regulated under the Food Act 2014, and the Dietary Supplements Regulations 1985. Illnesses and deaths are not being signalled/recorded despite high levels of consumption of food and dietary supplements, by over 50% of the New Zealand population.

    a. The Regulatory Impact Statement and Explanatory note to the Bill demonstrate an absence of scientific expertise regarding the biological relevance of nutrition; the role of nutritional supplements for the maintenance of health. Ignorance surrounding the issue of combinatory effects is also evident. Such considerations require different scientific approaches to when considering the toxicological impact from active ingredients in drug manufacture. A later November 2022 RIS Supplementary Analysis[3] did not address these points.

    b. The Bill and documents do not discuss the risk-ratio of natural health products.

    c. Small entities and independent suppliers were excluded from consultation and NHP clauses are disproportionately authoritarian/pecuniary in comparison to their risk of harm.

    d. Legislation and rules exclude the enormous body of published scientific research on the role of food and nutrition in protection of health. Removal of terms including 'dietary' (Dietary Supplements Regulations 1985) and 'food' (Food Act 2014) signify that the value of food and nutrition to the maintenance of health is not a relevant consideration for the regulator.

5. The blindspots in this Bill are extensive. Public institutions should be protected by robust accountability mechanisms. The system architecture (primary legislation) should promote transparency. The Bill fails to achieve or implement strong accountability mechanisms.

6. The Bill's architecture prioritises information flows that privilege large commercial medical interests. Safety and efficacy claims flow from medical drug and device sponsors to the Regulator.

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1 https://www.parliament.nz/en/pb/sc/make-a-submission/document/53SCHE_SCF_BILL_130084/therapeutic-products-bill
[2] MoH (2021) https://www.health.govt.nz/system/files/documents/pages/regulatory_impact_statement_-_regulating_natural_health_products.pdf
[3] MoH (2022) https://www.health.govt.nz/system/files/documents/information-release/publication_-_regulatory_impact_statement_therapeutic_and_natural_health_products_regulation_-_supplementary_analysis_2022_no_1._1.pdf

a. Globally, regulators prioritise industry data when deciding on market authorisation of a drug or device. Thus, local regulators use sponsor's data to guide market authorisation, but also seek the advice of international colleagues, who also depend on the drug or device sponsor.

7. The Bill contains poorly drafted and inadequate principles. Systems and structures would result in legislation that produces ambiguities and contradictions. Officials acting under the powers of a future Act will struggle to fulfill the purpose of that Act, in the public interest.:

    a. The claim that Ministers and Officials will act *proportionately* is an unaccountable claim. The term is not defined. In effect, Ministers and officials do not have a legal framework which would assure the public that actions will be accountable, transparent and *proportionate* to any risk of any regulated product.

    b. Officials have no capacity to conduct enquiry outside of current institutional arrangements & norms – i.e., there is no requirement to identify and report on risk in the scientific literature. Officials have no appellate processes, should there be internal and external (biased) political pressure to approve a product or maintain market access in times of controversy.

8. Existing constitutional and administrative law principles require decision makers (inclusive of regulatory agencies, to *look outside company data*. They are required to consider and give adequate weight to all relevant information.

    a. The penalties for failure to do so should be laid down and available through readily accessible judicial review to consider the legality/illegality of the all decision making.

9. The Bill's principles, systems and structures create a scaffolding which is directed in service of the biotechnology and medical drug and device market.

    a. There is no obligation for the Regulator to consider data outside of the Sponsor.

    b. Industry sectors ordinarily seek to influence regulations and rules of regulators. This is a key element of corporate strategy. 'Regulatory capture is the process through which special interests affect state intervention in any of its forms.' [4]

    c. Regulatory institutions are tightly networked and share knowledge. The sharing of the same attitudes, beliefs and values, are amplified when Sponsor data is central to regulation.

10. The absence of transparency mechanisms for decision-making and data flows encourage misconduct:

    'Power and knowledge, or rather the concealment of knowledge – secrecy – are two significant predictors of misconduct that can be seen in a number of institutional contexts.'[5]

11. Two issues exacerbate the potential for *misconduct* and *abuse of power*:

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[4] Saltelli A. et al (2022) Science, the endless frontier of regulatory capture. *Futures*, 135:102860 https://doi.org/10.1016/j.futures.2021.102860

[5] Crompvoets, S. (2021). Blood Lust, Trust and Blame. Monash University Publishing, In the National Interest series.

a. The Bill is an omnibus Bill. The principles and rules in the draft Bill are inadequate for the purpose of guiding thousands of pages of secondary legislation.

b. The passing of the Secondary Legislation Act 2019 amplified the capacity for officials to swiftly institute rules, without accountability to the public. The passing of this Act preceded the enormous quantity of Orders that were produced throughout the COVID-19 pandemic in great secrecy, between senior officials and the Parliamentary Counsel Office.

12. The intention of the Therapeutic Products Bill is that secondary legislation will be extensive. There is no assurance that the content of the Therapeutic Products Bill will properly guide the actions of officials, in the public interest, and promote trust.

13. To reduce blindspots, and remove risk of commercial bias the PSGR suggest that the *following must be included at high level in the primary legislation* (I.e., Therapeutic Products Bill):

a. Regulatory *decision-making* processes must be clearly outlined.

b. Rules should *require the Regulator by law* to look outside of *private company supplied data* to identify issues relating to the safety and efficacy of products, with dedicated funding specifically directed for this purpose.

c. The Regulator should be legally required to consider *primary data*, and disclose all reports to the public, with dedicated funding specifically directed for this purpose.

d. Recognise that power networks are opaque. *Institutional associations* and *key methods of information gathering* to assess the safety and efficacy of a product cannot readily be disclosed, but should be.

e. The Regulator should be required to *publicly present* all information used in decisions.

f. The Bill *must not* recommend/require alignment with global institutions.

[1] POOR LEGISLATION, A TINY REGULATOR & BIG BUSINESS

14. New Zealand is a small jurisdiction, primary legislation must be simple and straightforward with strong, legally relevant purpose and principles and rules that provide direction to fulfill the purpose of the legislation.

15. Dietary and food supplements are regulated under two schemes, the Food Act 2014, and the Dietary Supplements Regulations 1985. The Ministry for Primary Industries has an additional legal duty to monitor safety of food and dietary substances, providing an additional mechanism for local produce.

a. These schemes can be updated and improved. There is no need to redraft this legislation.

16. The new Medicines Act must be wisely designed to ensure the safe regulation of thousands of medical products and promote and retain public trust.

a. In 2020/21 Pharmac[6] reported prescription items increased by 3% from the year before. 140,000 hospital medical devices are line items on the pharmaceutical schedule. It is difficult to understand how many thousand medicines are regulated and approved for market access through the Medicines Act.

17. It is probable that New Zealand officials will struggle with the existing burden of medicines regulation if the proposed regulator is to ensure safety across the product lifecycle, as new information comes to light.

18. The Therapeutic Products Bill demonstrates that even though the government 'promises' to regulate appropriately, there is no sophisticated approach – no expertise demonstrated in relation to oversight of dietary and nutritional supplements. As a consequence the approach is overtly authoritarian.

19. Despite the RIS being released in May 2021, the food and dietary supplements industry has not been consulted. It is apparent that adequate resources have been directed to the construction of a 238 page Bill – but no time directed to consultation with the industry most affected by the Bill.

20. Cabinet Minutes claim that the: 'natural health product regulatory scheme are aligned with those for the therapeutic products regulatory scheme, which are that it:

    5.1 meets expectations of risk management and assurance of acceptable safety'

21. This is incorrect as there is no definition of what risk management, or acceptable safety involves for natural health products.

22. There is no evidence that the lists published in 2016 will be excluded from the new legislation. The lists *included* many banned toxic synthetic and chemical ingredients while *restricting* known herbs and spices. The restrictions of herbs and spices did not reflect established cultural practice and scientific knowledge.

23. The Ministry of Health and Medsafe will be responsible for leading the implementation of the Bill.

24. July 7 2021, the Cabinet Social Wellbeing Committee noted that in 2018 it was agreed that 'natural health products be excluded from the Therapeutic Products Bill.' The Committee then agreed that natural health products would be absorbed into the Therapeutic Products Bill.[7]

25. In such an overwhelmed and likely under-resourced regulatory scheme, it is contradictory that Cabinet Ministers and senior officials would elect to incorporate food and dietary supplements.

    a. There is a disproportionate focus on natural health products that while focussing less on medicines and devices, which require more rigorous oversight. For example, clauses 119 & 120 set out criteria for medicines and medical devices, while 122-125 sets out the criteria for NHPs.

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[6] Pharmac 2020/2021 Annual Report. https://pharmac.govt.nz/assets/Annual-Report-2020-2021.pdf

[7] Cabinet Social Wellbeing Committee Regulating Natural Health Products. 8p4bjb1qby 2021-07-27 11:07:05 https://www.health.govt.nz/system/files/documents/pages/swc-21-min-0109_minute.pdf

b. There is no effort to publicly review and transparently report on the fundamentally different risk profile of drugs and medical devices, as compared with dietary and food supplements.

c. The size of food and dietary supplement industries ranges from large billion dollar medical corporations to small, often family-owned businesses and everything in between

d. Hence the class of dietary and food supplements is vastly different in risk, and therefore lacks the same political clout as the big pharmaceutical corporations

e. Including food and dietary supplements in a future Act is impractical, as well as economically, morally and legally reprehensible.

26. Section [15] above drew attention to obligations which promote transparency, as clear deficits can be demonstrated in the Bill:

    a. Information and decision-making principles, systems and processes used by the Regulator to assess safety and efficacy for *market authorisation* are undefined, while all obligations are placed on the sponsor.

    b. Many clauses, such as for off-label use, are worryingly vague.

    c. Accountability is not defined – the public has no clear idea of how the Act would achieve this.

    d. Powers given to the Regulator, such as to place moratoriums on products, do not require the Regulator to publicly justify their actions.

    e. Institutional actors who may influence decision-making are not identified.

    f. Actions by officials that are inconsistent with overarching purpose, and the principles and rules, must be able to be queried in a court of law or in Parliament. However there is no transparency to protect officials who might query organisational behaviours.

27. In contrast to the obligations of the Regulator, which are largely downplayed and minimised, Offences (penalties) are mentioned some 200 times in the body of the Bill.

28. The Bill's effect is to create a pathway for arbitrary implementation of penalties. Officials must be required by law to primarily base consideration around a product's long-term safety profile as demonstrated by the scientific literature.

29. The effect of a great deal of this Bill is suppression of physician and practitioner autonomy. Autonomy is central to the practice of medicine, and actions taken to reverse chronic and environmentally mediated syndromes and diseases. Presentation of a health problem is normally highly individual, requiring tailored care modalities to target the drivers; and manage the multiple comorbidities, drug regimes, and the capacities of the person sitting in the practitioner's office.

30. Officials and Ministers may elect to dismiss public claims that the design of this prospective legislation explicitly and implicitly favours large and influential biotechnology, pharmaceutical and medical corporations. The expanding and worrying influence of such corporates has been observed by the concerned public.

31. Mandates have demonstrated a preparedness that the State will enact Orders and rules which seriously erode medical rights and autonomy of practitioners and the public of New Zealand.

    a. Officials have demonstrated that they will structure legislation based on claims by a biologic drug Sponsor. Officials will set aside obligations in the Health Act 1956 which require officials take action in *proportion* to risk. The State has established a precedent whereby the State will ignore risk by age and health status, even where a treatment is accompanied by dubious safety and efficacy claims and severe gaps in evidentiary data. The State has demonstrated a preparedness to set aside consideration of the long-term risk from exposure to a novel, untested mRNA technology which is designed to alter genetic function.

32. Institutional power structures, and related conflicts of interest represent a threat to the safe regulation of medical and technological health devices. The dominant biotechnology, pharmaceutical and medical investors and developers actively seek to control information and influence decision-making to entrench and extend market power. Investors in these corporations include the Bill & Melinda Gates Foundation and Wellcome Trust who also influence World Health Organization policy.

    a. These are powerful multi-billion dollar corporate entities. They sponsor media and scientific journals; co-draft trade agreements; engage in behind-the-scenes arrangements with governments; and are members of large lobbyist organisations, such as the financially secretive World Economic Forum.[8] [9]

    b. Increasing arrangements fusing biotechnology, the pharmaceutical and medical industries with digital surveillance technologies and government agendas, present clear risks to democracies. Secrecy arrangements prevent scrutiny, and laws are poorly drafted and inadequate. They fail to address overlapping ethical, moral and human rights concerns.

33. Regulators are susceptible to regulatory capture, as license fees for market approval are represented as a fee for access to a market. The corporation seeking approval is large, influential, and extensively resourced. The business model is one of dependence, where the regulator depends on industry income for the agency's survival, such as the Food and Drug Administration in the U.S. and the Therapeutic Goods Administration in Australia. A recent paper[10] identified several factors which contribute to capture:

    - Industry fees form the majority of regulatory agency funding. This industry funded 'capture', without external public funding, has contributed to sustained declines in evidentiary standards.

    - External advisors with conflicts of interests, historic relationships with industry.

    - Reliance on summaries provided by the drug sponsor, rather than independent assessment of clinical data.

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[8] McKibben G. Members and partners. Letter https://web.worldbank.org/archive/website00818/WEB/OTHER/MEMBERS_.HTM
[9] Garsten C & Sörbom A. (2021) Discretionary Governance Selection, Secrecy, and Status within the World Economic Forum. *Global* Governance 27:540-560. doi:10.1163/19426720-02704006
[10] Demasi, M. (2022). From FDA to MHRA: are drug regulators for hire? *BMJ* 2022;377:o1538. http://dx.doi.org/10.1136/bmj.o1538

- Pressure for speedy approvals which bypass and weaken safety-based procedures. 'Expedited pathways' – accelerated approval processes, increase likelihood in approvals for drugs and vaccines that previously would have been withdrawn for safety reasons.

- The revolving door where regulatory officials work or consult for the companies they regulated.

34. In this environment of vastly lop-sided power, it is the role of governments, and their regulatory agencies, to protect the safety of civil society and prevent abuse of power.

35. The absence of dietary and nutrition expertise across the public sector results in an absence of advocates to inform the Parliamentary Counsel Office, and guide the construction of this Bill.

36. The expertise gap contributes to ambiguities and grave uncertainties that would prevent this Bill from achieving the stated purposes of the prospective legislation. Instead of promoting public trust, the Bill and supporting documents encourage scepticism and mistrust in the regulatory process.

37. The Bill claims that rights will not be infringed upon. However, the Bill is likely to restrict the traditional practices of ethnic communities as well as historic and established practices of communities of European origin.

    a. The Bill is vastly uncertain as to when basic nutrition and dietary supplements across cultures, dovetails with distinct practitioner modalities.

38. A deletion in part of one sentence could alter legislation sufficiently to require NHPs to be regulated as medicines. Clause 22 states:

    22 Medicine

    (1) A therapeutic product is a medicine if it—

    (a) is a therapeutic product under section 16(1)(a) or (b) ; and

    (b) achieves, or is likely to achieve, its principal intended action by pharmacological, immunological, metabolic, or genetic means.

39. A simple change, the removal of 22(3)(a) could result in the declaration that NHPs are to be regulated as medicine.

40. As NHPs can exert immunological and metabolic effects, they could be regulated as medicines despite an extensive safety record, on request from large commercial industries.

41. Current processes of application and approvals for pharmaceutical drugs are inappropriate for nutritional and dietary supplements which may be complex mixtures of whole foods, where the benefit arises from the combination of ingredients or nutrients.

[2] FAILURE TO CONSIDER ACTIVE PROTECTION OBLIGATIONS TO MĀORI.

42. All parts in this objection paper to the Health Select committee emphasise that the legislative scaffolding is inadequate for the purpose. These deficits result in a potential legislation that may be unable to fulfil the obligations inherent in the principles of the Treaty of Waitangi.

43. There is a failure to incorporate adequate accountability and transparency mechanisms, in particular, to ensure the Regulator must disclose company data and informational networks.

44. The way networks of power and information flow, offers privilege to large, offshore institutions. The poor design, narrow principles and greater focus on the behaviour of the *regulated*, rather than the regulators and the medical drug and device sponsors, reproduce traditional relations of power that *prima facie* vastly disadvantage Māori as treaty partners.

45. The principle of Partnership may be undermined if the Crown does not disclose corporate data used to justify market authorisation, or a moratorium order, to Māori, inclusive of whānau, hapū, and iwi.

46. The principle of Partnership may be undermined if the Crown adopts the decision of foreign regulators and institutions, when these institutions themselves primarily rely on corporate data, and are funded by organisations which are themselves funded by large private interests.

47. The principle of Partnership may be undermined if the Crown fails to dedicate proportional and adequate resources to inform itself of the science of dietary nutrition for the protection of health, including mental health.

48. The Hauora report has noted that:

    'As part of active protection, the Crown is required to keep itself informed of the relevant circumstances as they apply to Māori needs, including ensuring equitable access.'[11]

49. As the Hauora report notes, while the Crown cannot be held wholly responsible for Maori ill health, the principle of active protection requires the Crown to make available:

    'health services that reasonably and adequately attempt to close inequitable gaps in health outcomes with non-Māori.'[12]

50. 'The voice of nutrition is alarmingly quiet.'[13] Nutrition science, research and education is vastly underfunded. Nutrition science is not presented or prioritised as a scientific discipline with equal weighting, or gravitas to other scientific disciplines which focus on innovations that are patentable.

    a. Nutrition is not valued scientifically, therefore nutritional interventions are not prioritised.[14]

51. This Bill cannot protect Māori health. The demonstrable institutional ignorance among officials, in the RIS, and in the Bill shows a failure to consider the role of nutrition and dietary supplements in redressing inequities which result from structural and economic barriers to ancestral food access.

    b. Bill documents ignore the physiological difference across people. Nutrients cannot be simply regulated toxicologically. Some people require more of a nutrient than others – due to

[11] Waitangi Tribunal Report (2019) Hauora. P.32
[12] Waitangi Tribunal Report (2019) Hauora. P. 31
[13] Coad J. & Pedley K. (2020) Nutrition in New Zealand: Can the Past Offer Lessons for the Present and Guidance for the Future? Nutrients 2020, 12, 3433; doi:10.3390/nu12113433
[14] Blampied et al (2020). Disasters, policies and micronutrients: the intersect among ethics, evidence and effective action. *NZMJ,* 133;1508:8-11

genetics, and physiological differences such as digestive challenges. People who are low in a specific nutrient may require large doses in order to replenish natural levels.

c. Government has no language to define between average levels of nutrition dosages and optimum levels which promote and protect health.

52. In regards to its role in the 'care and protection system, the Crown accepts that tamariki Māori and the whānau unit are taonga requiring protection; from this flows Tiriti / Treaty obligations to the individual tamaiti, whānau, hapū, and iwi.'[15]

53. The principle of 'active protection' of Māori rights and interests under the Treaty means the Crown must not only return power and control to Māori but also 'direct reliable and proportionate resources towards laying a durable foundation for whānau Māori to thrive as Māori'.[16]

d. The Tribunal Napier Hospital inquiry report found that the 'principle of active protection includes the Crown's responsibility to protect actively Māori health and wellbeing through the provision of health services'[17] – and that:

'Combating ill health amongst Māori, whether by medical or other means, was therefore part of the agenda of active protection that the British rulers took on under the Treaty of Waitangi.' [18]

e. The Oranga Tamariki Urgent Inquiry concerned the tamariki Māori and non-Māori children being taken into State care. The Inquiry identified the broader forces of colonisation, structural racism and the ongoing effect of historical injustice systemic structures, processes and norms that resulted in vastly disproportionate more Māori children being taken into care than non-Māori children. The Crown, in this case acknowledged that poor practice, lack of engagement and poor cultural understanding added to promote distrust and confidence in the Crown. This was also driven by a 'failure by the Crown to honour the guarantee to Māori of the right of cultural continuity embodied in the guarantee of tino rangatiratanga over their kāinga'.[19]

f. 'Active protection means recognising that Māori parents struggling in poverty have an equal right as citizens to meet their children's needs as do the better-off in society.'[20]

54. The principle of active protection requires that redressing health inequities that extends far beyond equal access to medication, to active health protection and reduction of disease. Inherent in this is an obligation to take reasonable steps to protect health.

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[15] Waitangi Tribunal Report (2021). HE PĀHARAK E K E, HE R I TO WHAKAKĪKĪNGA WHĀRUARUA, Oranga Tamariki Urgent Inquiry. WAI2915. https://forms.justice.govt.nz/search/Documents/WT/wt_DOC_171027305/He%20Paharakeke%20W.pdf Waitangi Tribunal Report (2021). Page 6.

[16] Waitangi Tribunal Report (2021). HE PĀHARAK E K E, HE R I TO WHAKAKĪKĪNGA WHĀRUARUA, Oranga Tamariki Urgent Inquiry. WAI2915. https://forms.justice.govt.nz/search/Documents/WT/wt_DOC_171027305/He%20Paharakeke%20W.pdf

[17] Waitangi Tribunal Report (2019) Hauora. Report on Stage One of the Health Services and Outcomes Kaupapa Inquiry. WAI 2575

[18] Waitangi Tribunal, The Napier Hospital and Health Services Report. P.53

[19] Waitangi Tribunal Report (2021). (xv)

[20] Waitangi Tribunal Report (2021). P.20

g. The state of scientific evidence in the scientific literature identifying the relationship of nutrition and health is not reflected in any Ministry or Crown entity.

h. Access to nutrition for non-Māori via diet, or nutritional supplements outpaces access for Māori. Thus, it is not medical equity, but *nutritional* equity that *sustains* disadvantage.

i. The failure of the Crown to prioritise nutrition promotes structural disadvantage, and this amplifies over generations as mothers enter pregnancy with inadequate diets.

j. Active protection requires that health services are targeted to individual needs. Protection of the chronic disease and mental illness pandemic experienced by Māori, at younger and younger ages, requires a dietary and nutritional approach as much as a medical approach.

55. The Tū Mai te Rangi ! report noted that

'the failure actively to protect Māori Treaty rights when necessary is as much a breach of the Treaty as the active removal of those rights.'[21]

56. The lack of access to ancestral diets and adequate nutrition has produced intergenerational suffering. Māori have experienced decades of health disparity and are at increased risk of disease and early death than non-Māori.[22] [23] [24]

a. The presence of multiple health conditions is now more common than one health condition.[25]

b. Poor stewardship by the State[26] has favoured corporations supplying cheap, highly processed, nutrient-poor foods,[27] resulting in an obesogenic environment.[28]

c. Poly-pharmacy to manage multiple conditions can drive further harm, including undesirable adverse events, and the deterioration and destruction of the gut microbiota.[29]

d. There is evidence that regulators consider that formulations can be regarded as a medicine due to therapeutic benefits, however, this trigger then results in higher bars, such as licensing, or empirical 'proof' – a regulatory equivalence – that is disconnected to the foundational

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[21] Waitangi Tribunal (2017) Tū Mai te Rangi ! Report on the Crown and Disproportionate Reoffending Rates. p21.
[22] Ministry of Health (2018). Health and Independence Report 2017. The Director-General of Health's Annual Report on the State of Public Health. Ministry of Health, Wellington. https://www.health.govt.nz/system/files/documents/publications/health-and-independence-report-2017-v2.pdf
[23] King, A. 2001. The New Zealand Health Strategy. Wellington: Ministry of Health
[24] Ajwani et al 2003. Decades of Disparity. Ethnic Mortality Trends in New Zealand 1980-1999. Wellington: Ministry of Health and University of Otago.
[25] Millar, E., Dowell, A., Lawrenson, R., Mangin, D., & Sarfati, D. (2018). Clinical guidelines: what happens when people have multiple conditions. NZMJ, 73-81.
[26] Baker et al. (2018). What Enables and Constrains the Inclusion of the Social Determinants of Health Inequities in Government Policy Agendas? A Narrative Review. Int J Health Policy Manag, 7(2), 101-111. https://doi.org/10.15171/IJHPM.2017.130
[27] Lane et al (2020). Ultra-processed food and chronic non-communicable diseases: A systematic review and meta-analysis of 43 observational studies. *Obesity Reviews.* 22(3):e13146. doi: 10.1111/obr.13146
[28] Wild et al. (2020) Challenges of making healthy lifestyle changes for families in Aotearoa/New Zealand. Public Health Nutrition, 24, 7, 1906–1915
[29] Ecks, S. Multimorbidity, Polyiatrogenesis, and COVID-19. Medical Anthropology Quarterly, https://doi.org/0.1111/maq.12626

issue – that nutritional supplements address biological deficiency, rather than the suppression of symptoms offered by a synthetic drug.

e. Often symptoms are tied to more complex aetiologies (underlying drivers) associated with poor diets that drugs do not address, but which drive other comorbid conditions.[30]

f. Failing to prioritise nutritional interventions, when the data is present, such as micronutrients for depression, anxiety and ADHD,[31] [32] [33] or vitamin D for immune health[34] [35] [36] amplify health and racial disparities, as wealthy families can source and pay for micronutrients, while low-income and disadvantaged families cannot.

57. During the COVID-19 pandemic, Māori were at higher risk of serious COVID-19 disease and death than non- Māori, because of their often diet-related chronic disease status[37] [38] [39] and accompanying nutrient deficiencies.[40]

58. The State demonstrated that in an emergency event, persistent injustice regarding access to dietary nutrition would be ignored. The Minister for COVID-19, the Hon Chris Hipkins made no effort during the pandemic to address diet and nutrition inequities, either related to access to whole food, or through access to nutritional supplements that Māori are deficient in, such as vitamin D3.

59. Rongoa Māori practitioners were removed from their positions for failing to accept a novel mRNA genetic vaccine that never promised to prevent transmission and often only generated the production of antibodies for a short time. The Minister for COVID-19 persistently ignored the issue of injury and death from the mRNA gene therapy injection.

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[30] Lustig R. (2021) Metabolical. Yellow Kite, Hodder & Stoughton Ltd.

[31] Rucklidge J. et al (2021) Massacre, Earthquake, Flood Translational Science Evidence That the Use of Micronutrients Postdisaster Reduces the Risk of Post-Traumatic Stress in Survivors of Disasters. *International Perspectives in Psychology* (2021), 10(1), 39–54. https://doi.org/10.1027/2157-3891/a000003

[32] Rucklidge J. et al (2021) Nutrition Provides the Essential Foundation for Optimizing Mental Health. *Evidence-Based Practice in Child and Adolescent Mental Health*, 6:1, 131-154, DOI: 10.1080/23794925.2021.1875342

[33] Kaplan BJ. and Rucklidge JJ. (2021) The Better Brain Overcome Anxiety, Combat Depression, and Reduce ADHD and Stress with Nutrition. Houghton Mifflin. 368.

[34] Argano C et al (2023) Protective Effect of Vitamin D Supplementation on COVID-19-Related Intensive Care Hospitalization and Mortality: Definitive Evidence from Meta-Analysis and Trial Sequential Analysis. *Pharmaceuticals*, 16:130 https://doi.org/10.3390/ph16010130

[35] Greiller CL & Martineau AR (2015) Modulation of the Immune Response to Respiratory Viruses by Vitamin D. Nutrients 2015, 7(6), 4240-4270; https://doi.org/10.3390/nu7064240

[36] Yildiz M et al (2021) The prognostic signifi cance of vitamin D deficiency in patients with COVID-19 pneumonia. *Bratisl Med J* 2021; 122 (10)744-747. DOI: 10.4149/BLL_2021_119

[37] Al Heialy S., et al (2021). Combination of obesity and co-morbidities leads to unfavorable outcomes in COVID-19 patients. Saudi J. Biol. Sci. 28, 1445-1450. https://doi.org/10.1016/j.sjbs.2020.11.081

[38] Steyn et al. (2020). Estimated inequities in COVID-19 infection fatality rates by ethnicity for Aotearoa New Zealand. Te Pūnaha Matatini. April 14, 2020. Unpublished report https://cpb-ap-se2.wpmucdn.com/blogs.auckland.ac.nz/dist/d/75/files/2020/04/Estimated-ifrs_draft12.ACTUALFINAL.pdf

[39] Patel et al 2020. Poverty, inequality and COVID-19: the forgotten vulnerable. Public Health.183: 110–111.

[40] Carpagnano GE et al (2020) Vitamin D deficiency as a predictor of poor prognosis in patients with acute respiratory failure due to COVID-19. *Journal of Endocrinological Investigation* 44:765–771. https://doi.org/10.1007/s40618-020-01370-x

60. The State demonstrably and persistently ignored the potential for multi-target ambulatory treatment to prevent hospitalisation and death,[41] particularly in high-risk groups, for vaccine failure.[42]

    a. The evidence that the mRNA gene therapy waned, did not prevent transmission, and could cause serious harm had been globally recognised by medical specialists and scientists before population level mandates were in law in New Zealand.[43]

61. The drug producer Pfizer/BioNTech recognised in their December 2020 that people with multiple comorbidities might not respond adequately to the drug, due to immune suppression.[44]

62. This Bill is not consistent with the Treaty of Waitangi as Cabinet and the RIS have failed to reasonably consider that dietary and nutritional deficiencies exacerbate systemic and structural inequity experienced by Māori and the importance of access to safe dietary supplements to support reversal and remission of health conditions.

    a. The documents also downplay the persistent problem of drug-drug interactions experienced disproportionately by Māori, and ignore the importance of dietary nutrition;

    b. The Privy Council has considered that the relationship envisaged in the Treaty was one "founded on reasonableness, mutual cooperation and trust". The nature of this relationship requires the Crown in carrying out its Treaty obligations to take "such action as is reasonable in prevailing circumstances". [45]

    c. The Waitangi Tribunal has 'suggested that the Crown should exercise a "double trusteeship" role to offset the power imbalance between the partners, namely 'a duty to protect the Māori duty to protect and an obligation to strengthen Māori to strengthen themselves'.[46]

    d. Structural changes remain outside of policy that can help address the social and political drivers of healthy inequity.

    e. A case study is provided which demonstrates that safety and efficacy processes for biologic drugs, designed to alter genetic functioning are severely deficient, and where fast-tracking results in novel technologies being approved.

    f. A case study is provided to demonstrate the problem where use of psychotropic drugs has increased substantially in recent years[47]; but already present systemic barriers to approval of

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[41] McCullough, P.A. et al. (2020). Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). Reviews in Cardiovascular Medicine, 21(4), 517-530. https://doi.org/10.31083/j.rcm.2020.04.264

[42] Bruning J. (2022) COVID-19 Emergency Powers: The New Zealand State, Medical Capture and the Role of Strategic Ignorance. (2019-2022).

[43] 2022 REPORT: October 2021 Submissions to the COVID-19 Public Health Response Amendment Bill (No 2). https://psgr.org.nz/sars-cov-2-covid-19/246-submission-to-the-covid-19-public-health-response-amendment-bill-no-2

[44] Vaccines and Related Biological Products Advisory Committee Meeting December 10, 2020 FDA Briefing Document Pfizer-BioNTech COVID-19 Vaccine Sponsor: Pfizer and BioNTech. https://www.fda.gov/media/144245/download

[45] The Principles of the Treaty of Waitangi as expressed by the Courts and the Waitangi Tribunal. P.78-79 https://waitangitribunal.govt.nz/treaty-of-waitangi/principles-of-the-treaty

[46] The Principles of the Treaty of Waitangi as expressed by the Courts and the Waitangi Tribunal. P.82

47 Barczyk et al 2019. Psychotropic Medication Prescription Rates and Trends for New Zealand Children and Adolescents 2008-2016. J Child Adolesc Psychopharmacol. 2020 Mar;30(2):87-96. doi: 10.1089/cap.2019.0032.

vitamin and nutrient treatments designed to treat and reverse mental illness such as depression, anxiety and ADHD.

g. A case study is provided to demonstrate the ease with which medical drugs with very limited safety data, mostly industry funded, are approved. When adverse events are reported in the literature, these papers are often ignored.

63. This specialist expertise is required for oversight of dietary and food supplements, and is a key reason why these natural health products should be regulated separately to pharmaceutical, biological and digital therapeutics.

[3] IMPROVEMENT REQUIRED : Regulatory transparency for market authorisation.

64. The Therapeutic Products legislation does not currently, but *must* require regulators to be critically proactive in review of applications for market authorisation in order to maintain public trust. The *prima facie* naïve perspective of the Bill suggests that all information and safety/efficacy claims can be accepted at face value without further investigation.

    a. Review of scientific literature must take account of the potential for conflicts of interest where medical journals publish studies by industry actors who also advertise in medical journals.[48] [49] [50]

    b. Publishing of information to enhance claims is recognised as 'information laundering.'

65. The culture of officials working under the Therapeutic Products legislation must be protected from undue influence from the pharmaceutical/medical industry. Rules in the Medicines Act must take all action to prevent conflicts of interest in regulatory decision-making. This will reduce the potential for regulatory capture whereby the regulator prioritises the interests of the regulated industry over the public interest.

66. The Bill imposes a duty on the Minister of Health administering the Act and the regulator to consult persons and organisations that the Minister or regulator considers appropriate, having regard to the subject matter of the proposed secondary legislation. This consultation must occur prior to making the secondary legislation.

67. There must be an explicit clause built into the primary legislation requiring that the medical, biotechnology and pharmaceutical industry and individuals or groups with lobby affiliations and financial conflicts of interest, are prohibited from consultation for the purposes of production of primary or secondary legislation.

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[48] Smith R. (2003) Medical journals and pharmaceutical companies: uneasy bedfellows. *BMJ* 326:1202–5

[49] 'It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgement of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of The New England Journal of Medicine.' Angell M, New York Review of Books, January 19, 2009.

[50] Demasi, M. (2020). While their ads are prevalent, drug companies and medical journals will remain uneasy bedfellows. Michael West Media. https://michaelwest.com.au/while-their-ads-are-prevalent-drug-companies-and-medical-journals-will-remain-uneasy-bedfellows/

68. Rules in the Therapeutic Products legislation must explicitly deny medical, biotechnology and pharmaceutical industry and individuals or groups with lobby affiliations and financial conflicts of interest, access to officials and to regulatory decision-making processes.

69. All information from industry lobby groups must be immediately posted for public access.

70. We suggest officials take into account Council of Europe recommendations (2015)[51]:

    a. place an obligation on pharmaceutical companies to declare their linked interests with all health sector players, to make these declarations accessible to the public, and to establish an independent authority responsible for monitoring this matter (6.1.3);

    b. ensure absolute transparency regarding the linked interests of experts working with the health authorities and make sure that persons with a conflict of interest are excluded from sensitive decision-making processes (6.1.4);

    c. ensure that health-related decisions, including decisions on criteria for defining illnesses and thresholds for treatment, are taken on the basis of individual and public health considerations and are not profit-driven (6.1.5);

    d. introduce strict regulations governing the movement from a position in the public sector to one in the private sector (and vice versa), between the health authorities and the pharmaceutical industry(6.1.6);

    e. prohibit any agreement between pharmaceutical companies which aims to delay, without medical justification, the marketing of generic medicines (7.0).

71. Medical drugs, including biologics and medical devices:

    a. The safety and efficacy of these products extends beyond short term acute harm, to long term, unanticipated and difficult to detect harms.

    b. There remains insufficient focus on the stewardship of medical therapeutic products across their lifecycle as information regarding the safety and efficacy of therapeutic products changes over time.

    c. Therefore, it is not only market authorisation that is of *primary* concern, but long-term oversight.

    d. The importance of feedback loops from the scientific literature and adverse event reporting systems are downplayed in the Bill.

    e. Company trials should be a cornerstone of regulatory approval, not the central foundation.

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[51] Council of Europe. Resolution 2071 (2015) Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests? Author(s): Parliamentary Assembly Origin - Assembly debate on 29 September 2015 (30th Sitting) (see Doc. 13869, report of the Committee on Social Affairs, Health and Sustainable Development, rapporteur: Ms Liliane Maury Pasquier). Text adopted by the Assembly on 29 September 2015 (30th Sitting). http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=22154&lang=en

f. The Explanatory Notes state that medical devices that are lawfully supplied before the Bill commences will have a transitional period of 2-5 years to seek market authorisation. It is unclear whether there are loopholes here which might enable unsafe devices to gain entry, then delay applications under the new Act.

72. The section discussing market authorisation does not articulate principles guiding market authorisation. Clause 119 sets out the requirements for *evaluating* a medicine or medical device; while Clause 120 sets out the criteria for a *market authorisation* for a medicine or medical device. Clause 126 lists the details that must be included in a products market authorisation.

73. Clinical trial data supporting market authorisation:

    a. The new Act must require that all clinical trial data for medical drugs and devices with market authorisation must be in the possession of the regulator; and

    b. The regulators must be resourced to actively inspect and review clinical trial data; and

    c. Clinical study reports must be publicly available on request. No data collected can be omitted.

    d. 'Less bureaucracy and secrecy and more sunlight is needed if regulation is to regain its lost reputation and fulfil its public health mission.' [52]

74. Formalisation of clinical trial data requirements are important to promote trust and transparency. The current Bill does not make allowance for the potential for industry to supply biased studies.

75. A 2017 Cochrane review stated:

    'Sponsorship of drug and device studies by the manufacturing company leads to more favorable efficacy results and conclusions than sponsorship by other sources. Our analyses suggest the existence of an industry bias that cannot be explained by standard 'Risk of bias' assessments.[53]

    a. The sponsors are the holders of the market authorisations. The obligation of the sponsor to provide data, and the absence of a role for the regulator in reviewing the independently published scientific evidence produces a morally questionable culture that favours industry data.

    b. The framework for regulations and rules relating to market authorisation for medicines and medical devices (Part 3 and 4) does not transparently require the regulator to actively review data, nor is there funding to ensure the regulator has capacity to undertake such reviews, for products during authorisation and post-approval.

[52] Doshi P & Jefferson T. (2018). Disclose Data Publicly, without Restriction. ASLME 45:2. https://doi.org/10.1177/1073110517750620
[53] Lundh A, Lexchin J, Mintzes B, Schroll JB, Bero L. Industry sponsorship and research outcome. Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: MR000033. DOI: 10.1002/14651858.MR000033.pub3.

[4] IMPROVEMENT REQUIRED: Post-market surveillance and adverse event regulations.

76. Risk from medical drugs and devices have been downplayed and ignored in the Bill and the RIS as the new Regulator does not have high level obligations imposed in this omnibus bill.

77. Principles and pathways of adverse event reporting must be specified in the primary legislation.

78. Reporting processes are required to come from the industry sponsor, and current 'service-to-industry' systems are seriously deficient.[54] A 2015 study found that:

    'only about half of reports of serious side effects submitted by manufacturers met basic standards for completeness, containing a patient's age, sex and the date the event took place.'[55]

79. Adverse drug experiences, or iatrogenic events from medical injury are relatively common, and have been estimated at 1% of total deaths.[56] [57] A 1995 report in JAMA[58] stated:

    'over a million patients are injured in U.S hospitals each year and approximately 280,000 die annually as a result of these injuries, therefore the iatrogenic death rate dwarfs the annual automobile accident mortality rate of 45,000 and accounts for more deaths than all other accidents combined.'

80. The safety and efficacy of novel biologics and novel medical devices remain mired in uncertainty. This field is largely untested and experimental. As stated in the Bill, biologics include medicines made from biological components, gene therapies, and advanced cell and tissue therapies; and medical devices that are software, production systems, whole organs, and tissue grafts.

81. The extent to which the New Zealand *regulator* of medicines and medical devices will conduct post-market surveillance and monitoring beyond the review of directly industry supplied data is unclear.

    a. The sponsor is required to have a 'post-market surveillance and response system to provide surveillance of the product's safety and quality, and efficacy (for a medicine) or performance (for a medical device)' (Clause 142).

82. This must be clearly structured in the primary legislation in order to inform and guide secondary legislation. This is required to secure public trust in regulatory activities.

83. 'The post-market surveillance and response system' (the system) must be plainly and transparently articulated so that the public may understand how this occurs. As such, the current text in the draft Bill (Clause 203) is inadequate for the purpose, as it does not describe the pathways, and the extent of post-market surveillance and monitoring.

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[54] Zolezzi M & Parsotam N (2005). Adverse drug reaction reporting in New Zealand: implications for pharmacists. *Therapeutics and Clinical Risk Management* 1;3:181-188

[55] New York Times (2015). Drug Makers' Data on Side Effects Is Called Lacking in a Report (New York Times, February 2, 2015)

[56] Khaskheli M. et al (2014) Iatrogenic risks and maternal health: Issues and outcome. . Pak J Med Sci 2014;30(1):111-115. doi: http://dx.doi.org/10.12669/pjms.301.4062

[57] Leape, Lucian L., Error in Medicine. JAMA 272(23):1851-57. 1994

[58] Bates DW, Cutten DJ, Laird N, Petersen LA, Small SD, Servi D, et al. Incidence of adverse drug events and potential adverse drug events implication for prevention. ADE prevention study group. JAMA. 1995;274(1):29-34.

84. The characteristics of drugs place them in a risk class that are *orders of magnitude* more harmful than that presented by dietary and nutritional supplements. There is a vast difference in risk of harm from adverse events, or iatrogenic injury from exposure to medicines.[59]

85. Medicines and medical devices are such an entirely different toxicological, pharmacological and safety profile that they are a vastly different category, requiring a different *regulatory culture*, and vastly different *scientific expertise* than food and dietary supplements.

86. Medicines, including those made from biological components, gene therapies, and advanced cell and tissue therapies; and medical devices that are software, production systems, whole organs, and tissue grafts are extensively more risky than dietary and food supplements. Medicines are intended to alleviate and suppress specific symptoms and disease presentations, rather than system-wide drivers.

87. It has been recognised for decades that the safety profile for medical drugs is far worse than for nutritional and dietary supplements.[60] A year 2000 Australian submission noted that 'the past decade more than 100,000 Australasians have been killed by properly researched, properly regulated, properly prescribed and properly used drugs' – while over the same period there was one disputed death from dietary supplements.[61]

88. One active ingredient in a medical drug may have a different toxicological risk profile than another active ingredient. Several may be integrated into a formulation. Doctors spend years studying the toxicological and tolerance profile of drugs, and iatrogenic risk guides all decision-making.

89. Adverse drug events are under-reported by between 5% and 20%.[62] [63] [64] A New Zealand study demonstrated that maternal and perinatal adverse events were 'significantly under-reported.'[65]

90. In New Zealand as much as 12% of hospital admissions may be associated with an adverse event.[66]

91. The claim that 'benefits will outweigh risks' by absorbing food and dietary supplements into the Therapeutic Products Bill cannot be justified if adverse event reporting is downplayed.

92. Medsafe roles and functions are not outlined in the Bill. Medsafe is not an independent entity but a business unit within the Ministry of Health. Medsafe currently administers the Medicines Act 1981 (and the Medicines Regulation 1984) and is responsible for the regulation of therapeutic products in New Zealand.

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[59] Light D (2010). The Risks of Prescription Drugs. Columbia University Press, New York.
[60] Illich, Ivan. 1975. Medical Nemesis: The Expropriation of Health. London, England: Calder & Boyars.
[61] National Nutritional Foods Association of New Zealand (2000) 1. Review of Cost Recovery By Commonwealth Agencies: Australian Productivity Commission
2. Review of Sovereignty Issues relating to International Treaties: New Zealand Parliament's Regulations Review Committee Inquiry. https://www.pc.gov.au/inquiries/completed/cost-recovery/submissions/national_nutritional_foods_association_of_nz_/sub011.pdf
[62] Lazarus R et al (2007) Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS). Grant ID: R18 HS 017045. Submitted to:The Agency for Healthcare Research and Quality (AHRQ) U.S. Department of Health and Human Services
[63] Dickinson, JG. FDA seeks to double effort on confusing drug names. Dickinson 's FDA Review . 2000 Mar;7(3):13-4.
[64] Bates DW. Drugs and adverse drug reactions: how worried should we be? JAMA . 1998 Apr 15;279(15):1216-7.
[65] Farquar C. et al (2015). Under-reporting of maternal and perinatal adverse events in New Zealand. . BMJ Open 2015;5:e007970. doi:10.1136/bmjopen-2015-007970
[66] Davis P et al (2002) Adverse events in New Zealand public hospitals I: occurrence and impact. New Zealand Medical Journal 115(1167). https://researchspace.auckland.ac.nz/handle/2292/15553

a. There appears to be a conflict of interest as the Ministry of Health is the agency involved in drug approvals, but Medsafe which might produce information which might contradict Ministry positions, are under direct control of the Ministry of Health.

b. Independent funding for Medsafe to conduct active inquiry – or the authority which replaces Medsafe, should be appropriate to the range of inquiry required to consider international court decisions, the scientific literature and respond and report on all adverse events in a timely manner.

93. Will Medsafe be completely disestablished? Will Medsafe transition to the new regulator? Why is this so difficult to understand?

94. The post-market surveillance and response system - 'The system' must specify in primary legislation:

b. The obligation that surveillance activities will be conducted independently of the sponsor (in addition to information provided by the sponsor);

c. Specific reporting *processes* and procedures for adverse events (ADEs).

95. Primary legislation should specify system level obligations and structures for sourcing information and analysing safety and efficacy independently of the manufacturer/sponsor. This can include:

d. Which New Zealand authorities (including regional health services) conduct ADE monitoring and reporting, how this occurs and how often.

e. Which specific offshore regulatory agencies and institutions are consulted (see part [10]).

f. An obligation to fund the Regulator so they may conduct these activities freely.

g. Obligation and procedures for regulatory surveillance of the scientific literature for harm signals (e.g., such as surveying meta-analyses, prioritising non-industry funded publications).

i. For example, the regulator would be required to review meta-analyses in the *independent* scientific literature and publish them on a database.

h. Obligation and procedures to surveil the legal literature to identify international court action. This includes an obligation where the regulator is required to take account of findings (including through the discovery process) in local and international court cases.

i. An obligation to analyse risk profile by age group and health status.

j. An obligation that the regulator is required to provide public access to all supporting information and data considered, relating to:

i. The announcement of a Moratorium Order.

ii. Application for market access for a new drug or device that has completed clinical trials.

iii. Approval of any drug or device that has not completed clinical trials, but is released for public use.

96. The requirements in the above section are designed to produce a legal obligation for the Regulator to consider other information other than privately produced industry data and promote transparency.

97. This ensures that the Regulator is obliged to triangulate information and evidence outside of industry claims, thereby preventing regulatory capture, and that the public may observe which information is considered.

98. These requirements are a particularly important legal framework for regulatory officials (including whistle blowers) who observe evidence that the medical drug or device may not fulfill safety or efficacy claims, to document risk, in the knowledge that they are obliged to look more broadly (I.e. take account of relevant considerations).

[5] IMPROVEMENT REQUIRED: Risk that barriers to off-label use may increase.

99. The Therapeutic Products Bill If the medicine or device is used for a different purpose or indication, that is referred to as off-label use. Off-label use is an important source of innovation by doctors, particularly concerning complex conditions that may be poorly served by present medications. Doctors often prescribe medicines off-label that have a long history of safe use, where there is an identified pathway that has been observed in the scientific literature that might assist with a patient's symptoms.

100. Off-label prescribing may track ahead of regulatory knowledge as doctors review the scientific literature and discuss findings with colleagues domestically and offshore. These medications might be off-patent and be cheap to access.

101. The Bill is unclear as to how off-label use will be permitted. The Guidance Note (page 45) intimates that off-label use may be permitted 'only if they are allowed to do so with products that do not have a NZ authorisation'.

102. This indicates that doctors are only allowed specified 'allowed' use based on regulatory permissions for off-label use.

103. Such regulations would remove the doctors freedom to prescribe, and place power in regulatory agencies. However regulatory agencies do not review the independent scientific literature, and often lag behind physician knowledges.

[6] IMPROVEMENT REQUIRED: Product moratorium orders lack transparency.

104. The Medicines Act 1981 was much more process oriented in the prohibition/banning of medicines:

a. (Clause 36) The Minister could prohibit following a notice by the Director General

b. (Clause 37) The Minister could prohibit for a specified period not exceeding one year, and could not exercise the power more than once for a drug or device.

c. (Clause 48) The Minister could by notice in the Gazette prohibit a class or description of medicines. But this the Minister could only do following a recommendation of a responsible authority, such as the medical council.

105. However, the Therapeutic Products Bill enables the regulator to make a Product Moratorium order (Clause 222) which 'prohibits people carrying on supply chain activities with the product or advertising or recommending it'… 'while the Regulator evaluates the product and takes any other appropriate action to manage those risks'.

a. All reasoning behind a moratorium order must clearly be disclosed in a report that is then made published publicly.

b. The Bill currently states that the regulator may do this if the Regulator 'suspects that a product exposes the public to risk of death, serious injury or serious illness, or creates a significant risk to personal or public health.

c. However, there is no requirement that the Regulator must publicly justify the rationale behind the Product Moratorium Order.

d. Clause 222 contains the potential for injustices to arise while products are scheduled for evaluation, or are being evaluated, without the Regulator having to clearly articulate the rationale for the regulatory order.

e. Moratorium orders present a much greater risk to small and medium sized firms. A holding pattern for a small or medium sized firm might put them out of business, while large corporations may be relatively unharmed.

f. Clause 222 deviates from the Medicines Act giving this capacity to the Regulator, to officials.

106. (Clause 33) 'A therapeutic product is a prohibited product if the regulations say it is.' There is no requirement for the Regulator or responsible Minister to explain why a product is designated a prohibited product. The Bill states that this cannot occur unless the Minister is satisfied 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.

107. However, there is no requirement that the Regulator must publicly justify the reason for the 'prohibited product' status.

108. Currently, this clause is arbitrary, scientifically unsound and lacking in transparency.

[7] REGULATORY IMPACT STATEMENT: Unfit for purpose

109. The PSGR object to the claim that the Impact Statement titled "Regulating Natural Health Products", produced by the Ministry of Health and dated 20 May 2021 is 'consulted, complete and convincing'. The PSGR do not consider it is balanced in its presentation of the information, nor that the major impacts are identified and assessed.

a. Page 5/24 claims that a Ministry QA panel reviewed this statement and considered that the Impact Statement met the quality assurance criteria.

110. The May 20, 2021 Regulatory Impact Statement (RIS) provided a selection of three options. These included whether there would be a standalone or natural health products (NHPs) would be absorbed into a Therapeutic Products Bill.

a. It appears that large corporations were exclusively consulted, while the independent NHP businesses and practitioners who would be disproportionately affected, were not.

b. What is the intersection here with competition rules? This was not clarified by the RIS.

111. On November 4, 2022, a RIS supplementary analysis was produced to support Cabinet's decision to introduce the Therapeutic Products Bill to Parliament in 2022. The analysis solely concerned the issue that lower-level sanctions relating to lower-level behaviours and practices, and Crown liability for breaches of the Medicines Act.[67]

112. The RIS claimed (p.6)[68]:

'there is limited quantitative evidence on the negative impact of the status quo on the New Zealand natural health product industry. There is also limited evidence on the actual harm to consumers from the use of natural health products through overuse, interactions with other products or medicines, use of unsafe products and/or use of natural health products for a condition that requires clinical care and prescription medicines.'

113. The RIS does not provide data on risk from NHPs, but states (page 4 & 9):

'Based on adverse reactions data from Australia and other international recall data, it is reasonable to assume that natural health products do result in harm in New Zealand.'

114. Neither the Ministry of Health nor Pharmac nor Cabinet has reviewed the literature to identify the state of knowledge and risk relating to iatrogenic harm from drugs and from drug-drug interactions, while claiming risk from NHPs.

115. Such a review, before the production of legislation and the investment in a bureaucratic framework would demonstrate the extent to which investment in a regulatory scheme is required that is *proportionate to risk*, i.e., is proportionate in relation to risk from drugs and medical devices and risk from NHPs. This did not happen.

116. Without considering the proportionate risk profile the regulatory framework cannot claim that a greater burden to relative risk will not fall on NHP suppliers.

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[67] Ministry of Health. Regulatory Impact Statement: Therapeutic and Natural Health Products Regulation –Supplementary Analysis 2022 No 1. auqg18bipj 2022-11-24 09:34:20. https://www.health.govt.nz/system/files/documents/information-release/publication_-_regulatory_impact_statement_therapeutic_and_natural_health_products_regulation_-_supplementary_analysis_2022_no_1._1.pdf

[68] Ryan, Fiona (2021, May 20). Coversheet: Regulating natural health products. Regulation of natural health products under the Therapeutic Products Bill. (Regulatory Impact Statement) https://www.health.govt.nz/system/files/documents/pages/regulatory_impact_statement_-_regulating_natural_health_products.pdf

117. Therefore the RIS has failed to weight, and place in context the added bureaucratic burden on a single regulator, ***and*** the burden placed on small and medium sized businesses for foods and nutritional supplements with a long history of safe use.

118. The scheme is grossly uncertain with potential for grave injustices. The RIS states that regulation will extend to controlling previously unregulated foods (page 3):

‘This proposal is for a new comprehensive and consistent regulatory scheme. It is likely to include producers who have not previously been subject to regulation and may involve additional costs to those currently regulated under other schemes, for example food or cosmetics… Consumers may bear some costs where producers pass on increased compliance costs. There is the potential for some products to be removed from sale if the compliance cost and/or regulatory burden makes them uneconomic.’

119. The prospective legislation appears to produce considerable bureaucratic and legal barriers to the inclusion of nutrients with a good safety profile while reducing barriers for the regulation and stewardship of novel drugs and devices, and of drugs with uncertain, or risky safety profiles.

120. Processes are entrenched in the Bill, and omissions in the Bill that inherently lower barriers to the inclusion of drugs on Pharmac schedules. These issues are not addressed in the RIS.

k. Legal, financial and lobbying resources of the drug sponsor.

l. Existing relations of the drug sponsor with regulatory agencies.

m. Bias to favouring clinical trials for approval. Recognition that drug sponsors will not fund clinical trials for offpatent/low margin drugs or nutrients.

n. Inability to recognise off-patent drugs with a strong safety profile, nor make allowance for different study designs which demonstrate efficacy, such as through observational and other trials. [69]

121. Processes are entrenched in the Bill, that inherently lower barriers to the inclusion of drugs on Pharmac schedules. These issues are not addressed in the RIS.

122. Page 3 demonstrates that Cabinet and the Ministry of Health is unwilling to consult on the merits of regulation or not of many foods with a long history of safe use, and instead view opposition as a political problem instead of an issue for consultation:

‘While most of the natural health products sector is cautiously supportive of regulation, there is a small group who oppose regulation of these products, and in particular regulation under the same scheme as medicines. There is a risk that if this group’s view gain traction, it could delay the passage of the Therapeutic Products Bill, and introduce uncertainty about the benefits of the proposal to regulate natural health products.

[69] Anglemeyer et al. Healthcare outcomes assessed with observational study designs compared with those assessed in randomized trials. Cochrane Database Syst Rev. (2014) Apr 29;2014(4):MR000034.

123. The RIS demonstrates that officials are poorly informed in the field of biological health, vitamins and minerals, and this is likely to result in arbitrary and unjustified decisions.

o. The Ministry of Health has demonstrated repeatedly that it has a poor understanding of how bodies differently absorb and process vitamins and minerals with a long history of safe use.

p. The RIS fails to address the different considerations when nutrients may substitute drugs for which there is poor tolerance, but the nutrient has a much better safety profile.

q. The Ministry has demonstrated inconsistency in dose permissions for certain vitamins.

r. The Ministry repeatedly fails to consider often system-wide of vitamins and minerals, consistent with the evidence in the scientific literature.

s. The Ministry has not undertaken enquiry to recognise the 'broad spectrum' benefit of nutrient mixtures.

124. The RIS is ignorant of the potential for ongoing conflict between the dietary and food supplements industry and the regulator regarding health claims that are inconsistent with the Ministry of Health position.

a. The separation of the Regulator from the scientific literature 'scientific evidence' ensures that the Regulator will not have expertise in the of health benefits of nutrition-related supplements.

b. Medical doctors are not trained in nutrition, nor is there a cohort of expertise in Ministries or Crown Institutes that are collegial with natural health practitioners in Aotearoa New Zealand, and where feedback loops benefit both researchers and practitioners.

c. The Ministry of Health (MoH) does not conduct reviews of the literature for dietary and nutritional supplements, and in many cases the MoH position does not reflect the weight of evidence in the literature.

d. It is likely the regulator will deny a claim on a label if it is inconsistent with Ministry of Health advice, yet that Ministry often lags behind known nutritional knowledge.

i. For example, New Zealand continues to ignore the association of high vitamin D levels with immune health. [70] Therefore, this would be denied, but it would be denied on the basis of institutional ignorance.

[8] NATURAL HEALTH PRODUCTS: Requires distinctly different regulatory culture.

125. Food and dietary supplements, currently regulated under the Food Act 2014, and the Dietary Supplements Regulations 1985 must be retained separately as a distinct regulatory category.

[70] Greiller CL & Martineau AR (2015) Modulation of the Immune Response to Respiratory Viruses by Vitamin D. Nutrients 2015, 7(6), 4240-4270; https://doi.org/10.3390/nu7064240

126. The decision to fold dietary (nutritional) supplements (natural health products) is unjustified by information contained in related Cabinet documents, including Cabinet memos, minutes and Regulatory Impact Statements (RIS). It is a decision that is arbitrary.

127. The Ministry of Health 2018 position[71] [72] stated: 'The Government intends to exclude natural health products (including rongoā Māori and dietary supplements) from regulation under this new legislation.'

128. The decision to shelve food and nutrition inside medical drug and device regulation has not been adequately substantiated.

129. The supporting documents for this Bill[73] demonstrate that officials have not reviewed the underpinning scientific issues that result in a vast difference between both consumption patterns and the potential for risk of death or harm following exposure:- for the (a) pharmaceutical and biological drugs and devices; versus the (b) food or dietary supplements (also known as natural health products).

130. Clauses are disproportionately authoritarian/pecuniary in comparison to the risk ratio of food and dietary supplements.

a. A search on Google Scholar for mortality adverse event dietary nutrition supplements fails to provide an estimate of global deaths from dietary and nutritional supplements, The major risk may be ingredients rather than the nutritional supplements, and this is for a fraction of the supplements taken. Research papers identify potential pathways for risk,[74] but the reported death risk are orders of magnitude lower in the dietary and nutritional supplements category.

131. Food and nutritional supplements have a long history of safe use, and detoxification and metabolic pathways are present in humans.

132. Cabinet/Parliamentary Counsel Office have made no effort to define expertise in relation to natural health – nutritional and dietary - products.

133. Relevant expertise for natural health practitioners remain undefined.

b. The content of this Bill and supporting documents reflects a pervasive institutional ignorance across the policy and legislation concerning food, nutrition and wellbeing. The New Zealand government persistently ignores and downplays the scientific importance and the critical role of food and dietary supplements in the protection and maintenance of human health.

c. No mention is made of registered natural medicine/medical herbalists; naturopaths and homeopaths.

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[71] Therapeutic Products Bill (2018) Draft for Consultation. https://consult.health.govt.nz/medsafe/therapeutic-products-exposure-draft-consultation/supporting_documents/therapeuticsproductsbill.pdf

[72] Ministry of Health. (2018) Therapeutic Products Regulatory Scheme Consultation document https://www.health.govt.nz/system/files/documents/publications/therapeutic-products-regulatory-scheme-consultation-document_dec18.docx

[73] On the Ministry of Health Website

[74] Ronis MJJ et al (2018). Adverse Effects of Nutraceuticals and Dietary Supplements. Annu. Rev. Pharmacol. Toxicol. 2018. 58:583–601

d. Medical doctors have inadequate expertise in nutrition and cannot be broadly considered experts.

e. Therefore it can be presumed that they will be excluded from advisory committees (Clause 347).

134. Clauses which generically include dispensers of food and dietary supplements impose disproportionately higher penalties by risk basis for non-medical suppliers.

f. Eg. **252 Offence for impermissible health benefit claims about NHPs.** Individuals could be liable for $200,000 or 5 years in prison.

g. The chilling effect on food/dietary supplement practice claims is vastly disproportionate to the health risk.

135. Thus, it is not surprising that Ministers and officials would presume that regulation of food and dietary supplements can be absorbed in medical products regulation and considered a category of medical product. This is incorrect.

136. There is an extraordinary and disproportionate focus on NHPs, in comparison to biologics or pharmaceuticals. NHPs are mentioned 265 times, while biologics (which include gene therapies) which are often novel and untested, and pharmaceutical products (active pharmaceutical ingredients, APIs, are mentioned 62 times).

137. The Bill drafters appear to have been ignorant of the necessity to regulate both the active ingredients (which may be multiple) and the finished product which goes to market.[75] An example of inconsistency is the focus on formulant and additive ingredients for NHPs, which are not discussed for biological nor pharmaceutical drugs.

138. This ignorance and the policy vacuum *perpetuate health inequities*. Resultant policy and legislative architecture (explicitly and implicitly) perpetuate structural barriers to access to essential nutrients and foods for low income and marginalised groups. This includes failure to regulate harmful foods; increase access to healthy vegetables, proteins and fats; and deny access to nutritional supplements, by failing to incorporate nutritional supplements on the Pharmac register for these groups.

139. The ignorance and the policy vacuum smacks of race-based colonialism as officials have not considered the historic and cultural use of herbs, minerals and nutrients by minority groups who have, over centuries had practices restricted by colonial invaders.

140. Food and dietary supplements impact body processes at the system level, at times the combinatory effects, the relationships may not be well understood, but there is an historic, cultural and practitioner knowledges and practice demonstrate that there is benefit, and safety in using the nutrients, and nutrient mixture.

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[75] I.e.. in the European Union this is clearly delineated. https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/biological-guidelines

141. Nutrient mixtures are frequently synergistic, such as to protect the immune system or mental health. Drugs and devices are designed to alleviate a symptom; to monitor; or correct a deficient organ or hormonal pathway. Often drugs require partner drugs to alleviate the adverse effects of the first drug.

142. Economies and governments supporting stable and healthy populations, with much more sophisticated approaches to policy development and dietary nutrition, regulate dietary and food supplements separately to medical and biological pharmaceutical treatments.

[9] CONTRADICTORY: THE CLAIM THAT BENEFITS WILL OUTWEIGH THE RISKS

143. The 'proportionate' claim – where regulation should be proportionate to risks and benefits of a product, cannot be upheld as the framework does not provide sufficient powers for the Regulator that enable the Regulator to make all relevant considerations.

144. In particular, the Regulator is currently unable to consider issues of safety and efficacy outside of the provision and review of industry data, including the data used by collegial regulatory agencies.

a. 4 Principles guiding exercise of powers under Act

The Regulator, Minister, and any other person exercising a power under this Act must be guided by the purpose of this Act and the following principles:

(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.'

b. 119 Evaluation of medicine or medical device

(2) The nature and extent of the Regulator's evaluation of the product must be appropriate and proportionate having regard to—

(a) the likely benefits of, and risks associated with, the product; and

(b) the extent of any previous evaluation of the product or a related product; and

(c) any matters set out in the regulations; and

(d) all of the circumstances of the case.

145. The word 'proportionate', even though mentioned 288 times, remains largely undefined.

146. Therefore, the promise that is in effect a *bland assurance* creates absurdities[76] and uncertainties that are likely to promote mistrust that the Regulator is an effective agent of the Sponsor.

[76] Anything which Is so irrational, unnatural, or inconvenient that it cannot be supposed to have been within the intention of men of ordinary intelligence and discretion. (Recognising that this is US law, however it provides illustration). https://dictionary.thelaw.com/absurdity/

147. The failure to build in mechanisms conduct monitoring and surveillance outside of the provision of industry data, described in Section [4] above, produces the greatest indication that such a claim can never be ethically or scientifically upheld.

148. The PSGR recommend: Where risk benefit analyses rely on claims from overseas regulators or institutions they must account for bias (private sector influence).

a. All studies used by those international regulators and institutions must be published as appendices in an evaluation.

b. Financial support to the institutions from non-government institutions must be declared.

149. An example that regulation is proportionate can be observed in the bureaucratic mess that might accompany Clause 67 and 68.

150. Clause 67 claims a natural health product may avoid the requirement for market authorisation if the product is a 'low concentration NHP'. This is arbitrary, and potentially produces injustices:

a. Concentration has nothing to do with toxicity – so the concentration rule is arbitrary.

b. Concentration may have considerable health benefits, yet this consideration is not required to be considered by the regulator despite an obligation in law to protect health.

c. The bureaucratic demands for this will disproportionately impact smaller businesses.

151. Clause 68 'prohibits a person from importing a medicine, a medical device, or an NHP with a market authorisation in the course of a business or undertaking unless they are the product's sponsor, they have the sponsor's consent, or they are allowed to import it without the sponsor's consent.

a. Small and medium distributors of natural health products will be at the mercy of large institutions who become the 'sponsor' and will exert predatory tactics.

b. 'Subpart 3 of Part 3 of the Bill allows certain classes of people to import, supply, or export a product that does not have a market authorisation.' This benefits larger, predatory industries that may have other strategic interests at play (such as synthetic substitution of ingredients.)

c. This produces pervasive uncertainty across all food supplements industries, and represents a potential bureaucratic nightmare for regulators due to the often complex nutrient mixtures in dietary and food supplements.

152. Because of this absurd situation, there is grave potential for restrictive rules which become burdensome, arbitrary and inconsistent.

[10] SERIOUS CONFLICTS OF INTEREST ACROSS INTERNATIONAL 'HEALTH' ORGS.

153. The text in 4 (c) of the Therapeutic Products Bill includes a statement of co-operation and alignment:

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

154. Overseas regulators also similarly rely exclusively, if not predominantly, on manufacturers claims to approve and reapprove drugs for market authorisation.[77]

155. Alignment with international standards and practice is not recommended where the institutions in questions have extensive networks and relationships with the medical drug, device and surveillance industries. Instead we propose:

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

156. Alignment is unethical and immoral due to pervasive political and financial conflicts of interest.

157. Such arrangements represent a threat to national sovereignty and threaten erosion of the obligations to Māori under the Treaty of Waitangi.

158. Risk benefit analyses must recognise the potential for conflicts of interest and clearly identify all financial support in all studies used in the analysis.

159. Bill Gates is the largest non- government funder of the World Health Organization (WHO), through his donations to the Bill and Melinda Gates Foundation (BMGF) which then directs money to the WHO.

a. The BMGF contributes 88% of the income from non-government sector. Other contributors include the Bloomberg Family Foundation, the Wellcome Trust and the Rockefeller Foundation. [78]

160. Four organizations, three with a 'common history' exercised immense influence throughout the COVID-19 pandemic. The organisations, Bill and

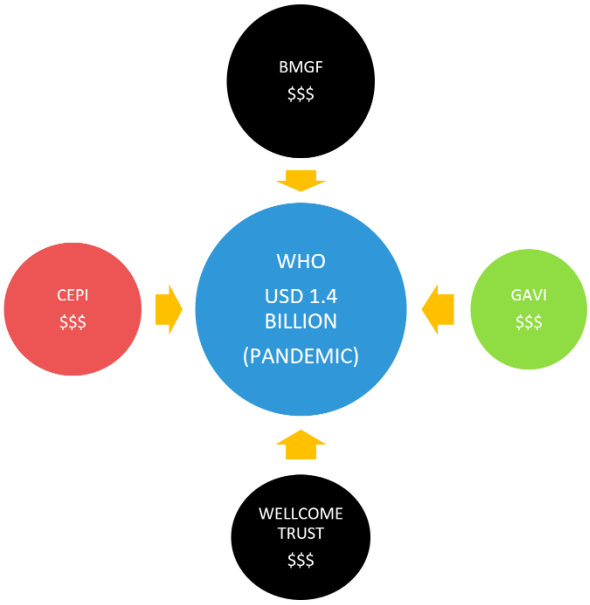

Figure 1 COVID-19 US$1.4B investment in the WHO

[77] Demasi, M. (2022). From FDA to MHRA: are drug regulators for hire? BMJ 2022;377:o1538. http://dx.doi.org/10.1136/bmj.o1538
[78] Branswell H (2022) https://www.statnews.com/2022/12/13/who-names-jeremy-farrar-director-of-the-wellcome-trust-as-chief-scientist/

Melinda Gates Foundation, the Wellcome Trust, Gavi and CEPI had unprecedented access to governments over this time. [79]

a. They donated $1.4 billion to the World Health Organization during the pandemic.

b. The BMGF directs funding to countries and organisations with the requirement that investment is enabling for GAVI, the vaccine alliance. In July 2021 the BMGF directed US$1.6 billion to GAVI, which had been 'pledged', earlier in June 2020.[80]

c. The BMGF is the founding financial vehicle for CEPI, with US$98,022,761 directed to the Norway-based organisation in November 2017. US$1.4 million was directed to CEPI July 2021.[81]

d. The intellectual property arrangements as a result of investing in new startups/venture capital are largely obscured.

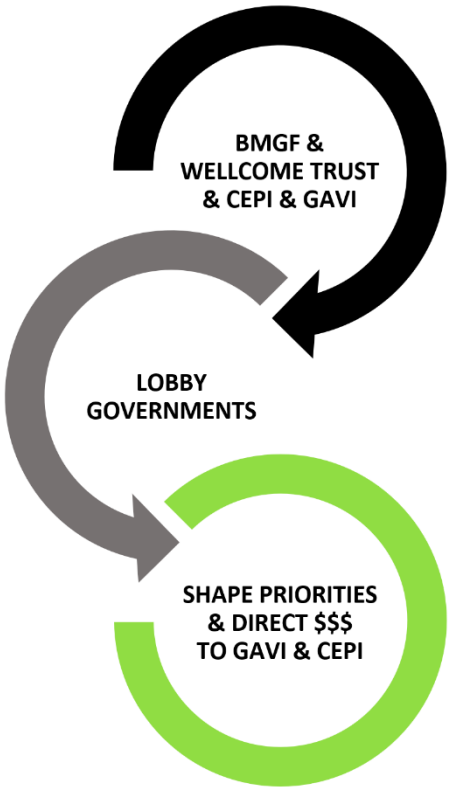

Figure 2 Lobbying as investment.

161. Bill Gates, the cochair of the BMGF personally directed around US$59 billion into the BMGF by February 2023.[82] Another US$8.3 billion was committed for 2023, totalling US$70 billion.[83]

a. The BMGF was established in 2000. By 1999 Bill Gates had directed US$17 billion to its predecessor, the William H. Gates Foundation.[84]

b. Gates has a real time net worth of US$107 billion. [85] In the year 2000 Gates' net worth was US$63 billion.[86]

162. The BMGF was established in 2000, and by 2002 had purchased shares in 9 pharmaceutical companies, to the value of US$200 million.[87]

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[79] Banco E (2022). How Bill Gates and partners used their clout to control the global Covid response — with little oversight. https://www.politico.com/news/2022/09/14/global-covid-pandemic-response-bill-gates-partners-00053969
[80] https://www.gatesfoundation.org/about/committed-grants
[81] https://www.gatesfoundation.org/about/committed-grants
[82] Forbes (2023) Bill Gates https://www.forbes.com/profile/bill-gates/
[83] Beaty T (2023)Is the Gates Foundation too powerful? https://www.fastcompany.com/90835767/is-the-gates-foundation-too-powerful
[84] Influence Watch. Bill and Melinda Gates Foundation. https://www.influencewatch.org/non-profit/bill-and-melinda-gates-foundation/
[85] Forbes (2023) Bill Gates https://www.forbes.com/profile/bill-gates/
[86] https://www.forbes.com/2008/06/23/gates-net-worth-tech-gates08-cx_af_0623fortune_slide.html?
[87] WSJ (2000) https://www.wsj.com/articles/SB10215776297486800000

163. The BMGF has extensive financial conflicts of interest. In 2019 the fund value sat at US$19 million, in the four years since the fund value has increased to US$35 million.[88] The fund holds shares and receives financial income through licensing agreements with pharmaceutical companies.

a. The BMGF invested in Merck in 2002. In March 2021, the BMGF committed US$45,549,976 to Merck Sharp & Dohme Corp for investment in a monthly pill for HIV prevention.[89] In 2022 the BMGF was granted licensing agreements for candidates for treatment of tuberculosis.[90]

b. Pharmaceutical investments include Pfizer and BioNTech.[91] The BMGF invested $55 million in BioNTech in September 2019.[92] By April 2021, the shares were valued at US$550 million.[93]

c. In October 2019 the BMGF and the World Economic Forum, in partnership with the John Hopkins Centre for Health Security, surprisingly, conducted a pandemic exercise for fictional coronavirus pandemic.[94]

d. By March 2019 the BMGF had directed US$1,051,128 to ModernaTX.[95] Moderna, founded in 2010, became a public company in 2018. Despite not having commercialised any product in the past, it became the largest biotech initial public offering in history.

e. By November 2021 the BMGF had directed US$4,918,943 to BioNTech.[96]

164. The Bill & Melinda Gates Foundation (BMGF), valued at $53.3 billion, is the largest private charitable foundation in the world. [97] The foundation is highly political and has extensive networked power across governments,[98] the vaccines and medical technologies sector.

a. The Bill & Melinda Gates Foundation is the second-largest funder to three organizations: Gavi, the Vaccine Alliance; the World Health Organization (WHO); and the Consultative Group for International Agricultural Research (CGIAR).[99]

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[88] SEC Form 13F Filing History https://fintel.io/i13fs/bill-melinda-gates-foundation-trust
[89] Committed Grants. Merck Sharp & Dohme Corp.https://www.gatesfoundation.org/about/committed-grants/2021/03/INV026778
[90] https://www.businesswire.com/news/home/20221018005485/en/Merck-and-the-Bill-Melinda-Gates-Medical-Research-Institute-Announce-Licensing-Agreement-for-Novel-Tuberculosis-Antibiotic-Candidates
[91] Speights K (2020). 4 Coronavirus Vaccine Stocks the Bill & Melinda Gates Foundation Is Betting On https://www.fool.com/investing/2020/09/24/4-coronavirus-vaccine-stocks-the-bill-melinda-gate/
[92] https://www.nasdaq.com/articles/4-coronavirus-vaccine-stocks-the-bill-melinda-gates-foundation-is-betting-on-2020-09-24
[93] Louise (2021). Bill Gates turned his $55 million vaccine investment in Pfizer's partner, BioNTech, into over $550 million in just under two years TechStartUps https://techstartups.com/2021/04/30/bill-gates-turned-55-million-investment-pfizers-partner-biontech-550-million-just-two-years/
[94] Johns Hopkins (2020) Statement about nCoV and our pandemic exercise https://www.centerforhealthsecurity.org/news/center-news/2020/2020-01-24-Statement-of-Clarification-Event201.html
[95] Gates Foundation Committed Grants. ModernaTX, Inc. https://www.gatesfoundation.org/about/committed-grants/2019/03/opp1203278
[96] https://www.gatesfoundation.org/about/committed-grants
[97] Forbes (2023) Bill Gates https://www.forbes.com/profile/bill-gates/
[98] Global Britain, Global Health https://archive.fo/I4Vf4
[99] McArthur JW & Rasumussen K (2018) Who actually funds the UN and other multilaterals? https://www.brookings.edu/blog/order-from-chaos/2018/01/09/who-actually-funds-the-un-and-other-multilaterals/

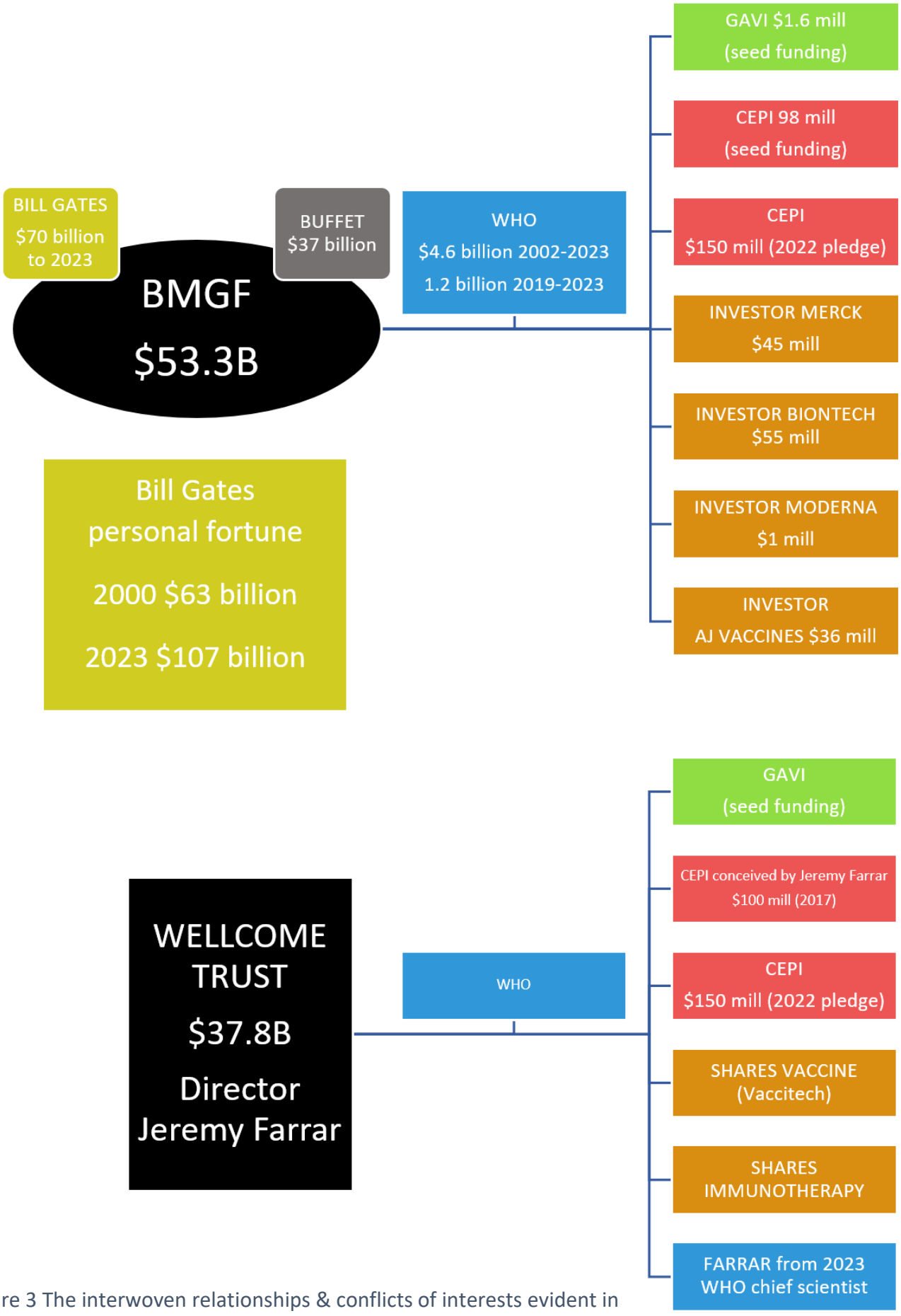

Figure 3 The interwoven relationships & conflicts of interests evident in the activities of two of the largest charitable foundations in the world.

Values drawn from the references cited in part [10] of this paper.

b. Over US$5 billion have been donated/pledged by the BMGF to GAVI.[100]

c. In 2017 the BMGF has funded the UK Medicine & Healthcare products Regulatory Agency (MHRA) to support a collaboration between the BMGF, MHRA and the World Health Organisation.[101] Grant funding in 2021amounted to US$3 million.[102]

d. In 2021, as pressure for global vaccine mandates was peaking, the foundation donated $300 million to global media outlets.[103] financial influence in media.

165. The WHO is reliant on non-government income with only a quarter of the WHO's income available to the WHO for discretionary purposes. Less than 20% of the WHO's operational budget comes from member countries.[104] Voluntary contributions (80%) are typically earmarked for specific projects. [105] [106]

166. Wellcome Trust director Jeremy Farrar was named the chief scientist of the WHO in December 2023.[107]

a. The Wellcome Trust was established through an endowment from Sir Henry Wellcome. The trust is the third richest charitable foundation with an investment portfolio GBP37.8 billion.[108]

b. Wellcome Trust is a venture capital investor, profiting from investment and then sales of private assets, such as immunotherapy biotech firm Kymab.[109] The Trust has investments in vaccine technology, including in the major shareholder of Vaccitech,[110] the biotech platform which was licensed to AstraZeneca for development of their mRNA vaccine.[111]

c. The Wellcome Trust made a 34.5% return in the 12 months to 30 September 2020, a gain of around GBP10 billion.[112]

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[100] "Annual Contributions and Proceeds". Gavi. Annual Contributions and Proceeds 31 March 2021. https://www.gavi.org/news/document-library/annual-contributions-and-proceeds-31-march-2021

[101] MHRA (2017) MHRA awarded over £980,000 for collaboration with the Bill and Melinda Gates Foundation and the World Health Organisation https://www.gov.uk/government/news/mhra-awarded-over-980000-for-collaboration-with-the-bill-and-melinda-gates-foundation-and-the-world-health-organisation

[102] https://www.gov.uk/government/publications/freedom-of-information-responses-from-the-mhra-week-commencing-17-may-2021/freedom-of-information-request-about-the-bill-and-melinda-gates-foundation-foi-21-509

[103] MaLeod A. (2021, November 15) Revealed: Documents show Bill Gates has Given $319 million to media outlets. MintPress News https://www.mintpressnews.com/documents-show-bill-gates-has-given-319-million-to-media-outlets/278943/

[104] Carbonaro, G. (2023). How is the World Health Organization funded and why does it rely so much on Bill Gates? https://www.euronews.com/next/2023/02/03/how-is-the-world-health-organization-funded-and-why-does-it-rely-so-much-on-bill-gates

[105] https://www.euronews.com/next/2023/02/03/how-is-the-world-health-organization-funded-and-why-does-it-rely-so-much-on-bill-gates

[106] Reddy, SK., et al (2018). The financial sustainability of the World Health Organization and the political economy of global health governance: a review of funding proposals. Globalization and Health. 14, 119

[107] Branswell H (2022) https://www.statnews.com/2022/12/13/who-names-jeremy-farrar-director-of-the-wellcome-trust-as-chief-scientist/

[108] Wellcome Trust Investments. https://wellcome.org/who-we-are/investments

[109] Moss G (2022). Wellcome says 34.5% returns will reinforce new strategy and raised ambitions. IPE. https://www.ipe.com/news/wellcome-says-345-returns-will-reinforce-new-strategy-and-raised-ambitions/10057320.article

[110] Kelso P. (2020) COVID-19: The multi-billion pound business of the Oxford vaccine. Sky News.

[111] Fortner R (2022) AstraZeneca's covid-19 (mis)adventure and the future of vaccine equity. *BMJ* 2022;379:o2592

[112] Kollewe J. (2022) The Wellcome Trust to spend GBP16 billion on research with focus on Covid vaccines. The Guardian.

167. The Global Fund has received over US$3 billion from the BMGF.[113] The Global Fund focus on investment in technological solutions to health crises, and the financial return on investment.[114]

168. The Coalition for Epidemic Preparedness (CEPI) is funded primarily to develop vaccine candidates for commercialisation. It was initiated by Jeremy Farrar.[115]

169. CEPI was founded by the governments of Norway and India, but also by the political lobbyist organisation World Economic Forum; the Bill and Melinda Gates Foundation (BMGF), and the Wellcome trust.

a. CEPI's vision is for the 'world to be able to respond to the next Disease X with a new vaccine in 100 days.'[116]

b. In November 2017 the BMGF directed millions of dollars to different projects in India, as well as $9.8 billion for the establishment of Norway-based CEPI.

c. CEPI's agreements with vaccine manufacturers are often secret. In a The Lancet report, 'Inger Berg Ørstavik, law professor at the University of Oslo, Oslo, Norway, specialising in patent licensing law and research and development agreements' considered that 'without more openness, neither CEPI nor the vaccine manufacturers the organisation funds can be held accountable.'[117]

d. In January 2020, in well-timed serendipity, CEPI funded Moderna, a company that had no previous experience in vaccine development.[118]

e. Investors have minority voting rights in CEPI.

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[113] The Global Fund (2023) A key partner of the Global Fund for financing, governance and advocacy https://www.theglobalfund.org/en/private-ngo-partners/resource-mobilization/bill-melinda-gates-foundation/

[114] Investment Case (2022) https://www.theglobalfund.org/media/11798/publication_seventh-replenishment-investment-case_report_en.pdf

[115] July 2015 paper in The New England Journal of Medicine, 'Establishing a Global Vaccine-Development Fund'

[116] CEPI.net

[117] Usher AD (2021) CEPI criticised for lack of transparency. 397:265-266 https://www.thelancet.com/action/showPdf?pii=S0140-6736%2821%2900143-4

[118] Moderna (2020, January 23). Moderna announces funding award from CEPI to accelerate development of messenger RNA (mRNA) vaccine against novel coronavirus. https://investors.modernatx.com/news/news-details/2020/Moderna-Announces-Funding-Award-from-CEPI-to-Accelerate-Development-of-Messenger-RNA-mRNA-Vaccine-Against-Novel-Coronavirus/default.aspx

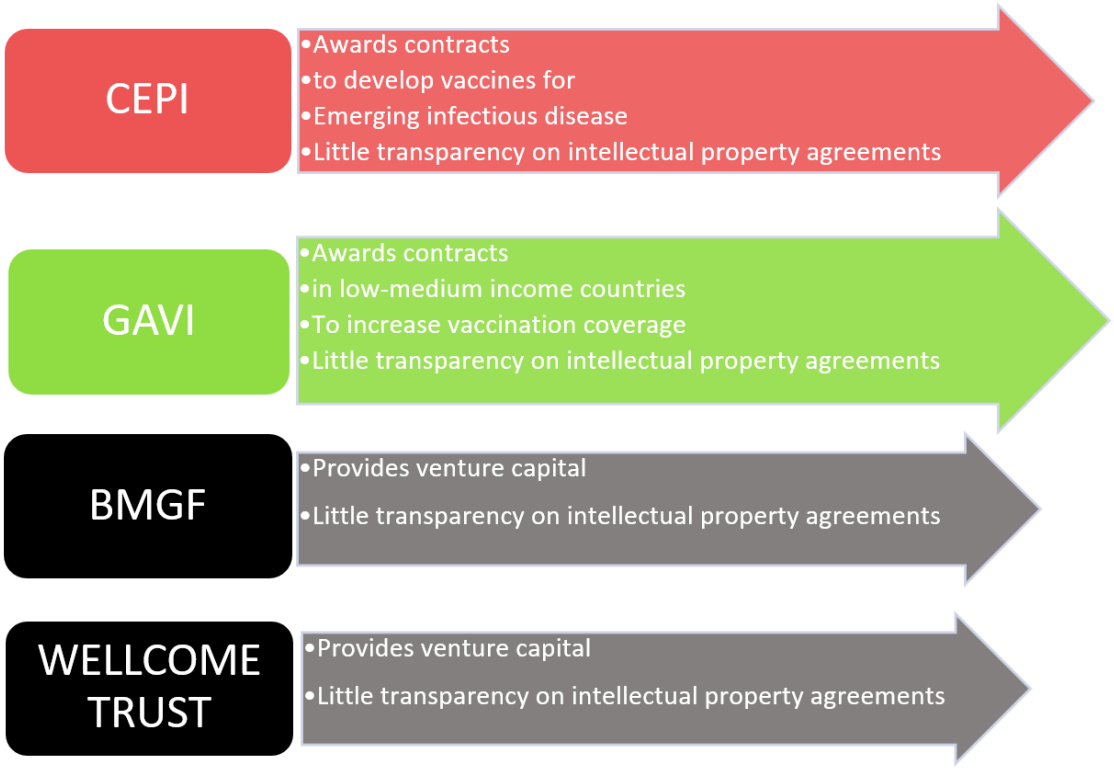

Figure 4 Representation of the overlapping interests of these organisations.

[11] CASE STUDIES: Protocols may favour toxic drugs and create barriers to nutrition access.

170. CASE STUDY – MICRONUTRIENTS FOR MENTAL HEALTH

a. Officials may be conflating potential risk of micronutrient treatment with adverse events for pharmaceuticals documented in the scientific literature.

b. Current guidelines struggle to recognise the overlapping benefit of multinutrient mixtures. For many diseases, including mental health[119], broad-spectrum formulas exhibit more robust effects than formulas with fewer ingredients.

c. Non-stimulant and stimulant clinical drug medication for ADHD are available on Pharmac, and can only be prescribed by a pharmacist or a paediatrician.

d. Prescription by a psychiatrist or paediatrician is in all probability because of the risk of adverse events. Doctors can diagnose depression, anxiety and other mental illnesses. It would seem that the main reason psychiatrists are tasked with overseeing ADHD medication is because of the adverse risk profile.

e. There is strong evidence that micronutrient alleviate many symptoms associated with ADHD, depression and anxiety. However, micronutrient treatments are not yet available on Pharmac.[120] Many psychiatric medications have been added to pharmaceutical schedules with

[119] Johnstone JM et al 2020. Multinutrients for the Treatment of Psychiatric Symptoms in Clinical Samples: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *Nutrients*, 12:3394. doi:10.3390/nu12113394
[120] Rucklidge J & Kaplan B. The Better Brain. Random House. ISBN 9781785043567

less evidence, and much more conflicting evidence than micronutrients for depression and anxiety.[121]

f. In a 3 week trial in children aged 6-12 years[122]

g. In a research study monitoring micronutrients in people exposed to extreme stress, (mosque shooting, earthquake and flooding),[123] side effects (dry mouth, headache, and constipation) were reported infrequently and were resolved by ensuring micronutrients were taken with food and sufficient water was consumed.

h. Side effects in children are low, if not negligible.

    i. A 2014 study in adults demonstrated no increased adverse events in the treatment group. [124]

    ii. A 2018 ten-week study in children[125] was extended to follow participants for one year. [126]

i. Micronutrients do not have the risk profile associated with clinical drugs that are prescribed for ADHD. [127] [128] Nutritional treatments do not impact growth parameters.[129]

j. ADHD treatments on the Pharmac schedule include non-stimulant Atomoxetine; and the stimulants Dexamfetamine sulfate, Methylphenidate hydrochloride, Methylphenidate hydrochloride extended-release and Modafinil[130]

k. Psychotropic medicine prescription rates for ADHD have tripled in fifteen years.[131]

l. Adverse events occur and occurrence can be relatively common.

    i. Non-stimulants such as atomoxetine can induce nausea, vomiting, fatigue, decreased appetite, headache, abdominal pain, somnolence, increased blood pressure and pulse.

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[121] Whitaker R. & Cosgrove L. Psychiatry under the Influence. Palgrave Macmillan (2015).
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Clonidine and guanfacine are associated with and increase in somnolence (drowsiness), fatigue, irritability, insomnia, and nightmares. Warning labels also include hypotension/bradycardia, somnolence/sedation, discontinuation, and allergic reactions, and cardiac conduction abnormalities. [132]

ii. Adverse events for amphetamines prescribed for ADHD include a 30% increased risk (versus placebo); 280% increased risk of difficulty sleeping; 530% increased risk of reduced appetite and 44% increased risk of abdominal pain. For methylphenidate there was a 29% increase in serious adverse events versus the placebo, difficulty sleeping increased by 60% and reduced appetite increased by 266%. Other adverse effects include increased blood pressure and pulse and headaches. It is suspected that adverse events are underreported. Amphetamines may increase risk for cardiovascular disease in adulthood. [133] [134]

iii. Patients can fail to respond to ADHD medication, and it can increase behavioural disturbances.[135]

m. In 2016, 2.36% of New Zealand youth, totalling 26,175 individuals, were prescribed at least one psychotropic medication, an increase of 65.03% from 2008. Rate of prescription for youth in 2016 and percentage increase since 2008 for each medication class were as follows: antidepressants: 1.07%, 78.33% increase; antipsychotics: 0.37%, 105.60% increase; anxiolytics: 0.15%, 50% increase; and sedatives and hypnotics: 0.22%, 37.50% increase. Stimulants were prescribed to 1.06% of the population, a 41.33% increase since 2011.[136]

n. The safety profile for micronutrient treatment for ADHD is very different.

171. **CASE STUDY – REMDESIVIR FOR COVID-19.**

172. The emergency approval for Remdesivir, with a list price of $390[137] per vial. Remdesivir was approved in September 2020 based on only 4 trials, only one of which was not prima facie supported by the sponsor, Gilead.[138] Yet evidence demonstrating that Remdesivir was harmful, was never integrated into Advisory Group considerations.

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173. CASE STUDY - BNT162b.

174. The SARS-CoV-2 spike (S) glycoprotein antigens encoded in RNA were formulated in lipid nanoparticles (LNPs), The LNPs enabled the code to not be detected, enabling the antigen to enter cells. These instructions were for the body to reproduce (encode) a spike protein in uncontrolled quantities. The drug had not completed clinical trials:

a. The new drug evaded animal trials, and carcinogenicity and genotoxicity trials;

b. The Ministry of Health obfuscated information demonstrating different risk profiles by age, gender and health status.

c. There was no signal established for when the drug would be withdrawn due to harm.

d. There were substantial barriers to reporting for citizens experiencing adverse events;

e. No research team was established to explore the potential for the spike protein to accumulate following exposure to sequential vaccines and boosters.

f. No research teams were funded to scientifically review the evidence on the potential for the drug to induce autoimmunity, vaccine enhanced disease, promote clotting, risk for cardiovascular and neurological disease.

g. There was no line of sight which enabled the New Zealand public to view the response of the Sponsor Pfizer, to the 58 obligations published in the Gazette, which included the interim report.[139]

END.

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