Physicians and Scientists for Global Responsibility New Zealand.

Phase-2

Submission to the Royal Commission of Inquiry into COVID-19 Lessons Learned Date April 27, 2025

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New Zealand Charitable Trust

PSGR would welcome an opportunity to speak to this submission.

Physicians and Scientists for Global Responsibility Charitable Trust (PSGR) works 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.

NZ Royal Commission COVID-19 Lessons Learned

PSGR thanks the Royal Commissioners for this opportunity to contribute to scrutiny and examination of key decisions that took place between February 2021 and October 2022 in <u>these areas</u>:

- The use of vaccines to manage COVID-19
- The use of lockdowns in 2021 and 2022
- Testing, tracing, and other public health tools.

'Legislation should be constitutionally sound—Legislation should be consistent with the Treaty of Waitangi and should reflect the fundamental values and principles of a democratic society, including in the processes by which it is made.' Legislation Guidelines 2021 Edition

INTRODUCTION

We hope to draw to the attention of the Commissioners a recognition of the systemic flaws in government, and that these systemic, overlapping flaws signal a dire warning, and emphasise the need for a call to action for system reform. We make suggestions in section [5] to illustrate how this may be achieved.

The principles enshrined in the Health Act 1956 were unethically set aside in the parent legislation¹: Paramount consideration of protection of health; respect for individuals; voluntary compliance; the individual to be informed; principle of proportionality; the least restrictive alternative; and that measures apply no longer than necessary.

The claim of an emergency established the conditions for a pervasive corruption of good democratic process and a setting aside of principles of ethics and human rights:

- Principles of infectious disease which was contained in <u>Part 3A the Health Act 1956</u> was ignored this includes the principle of proportionality and respect for individuals.
- The Bill of Rights Act was set aside.
- Medical ethics was dismissed and informed consent was ignored.
- Medicines authorisation processes were circumvented and short-circuited.
- Post-market safety monitoring was poorly executed
- The NZEPA declaration that BNT162b2 was not a new organism, failed any appropriate peer review.
- The precautionary principle was misapplied to claim that people should be injected.
- Privacy was sidelined because of the obligation to prove vaccination status.
- Human rights to freedom and the human right to health and to deny a medicine were set aside.
- The government used proxy processes to avoid direct mandates and claim that people had a choice in being vaccinated.
- All agencies with control over science funding were committed to the April 2021 roll-out goal.
- Pharmacovigilance failed from early stages, with doctors recognising that 'vaccine skepticism' could result in their being politically ostracised and professionally sanctioned.
- The coroner appeared to have no resourcing or powers to determine whether a death was caused by infection or a comorbidity, nor to assess vaccine induced injury.

¹ Health Act 1956 Part 3A Management of infectious diseases. Subpart 1—Overarching principles. https://www.legislation.govt.nz/act/public/1956/0065/latest/DLM305840.html

COVID-19 showed New Zealanders that the processes we took for granted, are easily disassembled and dispensed with. Regulatory rigor, select committee processes, the legislative process, the executive, information flows, can all be managed in service of a single goal that lacks an ethical evidence base.

PSGR's submission emphasises a deep procedural injustice that was imposed on the people of New Zealand. Our case concerns the government machinations between October-December 2021 that PSGR considers was deceptive, misleading, unfair and unjust.

This period was the time of the most egregious displays of human rights abuses by the Crown, including the human right to freedom and to health. We emphasise, where health means:

'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.'

The rights abuses were enabled because the government officials failed to consider scientific information and evidence that contradicted their world view. Officials 'narrowed their minds' and ignored a compendium of evidence that demonstrated that ongoing lockdowns, mandates and prevention of movement (i.e. freedoms) did not reflect the state of evidence from mid-2021 onwards.

PSGR emphasise that the avoidance of such a corrupted process, so that future generations may not have similar injustices imposed on them, requires a complex and coordinated response. Such a response requires the reacquainting of the public and officials with a layering of education and knowledge that includes public law, public health ethics, basic science and nutrition education, principles of public health and long-established epidemiological understanding that, for a century, has informed the practice of management of an infectious disease outbreak.

Censorship of public health doctors and general practitioners, scientists, ethicists, epidemiologists and other groups with expertise in chronic and communicable disease and the role of population health was a global phenomenon. Experts who differed from the global consensus points were silenced and techniques were used to shame and delegitimise their authority.^{2 3}

In March 2021, when the full roll-out to the entire population, the press release noted that:

'the biggest factor in lifting COVID-19 restrictions will be a timely and high uptake of the vaccine.'

Most egregiously, there was no allowance for herd immunity. There was no consideration of the unjust nature of mandating the novel technology on healthy populations, and the role that herd immunity could play in dampening down transmission and infection.

PSGR's October 11, 2021 submission⁴ is provided (section [3] below) as evidence to the Royal Commissioners that Members of Parliament were provided with soundly formed evidence that the vaccine was not sterile and would not prevent transmission of infection, that there was significant evidence known in early October 2021 (even with only ten days to assemble a submission) that the vaccine was neither effective nor safe.

² Shir-Raz, Y., Elisha, E., Martin, B. et al. Censorship and Suppression of Covid-19 Heterodoxy: Tactics and Counter-Tactics. Minerva 61, 407–433 (2023). https://doi.org/10.1007/s11024-022-09479-4

³ Liester M, Ashraf A, Callisperis P et al (2025). A Narrative Review of the COVID-19 Infodemic and Censorship in Healthcare. Secrecy and Society 3(2). DOI: https://doi.org/10.55917/ 2377-6188.1087

⁴ October 11, 2021 Submission COVID-19 Public Health Response Amendment Bill (No 2) https://www.parliament.nz/resource/en-

NZ/53SCHE_EVI_115898_HE16756/f803d4311783129cf51351e2593b36a272f11026

PSGR recommended prophylactic measures in in the form of medical (antiviral and antibiotic medications) nutritional and immune-support protocols. These should have been considered and applied to provide safety for all people at minimal cost and zero disruption to people and society. These could be taken from when infection from a virus was suspected, and reduce viral replication, and lower the risk of transmission, and reduce the likelihood that vulnerable populations would experience severe COVID-19. This protocol would have substantially reduced fear in the population.

As PSGR document below, the public's concerns were ignored and not discussed in the Departmental and Select Committee reports. This is despite the fact that the Minister for Covid-19, at the same time this legislation was being debated in Parliament, was engaged in drafting the next legislation, which would precede a cavalcade of secondary legislation, the Orders that would mandate all New Zealanders over 12, in some way as an 'affected person'.

The public, therefore, had no choice other than to reasonably trust that the Crown would take seriously its duty to protect health. The October-November 2021 Select Committee and Departmental Reports failed to summarise and disclose the evidence supplied by the public on the potential for waning, i.e. that the vaccine was leaky, and that evidence was accumulating that the vaccine could be harmful.

Protection, as per the Health Act 1956 should have ensured that the actions taken from 2020-2023 would be taken with utmost care, that the individual would be respected, and that policies would be based on the latest scientific evidence so as to protect health.

The Crown over this time had a fiduciary obligation to protect public health as the public had to trust that the Cabinet would act in the best interest of the individual, and the public would have to surrender to the laws that were subsequently made. The protection of the individual is critical, as harm from an intervention at an early age can result in decades of suffering, thus the benefits of an intervention to an elderly, frail person must be balanced against risk to healthy people. The Crown did not take such action.

If the Crown has the power to displace peoples' rights and interests, and the peoples' power to deal with this is restricted, it would seem that Crown's power and the corresponding vulnerability of people, give rise to a fiduciary obligation on the part of the Crown. 'The power to destroy or impair a people's interests in this way is extraordinary and is sufficient to attract regulation by Equity to ensure that the position is not abused. The fiduciary relationship arises, therefore out of the power of the Crown...'⁵

This set the stage for rules that could be applied with little regard for scientific process and convention, yet that they would be applied on the basis 'scientifically' that they were preventing 'potential adverse effects'.

 $^{^5}$ See for example: Mabo v The State of Queensland (No 2) (1992) 175 CLR 1. At 203.

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[1] BACKGROUND

One of the main instruments employed by governments to repress and deny fundamental rights and freedoms has been the illegal and unwarranted declaration of a state of emergency.⁶

"The suspension or derogation of certain civil and political rights is only allowed under specific situations of emergency that 'threaten the life of the nation'. Some safeguards must be put in place including the respect of some fundamental rights that cannot be suspended under any circumstance" (Office of the High Commissioner Human Rights, 2020)

Derogations from the International Covenant on Civil and Political Rights (ICCPR) such as a state of emergency must be carefully considered with the recognition that the principle obligation of the State is of protector of society. Only in extraordinary circumstances, as Article 4 states, which threatens the life of the

⁶ Agamben, G. 2008. State of exception. In State of Exception. University of Chicago Press

nation' may rights be suspended.⁷ How would International Human Rights Law interpret what 'threatening the life of the nation' might mean?:

In terms of IHRL, a public emergency threatening the life of a nation must therefore contain the following key characteristics: it must be actual or imminent; its effects must involve the whole nation; the continuance of the organized life of the community must be threatened; the crisis or danger must be exceptional in that that the standard measures for the maintenance of public safety, health, and order, are plainly inadequate (The Greek case, 1969; Mariniello, 2019).The criteria stress the extraordinary nature of a public emergency as being a situation where 'normality'' is undoubtedly impossible, and the ordinary day-to-day life of society cannot be followed. Derogation from rights recognized under international law "to respond to 'a threat to the life of the nation' is not exercised in a legal vacuum. It is authorized by law, and as such, it is subject to several legal principles and standards. A proclamation of a public emergency should be made in good faith based upon an objective assessment of the actual situation to determine to what extent, if any, it poses "a threat to the nation's life" (International Commission of Jurists, 1984).⁸

PSGR show here that these rights could be suspended by the narrow control of information and the failure of government Ministers, officials and the mainstream media to encourage or consider evidence that contradicted early lockdowns, mask mandates, social distancing and the policy goal of the vaccine roll-out.

In short, the processes of information management and legislation output were neither fair or just.

From early 2020, the Governments plan was to 'eliminate COVID-19 and to stamp out transmission within affected clusters. This is in line with The New Zealand Influenza Pandemic Plan and the four-level COVID-19 Alert system.' (April 2020, National Action Plan 3 National Crisis Management Centre). There was no discussion that this was a coronavirus, and that historic measures to deal with a viral infection would be required.

In May 2020 Attorney-General David Parker released the <u>COVID-19 Public Health Response Bill 2020</u> (2020/12) that would, overnight become the overarching law, hereafter the <u>Covid-19 Act (2020/12)</u>. The purpose of that Act was to prevent and limits the risk of, the outbreak or spread of COVID-19. Officials were given powers to act to avoid, mitigate, or remedy the actual or potential adverse effects of the COVID-19 outbreak (whether direct or indirect). No obligation was drafted into that Act that would require officials to weight the risks of their actions with any potential harms. Nor was COVID-19 specifically defined as a disease resulting in hospitalisation and death. With such vague legislation, officials could claim to be avoiding 'potential adverse effects', even if this was cold-like symptoms.

Therefore, this apparently dispensed with the obligations to judge risks of an intervention versus a benefit and to demand that the scientific information used to justify interventions was rigorous and trustworthy.

The legislation did not define whether 'COVID-19' meant the infection, SARS-Cov-2 or the illness. The legislation created the powers to chase cases and claim to prevent COVID-19 cases. Even though cases would mean that the population would shift more quickly to herd immunity, this was never a factor. The

⁷ International Covenant on Civil and Political Rights'. https://www.ohchr.org/en/instrumentsmechanisms/instruments/international-covenant-civil-and-political-rights

⁸ van Aardt W (2022) State of Emergency in South Africa, Mandatory Covid-19 vaccination and International Human Rights Law. 2022, *Institute of Comparative Law*. Legal and Social Aspects of Vaccination during the Covid-19 Pandemic.

https://www.academia.edu/96972623/State_of_Emergency_in_South_Africa_Mandatory_Covid_19_Vaccination_and_ International_Human_Rights_Law

<u>Covid-19 Act (2020/12)</u> was drafted, seemingly with no awareness for the traditional principles of pandemic management, which rotated around increasing herd immunity in the population, and public health ethics.

The legislation that gave government officials their powers, concerned infectivity. It did not concern risk of hospitalisation and death. Elimination of viral transmission was the key policy goal and it was promoted widely by prominent figures.^{9 10 11 12} In 2022, the case rate narrative continued to be a key driver for the stamp it out elimination strategy and traffic light system.¹³

Officials failed to draw attention to the role of herd immunity, and of the compounding evidence in the scientific literature that the vaccine was not likely to prevent transmission and that it was harmful (necessitating choice in whether it should be taken or not). Medical doctors, epidemiologists and other public health experts faced barriers to publication.

Medsafe has never formally stated that the vaccine is safe and effective. Pfizers application was 'for an RNA-based vaccine to *prevent* Coronavirus Disease 2019 (COVID-19) caused by the SARS-CoV-2 virus.'¹⁴ BNT162b2 was a biologic drug that was re-characterised as a vaccine. Medsafe has recognised the biologic technology as a 'higher risk medicine and the Gazette had granted a 'data protection period' for five years because the vaccine 'contains a new biological entity'.¹⁵

Traditional measures were constantly 'bent'. Responsibility for approving the technology was transferred from Medsafe approving to the Medicines Assessment Advisory Committee (MAAC) on January 28, 2021. Medsafe never stated clearly why the technology was safe and effective and was clearly hesitant:

Due to the unresolved concerns and additional quality, safety and efficacy data to be provided at the time of completion of the evaluation, Medsafe is unable to recommend that this product be granted consent.¹⁶

Delegation seemed to keep being transferred, as officials perhaps suspected the data did not prove the BNT162b2 product was neither safe nor effective.

On February 2, 2021, days after receiving the data, the MAAC recommended that provisional consent be granted. Medsafe then granted provisional consent for use of the Pfizer Comirnaty BNT162b2 vaccine for people 12 years and older.

⁹ Baker, M.G. et al. (2020). New Zealand's COVID-19 elimination strategy. Med J Aust. 213(5), 198-200e1. https://doi.org/10.5694/mja2.50735

¹⁰ Baker, M.G. et al. (2020, Apr 3) Editorial: NZMJ New Zealand's elimination strategy for the COVID-19 pandemic and what is required to make it work. The New Zealand Medical Journal, 133(1512), PMID: 32242173 https://journal.nzma.org.nz/journal-

articles/new-zealands-elimination-strategy-for-the-covid-19-pandemic-and-what-is-required-to-make-it-work

 ¹¹ Skegg D. (2021). Editorial: Defining covid-19 elimination. BMJ, 374, n1794. https://doi.org/10.1136/bmj.n1794
 ¹² James, A. et al. (2020, Dec 8). Modelling support for the continued elimination strategy. Report. Te Pūnaha Matatini December 8, 2020. https://cpb-ap-se2.wpmucdn.com/blogs.auckland.ac.nz/dist/d/75/files/2017/01/Elimination-Strategy-TPM-website.pdf

¹³ Office of the Prime Minister, (2022, Jan 25). Post-Cabinet Press Conference. Hansard Transcript. https://www.beehive.govt.nz/sites/default/files/2022-01/Hansard%20Transcript%20-%20Press%20Conference%20-%20Tuesday%2025%20January%202022_0.pdf

¹⁴ October 21, 2020. Regulatory Affairs Department, Pfizer. New Medicine Application. Official Information Act request Ref: H202106950 (31/162)

¹⁵ February 2, 2021. OIA, Ref: H202106950 Extract from the minutes of the 109 th meeting of the Medicines Assessment Advisory Committee held in Wellington on 2 February 2021 commencing at 9:30am

¹⁶ OIA request H202106950 p.76/162

New Zealand did not reach a level where there was a high level of hospitalisation and death following infection from SARS-Cov-2, however the process was fast-tracked using the provisional consent process. After it was revealed that provisional consent was only applicable to 'limited market'¹⁷, Parliament overrode this safety measure to ensure the entire population could receive the technology.

In early February-April warnings were published on the use of traditional antiviral products with a long history of safe use, including hydroxychloroquine and ivermectin, and that were recommended along with other medical and nutritional therapeutic treatments to prevent viral replication and lower the risk of sever COVID-19, including lower respiratory tract infections such as pneumonia, which is a common 'tipping point' for frail and severely multimorbid groups.

PSGR discuss in section [4] how the New Zealand Environmental Protection Authority skirted labelling the technology as a genetically modified organism, even though the manufacturer knew the drug was a biologic, i.e. was produced using techniques of genetic modification.

The government required that Pfizer comply with 58 conditions, yet there was no separate obligation for, and never required that government scientists review the literature on the changing evidence of efficacy and safety. Risk management plans were drafted by the corporation, leaving the control of 'risk management' effectively in the hands of the corporation.¹⁸

On February 5 2021, after provisional consent was granted, a COVID-19 Vaccine Technical Advisory Group (CV TAG) memo, including Dr Caroline McElnay, Director of Public Health communicated that there was a:

'relatively high prevalence of common side effects.'

By February 2021, Pfizer was aware of an extraordinary compendium of harms related to the vaccine, and that more people had died in the trials from the vaccine, than in the control arm.¹⁹

However, despite requests being made to understand if Pfizer had communicated this information to Ministry of Health officials, we do not know if Pfizer had communicated this information to officials in the New Zealand government, including the signatories to the Pfizer contract.

¹⁷ Nga Kaitiaki Tuku Iho Medical Action Society Incorporated v Minister of Health & Others

¹⁸ https://www.medsafe.govt.nz/COVID-19/Comirnaty-RMP.pdf

¹⁹ Pfizer Worldwide Safety. BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports. FDA-CBER-2021-5683-0000054. https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf

Table 1 below presents the main characteristics of the overall cases.

Table 1.	General Overview: Selected Characteristics of All Cases Received During
	the Reporting Interval

Characteristics		Relevant cases (N=42086)			
Gender:	Female	29914			
	Male	9182			
	No Data	2990			
Age range (years):	≤ 17	175ª			
0.01 -107 years	18-30	4953			
Mean $= 50.9$ years	31-50	13886			
n = 34952	51-64	7884			
	65-74	3098			
	≥ 75	5214			
	Unknown	6876			
Case outcome:	Recovered/Recovering	19582			
	Recovered with sequelae	520			
	Not recovered at the time of report	11361			
	Fatal	1223			
	Unknown	9400			

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

Pfizer Worldwide Safety. BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

Yet one month later, with Pfizer holding thousands of pages of evidence that their product conferred a wide spectrum of harms, on March 10, 2021, the Government confirmed that all New Zealanders would be injected with a novel biologic drug, Pfizer's BNT162b2 gene therapy, which was reclassified as a vaccine.

The purpose of mandated vaccinations?:

'to prevent, and limit the risk of, the outbreak or spread of COVID-19 by requiring work at certain places to be carried out by affected persons who are vaccinated.'

The courts may have been misled. In April 2021 the provisional consent approval was challenged as it was for a 'limited number of patients.' In the May 18 judgement, it is clear that Judge Ellis' deliberations were based a trust that the public health risk communicated by officials was accurate. Judge Ellis also stated a belief that:

'vaccination is not, and will not be, compulsory for the vast majority of the New Zealand public'

In April 2021 the government had a plan in place that all of New Zealand would be vaccinated.

The premise of the mandates: to prevent and limit the risk of outbreak or spread of COVID-19. This implied that a vaccinated person would not spread the infection SARS-Cov-2. There was no obligation to prevent hospitalisation and death and this was never the goal of the Pfizer trials.²⁰

²⁰Vaccines and Related Biological Products Advisory Committee Meeting December 10, 2020

The pandemic risk was persistently over-stated by institutions and governments. The absence of scientific evidence for lockdowns and enforcement measures stretched from New Zealand to the USA²¹ to Germany. ²² From 2020 COVID-19 was known to age specific.^{2324 25} Media reported that China had controlled the virus with extraordinarily abusive lockdowns, only to find the virus resurface. In Germany, leaked protocols of internal meetings at the Robert Koch Institute show that the covid countermeasures were without justification.^{26 27 28}

An analysis of the WHO, the World Bank and the G20 showed that risks were overstated, leading the authors of the analysis to ask whether the desire to address the perceived threat was driving the analysis, rather than whether the analysis was objectively determining the extent of threat.²⁹

New Zealand lockdowns and the injection campaign were not based on a high deathrate but on cases and infections based on real time reverse transcription polymerase chain reaction (PCR) tests. PCR tests were used by the government throughout the pandemic, yet scientists were not permitted to publicly criticise the instrument. For example, cycle thresholds could produce false positives and false negatives. PCR positive patients might not necessarily produce antibodies, they could stay positive for twelve weeks after infection and people could die from other morbidities, but the PCR test result would be inferred to be a COVID-19 death. It had been known for many years that PCR tests could be unreliable.³⁰

What might the public have reasonably expected? That the vaccine would be sterile and would not prevent transmission of infection, that it would be as effective as natural immunity. That the vaccines would prevent hospitalisation and death. By January 15 Government was expecting all New Zealand people to be injected under a sequencing framework (see Appendix (ii)) and on March 10th, 2021, the Minister for Covid-19 Response, Chris Hipkins had formally laid out the expectations that healthy people (referred to as tier or group 4) would be injected from July onwards.³¹

FDA Briefing Document Pfizer-BioNTech COVID-19 Vaccine https://www.fda.gov/media/144245/download ²¹ Two metres or one: what is the evidence for physical distancing in covid-19? BMJ 2020; 370 doi: https://doi.org/10.1136/bmj.m3223 (Published 25 August 2020)

²² Herby, J, Jonung L, Hanke SH (2022) A Literature Review and Meta-Analysis of the Effects of Lockdowns on COVID-19 Mortality. Studies in Applied Economics SAE/no.200/January2022. Johns Hopkins Institute for Applied Economics. https://sites.krieger.jhu.edu/iae/files/2022/01/A-Literature-Review-and-Meta-Analysis-of-the-Effects-of-Lockdownson-COVID-19-Mortality.pdf

²³ Ioannidis, J.P. et al. (2020). Population-level COVID-19 mortality risk for non-elderly individuals overall and for nonelderly individuals without underlying diseases in pandemic epicenters, Environ Res., 188, 109890. https://doi.org/10.1016/j.envres.2020.109890

²⁴ Levin AT et al (2020). Assessing the age specificity of infection fatality rates for COVID-19: systematic review, meta-analysis, and public policy implications. European Journal of Epidemiology (2020) 35:1123–1138 https://doi.org/10.1007/s10654-020-00698-1

²⁵ Ioannidis, J.P. (2021). Infection fatality rate of COVID-19 inferred from seroprevalence data. Bull World Health Organ. 99(1), 19- 33F. http://dx.doi.org/10.2471/BLT.20.265892

²⁶ Kuhbandner C, Homburg S, Walach H, Hockertz S (2022) Was Germany's Lockdown in Spring 2020 Necessary? How Bad Data Quality Can Turn a Simulation Into a Delusion that Shapes the Future. Futures 135 (2022) 102879. https://doi.org/10.1016/j.futures.2021.102879

²⁷ Robert Koch Institute COVID-19 Pandemic files. https://my.hidrive.com/share/2-hpbu3.3u#\$/

²⁸ Yanovskiy K and Socol Y (2021) COVID-19 Library. Filling the Gaps. https://dx.doi.org/10.2139/ssrn.3784709

²⁹ Wallace Brown G et al (2025) Re-evaluating Pandemic Risk within the Global Pandemic Prevention, Preparedness and Response Agenda (REPPARE). (University of Leeds.

³⁰ Costinescu S (Jan 22, 2007) Faith in Quick Test Leas to Epidemic that Wasn't. New York Times

³¹ Hipkins C (March 10, 2021). COVID-19 vaccine roll-out plan https://www.beehive.govt.nz/release/covid-19-vaccine-roll-out-plan

The Covid-19 Act (2020/12) had secured its powers via the Health Act 1956.³² Yet the Covid-19 Act (2020/12) displayed a disregard for the principles of infectious disease which was contained in <u>Part 3A the Health Act 1956</u>. It did not directly encode human rights, including the right to health but affirmed the <u>New Zealand Bill of Rights Act 1990</u> which includes the right to refuse to undergo medical treatment.

However, by April 2021, Pfizer had released its post-marketing report that demonstrated the extraordinary level of adverse events that the trial participants were experiencing.³³ Pfizer also knew by that date that more participants had died in the vaccine arm than the placebo arm in the C4591001 Clinical Trial Group. It is not clear whether the New Zealand government had received this information, which would be published as a supplementary appendix in Thomas, SJ et al.(2021) in September 2021.³⁴ The gradual decline in efficacy was noted by the authors, joining a growing body of data that confirmed that the vaccine did not prevent viral replication and transmission. (See image below).

	BNT162b2 (N=21,926)	Placebo (N=21,921)
Reported Cause of Death ^a	n	n
Deaths	15	14
Acute respiratory failure	0	1
Aortic rupture	0	1
Arteriosclerosis	2	0
Biliary cancer metastatic	0	1
COVID-19	0	2
COVID-19 pneumonia	1	0
Cardiac arrest	4	1
Cardiac failure congestive	1	0
Cardiorespiratory arrest	1	1
Chronic obstructive pulmonary disease	1	0
Death	0	1
Dementia	0	1
Emphysematous cholecystitis	1	0
Hemorrhagic stroke	0	1
Hypertensive heart disease	1	0
Lung cancer metastatic	1	0
Metastases to liver	0	1
Missing	0	1
Multiple organ dysfunction syndrome	0	2
Myocardial infarction	0	2
Overdose	0	1
Pneumonia	0	2
Sepsis	1	0
Septic shock	1	0
Shigella sepsis	1	0
Unevaluable event	1	0

Table S4 | Causes of Death from Dose 1 to Unblinding (Safety Population, \geq 16 Years Old). a. Multiple causes of death could be reported for each participant. There were no deaths among 12–15-year-old participants.

³² New Zealand Parliament. (May 12, 2020). COVID-19 Public Health Response Bill

https://www.parliament.nz/en/pb/bills-and-laws/bills-proposed-laws/document/BILL_97739/covid-19-public-health-response-bill

³³ Pfizer Worldwide Safety Report. (April 2021) 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports, by February 2021. https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf

³⁴ Thomas, S.J. et al. (2021). Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine. NEJM. 385,

^{1761-1773 (}Pfizer) https://doi.org/10.1056/NEJMoa2110345 Adverse Events Page 6.

Several years later evidence continues to accrue that the mRNA vaccines drove death rates and the scientists that author such papers continue to face barriers to publication.³⁵

There is no evidence that Chris Hipkins was ever briefed on the growing evidence that natural immunity conferred better long-term immunity, with the risks of a gene therapy that was designed to release a known inflammatory toxin, the spike protein. There is no evidence that Hipkins demanded that this work was done.

There was no published data coming out of the Ministry of Health which demonstrated a methods-based approach to assessing the problem of vaccine waning and the increasing evidence that vaccine-related adverse events were more common than historic expectation.

Unfortunately, no effort was made to clarify that a large proportion of the population by July 2021 may have experienced herd immunity, that injecting a healthy person who was not at risk of severe COVID-19 would be disproportionately at risk of a vaccine-related adverse events.

This is despite Pfizer having an enormous bank of data that demonstrated that a not-at-risk person would be disproportionately at risk from a vaccine-related adverse event and that these events could be stratified by age and gender.

The key decisions made between February 2021 and October 2022 were undertaken consequent to Cabinet memos where officials were consistently advised throughout the latter half of 2020 that a 'safe and effective vaccine' would be available. New Zealand's December 10, 2020 agreement coincided with the U.S. Vaccines and Related Biological Products Advisory Committee Meeting.³⁶

Joint Ministers agreed to purchase 750,000 courses of Pfizer Inc's vaccine candidate (1.5 million doses) with an earliest delivery date of March 2021.³⁷ That document did not include a requirement that the safety of the vaccine candidate (BNT162b2) would be assessed over time. That document discussed the risk of BNT162b2 being low quality but did not determine how that would be assessed.

By January 15 2021³⁸ Cabinet had decided that to 'expand eligibility for COVID-19 immunisation to everyone in New Zealand would promote equity and help us to maximise uptake of the vaccine.' The scientific information that Medsafe would use was based on data supplied by the manufacturer. That Cabinet document discusses following a standard 'proven process'.

Work was being undertaken at this time to draft a Cabinet paper: February 2021 update on the COVID-19 Immunisation Strategy. This strategy would become the 'lock-in' for the injection campaign.

New Zealand's COVID-19 Campaign rollout was based on a scientific claim – that healthy people being injected would prevent transmission and lower hospitalisation and disease, for which there was no concrete evidence.

There was no 'proven process'. 'Proven processes' were discarded and ignored by officials.

³⁵ Hulscher et al (2024). A Systematic Review Of Autopsy Findings In Deaths After COVID-19 Vaccination. *Science Public Health Policy and the Law.* Volume: v5.2019-2024 November 2024

³⁶ 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 ³⁷ Ministry of Health Briefing 10 December 2020. Health report no 20202260.

³⁸ Ministry of Health Briefing 15 January 2021. COVID-19 Vaccine and immunisation update for joint Ministers

In January 2022 New Zealand officials were expecting the highly transmissible variant Omicron. Omicron was unlikely to cause hospitalisation and death³⁹, yet this was not communicated as such. Officials were more concerned with driving vaccine update through the traffic light system and the paediatric vaccine, rather than in the changing evidence on safety and efficacy. As a January 2022 news article stated:⁴⁰

'The traffic light system won't help us very much because it was never designed to dampen down transmission, it was only designed to nudge people towards vaccination'

[2] THE LEGAL BASIS FOR POPULATION-LEVEL MANDATES

The Hon Chris Hipkins was Health Minister from 02/07/2020 until 06/11/2020 and after that date Andrew Little became Health Minister. Chris Hipkins was the Minister for Covid-19 Response from 06/11/2020 until 14/06/2022. Minister of Finance (Grant Robertson, who was also Deputy Prime Minister) and the Director General of Health (Ashley Bloomfield) were <u>signatories to the Pfizer contract</u> on behalf of the New Zealand Government.

Chris Hipkins had released the <u>Vaccine roll-out plan (March 10, 2021)</u> which intended to ensure that not-atrisk groups would be injected from July onwards.

Chris Hipkins released the Vaccine roll-out plan, and released all Orders made under <u>section 11</u> of the COVID-19 Public Health Response Act 2020, in accordance with <u>section 9</u> of that Act until 2022 (see appendix (i) for a list of Orders).

The <u>COVID-19 Public Health Response (Vaccinations) Order 2021 (2021/94)</u> had come into force on 30 April 2021. Order 2021/94 would be the legislative vehicle for updating vaccines mandates in the primary Act, following the passing of <u>COVID-19 Public Health Response Amendment Bill (No 2)</u>.

Chris Hipkins <u>COVID-19 Public Health Response Amendment Bill (No 2) 68-2</u>⁴¹ received Royal assent and became law on November 19, 2021. On day later the parent Act was <u>updated to incorporate 68-2</u>. Three days later, Chris Hipkins released the <u>COVID-19 Response (Vaccinations) Legislation Bill (2021/51)</u> which Parliament would pass all readings on that same day, November 23rd, 2021. The public took no part in any consultation.

The No.2. (68-2) Bill did not discuss vaccines and therefore 14,000 of the 15,000 submitters to the October Select Committee who generally discussed vaccine risks and vaccine mandates were ruled as out of scope.

Yet the very intention of Amendment Bill (No 2) 68-2 was to expand the legislative platform so that the <u>COVID-19 Response (Vaccinations) Legislation Act 2021 (2021/51)</u> could become law without legal barriers.

³⁹ Pre-Omicron eg. Axfors C. and Ioannidis P.A. Infection fatality rate of COVID-19 in community-dwelling populations 466 Nakagami, H. (2021). Development of COVID-19 vaccines utilizing gene therapy technology. International Immunology, 33:10;521-527. https://doi.org/10.1093/intimm/dxab013

⁴⁰ McKenzie, P. (2022, Jan 10). New Zealand not prepared for Omicron outbreak expected in 'matter of weeks', experts warn. The Guardian. https://www.theguardian.com/world/2022/jan/10/new-zealand-not-prepared-for-omicron-outbreak-expected-in-matter-of-weeks-experts-warn

⁴¹ Bill text: https://www.legislation.govt.nz/bill/government/2021/0068/latest/whole.html#LMS552303

Chris Hipkins was the Minister in charge of both pieces of legislation and understood clearly that vaccines would be mandated. On the <u>26 November, the COVID-19 Public Health Response Act 2020 (2020/12)</u> was updated to incorporate the <u>new vaccinations legislation (2021/51)</u>.

The New Zealand public were granted a total of 10 days (30 Sept to Oct 11) to send in their thoughts to the <u>COVID-19 Public Health Response Amendment Bill (No 2)</u>. In October 2021 the <u>Ministry of Health and the Ministry of Business (MoH)</u>, <u>Innovation and Employment (MBIE)</u> prepared a 'Departmental Report' in the response to the public submission to the COVID-19 Public Health Response Amendment Bill (No 2).⁴²

Public submissions were dismissed in one page, yet three days after that Bill being incorporated into law Chris Hipkins would release, and Parliament would approve, <u>legislation</u> that referred to vaccination or vaccine, dozens of times.

The dozens of doctors, scientists, public health professionals that submitted on the role of herd immunity, human rights, on the evidence that the BNT162b2 gene therapy could be demonstrated at this stage - to be neither safe nor effective, to wane, and to be too risky a technology to inject into healthy people were roundly ignored.

The focus of the Departmental Report was on infection prevention control. There was no focus on the safety of interventions and the state of scientific evidence. The Report did not discuss the requirement that any intervention should be evidence-based and scientifically justified.

MoH and MBIE's <u>Departmental Report (page 3)</u> acknowledged that some 14,000 submissions had expressed concerns on the interventions, and the potential for vaccination to become compulsory, or mandated.

The Departmental Report stated that *'vaccination is at the centre of the Government's response to COVID-*19. The Report did not engage with scientific evidence on the safety of evidence of the vaccination.

However, there were no methods based scientific reviews of the scientific literature being systematically undertaken to identify the relative risk of the virus and of the injection, and of the evidence that the injection would not prevent transmission.

This Bill was seen by the public as an important way of presenting the scientific evidence on the safety and efficacy of the sole medical intervention to Members of Parliament (MPs). However, MPs did not discuss some 14,000 concerns in their Select Committee report, and the Departmental Report reveals that 14,000 submissions were set aside and that the Committee would only focus on the 'minority of submissions (around 1000) which related directly to the Bill itself, and especially those in which submitters made specific recommendations to improve the Bill.'

Concerns over the safety and efficacy of the BNT162b2 gene therapy expressed by submitters was explicitly ignored as these comments were outside the scope of the Bill.

In response to a request by submitters requesting that the <u>COVID-19 Public Health Response Amendment</u> <u>Bill (No 2)</u> explicitly state that vaccination cannot be mandated under section 11, the <u>Departmental Report</u> <u>stated (page 42)</u> demonstrated the key role of vaccines that were not articulated in the Amendment Bill (No 2).:

https://psgr.org.nz/component/jdownloads/send/1-root/122-21-amendmentbillno2-report

⁴² COVID-19 Public Health Response Amendment Bill (No 2) Departmental Report Prepared by the Ministry of Health and the Ministry of Business, Innovation and Employment (MBIE) October 2021. https://psgr.org.pz/component/idownloads/cend/1-root/122-21-amendmentbillpo2-report

'Vaccination is one of the most important public health measures available to help combat COVID-19. It is important that the Government can support organisations and businesses whose staff are at a higher risk of being infected with COVID-19 to require vaccination of their staff. This provides a strong legal basis for those organisations to redeploy or terminate staff who refuse to be vaccinated and pose a risk to others in doing so. COVID-19 orders which mandate vaccination also provide New Zealand with an extra layer of protection. Any mandatory vaccination provision within a COVID-19 order must be a justified limitation on the rights and freedoms under the NZBORA.'

Chris Hipkins did not receive systematic, periodic updating of the science on viral or vaccine risk over this time and before he made Orders in Council.

THE ROLE OF SELECT COMMITTEES

The Select Committee were in place to introduce legislation that would specifically drive uptake of the Pfizer BNT162b2 gene therapy vaccine. At no stage did the Select Committee report nor the Departmental Report acknowledge the problem of the safety and efficacy of that technology.

The policy goal - of reducing risk through elimination using the BNT162b2 injection was the chief reason for Amendment No.2. legislation. This is evident from the introduction of vaccination into legislative text directly after the Bill received Royal assent and became integrated in the parent Act, the COVID-19 Public Health Response Bill 2020 (2020/12).

Despite the fact that MoH and MBIE's <u>Departmental Report</u> stated that vaccination was a key measure, that Departmental Report dismissed 14,000 people who by talking of the risks of vaccines, were not talking to the body of the Bill before them.

Any person talking about vaccines was therefore interpreted as being 'out of scope'. Vaccines, which were not referred to in the November 20th version of the COVID-19 Public Health Response Act 2020 were introduced in the November 26th reprint. Vaccines were mentioned 157 times in the November 26th version of Act which was the version (reprint) in place on December 4 2021, just prior to when mandates were expanded to require all New Zealanders get injected.

This was unethical and unjust. The issue at stake was a mandate of a medical biologic drug.

Select Committee or departmental reports following public consultation must:

'communicate a range of matters to the committee. It must summarise and analyse, in a comprehensive but concise fashion, the issues raised by submitters that are relevant to the bill. This is often done by including both a summary of the main themes in the submissions and a clause-by-clause analysis. The summary and analysis of submissions must be conducted in an impartial manner, and relevant submissions cannot be omitted for the sake of convenience or expedience. Submissions that raise issues beyond the policy scope of a bill may receive more limited comment, but advisers must be careful not to pronounce issues as being outside the legislative scope of the bill.'

<u>'Select committee scrutiny has been described as the House of Representatives' best way to improve the quality of legislation.'</u>

TIMELINE

• 30 Sept-Oct 11 2021. Chris Hipkins: <u>Minister in charge of the Amendment Bill No.2</u>. Ten days for the public to respond. PSGR's response is detailed in the section below.

- October 17 2021 (LI2021/94) Order. Amendments include Schedule 3, list of vaccines.
- October 18 2021 Cabinet agreed to move to 'minimise and protect COVID-19 strategy.
- October 2021: <u>Ministry of Health and MBIE joint Departmental Report</u> released.
- October 2021: <u>Health Committee report</u> does not discuss public concerns.
- <u>20 November 2021: COVID-19 Public Health Response Act 2020 updated</u> to reflect the amendment (2021 No 48). At this stage this primary Act does not mention vaccines.
- <u>23 November: COVID-19 Response (Vaccinations) Legislation Bill</u> released, Minister in Charge Chris Hipkins. No public consultation.
 - 'The amendments in this omnibus bill make vaccination a more prominent part of New Zealand's COVID-19 response framework.'
- <u>25 November: COVID-19 Response (Vaccinations) Legislation Act 2021.</u> (2021/51) Received Royal assent on November 25.
- <u>26 November: COVID-19 Public Health Response Act 2020 updated</u> to incorporate new obligations as per the COVID-19 Response (Vaccinations) Legislation Act 2021. This primary Act now mentions vaccines/vaccination 157 times.

EXPANDING VACCINATION

Neither the Departmental Report, nor the <u>Health Committee report</u> discussed concerns raised by submitters concerning the scientific evidence that presented that SARS-Cov-2 did not present a risk of hospitalisation and death and that the pharmaceutical intervention, the Pfizer BNT162b2 biologic vaccine was not as effective (i.e. it did not prevent transmission and infection) or effective, as government officials claimed.

PSGR's 16 page submission, reproduced below in section [3] provided clear scientific evidence that the law was legally and ethically questionable.

This evidence was not considered at all in either report.

The <u>Departmental Report</u> discussion on 'health and safety' did not discuss the risk of the gene therapy, the evidence of waning, and the concerns that healthy people did not require the intervention.

The scientific justification for the interventions was not discussed, even though this was a primary focus for many submitters, because it was understood that the mandated technology would not prevent transmission of infection – the primary reason for the government roll-out.

Official Information Act requests were made to understand if Chris Hipkins was being briefed through alternative routes on the published safety and efficacy data, based on risk by age, gender, pregnancy status and health status before each Order was rolled out, no evidence that the Minister was being briefed, so as to justify each Order, was provided. The releases by the advisory groups, and the 'CSU's', Covid Science Updates, never demonstrated a scientifically rigorous, robust, methods based approach to identifying the efficacy (including waning) and safety of the BNT162b2 gene therapy vaccine.

This Departmental Report was published at the same time the secondary legislation was being developed with Chris Hipkins as Minister in charge, to further mandates to healthy people.

The Departmental Report did not engage in discussion on the safety concerns of submitters, but instead focussed on interventions as 'safeguards'. The focus remained on transmission of infection.

PSGR note that there is a loophole wherein if a Minister changes portfolio, that that Minister may not respond to an Official Information Act concerning the former portfolio. This made it more difficult to assess

what information Chris Hipkins had been privy to. Other small changes altered the transparency of the Parliamentary process, making it more difficult to understand what information has been considered by officials. For example, during 2022 Bills Digests stopped being produced. Bills Digests would traditionally contain relevant policy papers used in the formulating of policy prior to the release of a Parliamentary Bill. This would enable the public quick access to relevant information.

Good democratic process requires that the actions of officials are transparent and accountable. The separation of powers is in place to reduce the potential for the abuse of power, which can quite swiftly lead to a decline in public trust. Officials are not broadly educated in constitutional and administrative law and there are few academics and legal experts that publicly draw attention to what is known as public law. Perhaps they only believe that the conventions and obligations drafted into the Legislation Design and Advisory Committee, Legislation Guidelines and the Cabinet Manual need to only vaguely be followed.

However, whatever is the situation, practices and processes used by MoH and MBIE officials, and by Cabinet (where secondary legislation is pushed out without regard for the evidence basis for that legislation (including for whether that 'emergency' would cause hospitalisation and death, and in relation to the Health Act 1956 obligations to protect health) signal an erosion of the foundations of democratic order.

New Zealand's combination of a 'highly centralised system of government of formally unlimited legislative power and strong executive dominance of the activities of the nation's Parliament'⁴³ has provided the foundation for officials to introduce statute in a virtually unchecked manner. New Zealand's unwritten constitution, the absence of an upper house and the dominance of executive government has left New Zealand wide open for the taking of powers.

PSGR express concern that common law is in the process of being eroded by the taking of statutory powers that over-ride and set aside common law norms. In addition, PSGR believes that there has also been an undermining of equity, that body of legal principles that supplement common law to ensure that justice and fairness is maintained. Equity acts as a check and balance on common law and statutory law.

Equity enables judicial discretion and is useful in circumstances that may be complex and uncertain, where it is difficult to foresee the future. 'Equity intervenes when law fails because of its generality'.^{44 45}

[3] PSGR'S OCTOBER 11 2021 SELECT COMMITTEE SUBMISSION – MPS WERE INFORMED OF VACCINE RISKS & QUESTIONABLE EFFICACY

This is PSGR's October 11, 2021 submission to the COVID-19 Public Health Response Amendment Bill (No 2). (PDF link).

A. POLICY FORMULATION FOR STATE MANAGEMENT OF PANDEMICS

1. The context for evaluating proposed legislation has two prior ingredients:

http://dx.doi.org/10.2139/ssrn.3734662

⁴³Geddis A. (2016). Parliamentary government in New Zealand: Lines of continuity and moments of change I•CON (2016), Vol. 14 No. 1, 99–118. doi:10.1093/icon/mow001

 ⁴⁴ Aristotle, The Nicomachean Ethics 1137b, at 314-15 (H. Rackham trans., Harvard Univ. Press rev. ed. 1934).
 ⁴⁵ Smith, Henry E., Equity as Meta-Law (October 15, 2020). Yale Law Journal, Forthcoming, Harvard Public Law Working Paper No. 20-33, Available at SSRN: https://ssrn.com/abstract=3734662 or

- a. The adequacy of the policy formulation process that has preceded a requirement for legislation; and
- b. The adequacy of identified endpoints that a proposed legislative initiative does or does not clearly target.

B. POLICY FORMULATION

- 2. Policy formulation is required by law to identify all relevant options for achieving desirable endpoints that are in the public interest and which protect the person.
- 3. There is no evidence, readily available, that shows that such policy formulation has been undertaken that complies with those requirements.

C. DESIRABLE END-POINTS

- 4. For effective state management of pandemic viruses it is well established (since the time of Louis Pasteur) that for a virus 'the terrain is everything' *i.e.* if a virus encounters a strong immune system, the virus is less likely to colonise its victims' cells successfully; and that person's cells will in future be well-prepared to reject any future invasions of that virus and its variants.
- 5. In summary, therefore, it follows that, if a person possesses a vigorous immune system, the virus will not find a 'terrain' that is conducive to its further reproduction.
- 6. It also follows, that a valid policy formulation for management of pandemic viruses must include consideration of state-supported personal healthcare (PHC) programme that helps individual people to prepare their highest-attainable immune function. There is an arguable obligation of government to have such a 'bottom-up' programme. [See the UNESCO⁴⁶ document at reference ⁴⁷.]
- 7. Many of the Principles and Articles in the same UNESCO reference document are highly-relevant and appear to be completely ignored by policy-makers and drafters of related legislation and this Bill.
- 8. Such a 'bottom-up' strategy addresses a compelling cluster of clear and key end-points: it limits the damage that a pandemic virus may otherwise cause; it limits the rate-of-spread of a virus; and it minimises social and economic damage that might otherwise be caused.
- 9. Such a policy can be extended as a first priority to economically-disadvantaged and those with inherent immune system disadvantages (e.g. the elderly, those on poorer diets and those with existing comorbid health conditions). That first priority lowers threats of otherwise overwhelming the health-care system arguably an important infra-structural issue. ⁴⁸
- 10. A state policy that sets out to support peoples' immune systems has the benefit of:
 - a. denying reproductive territory to a pandemic virus; and
 - b. damping down transmission of a virus to others.

⁴⁶ UNESCO. (2006). Universal declaration on bioethics and human rights. Paris. June 2006. SHS/EST/BIO/06/1 http://unesdoc.unesco.org/images/0014/001461/146180E.pdf

⁴⁷ UNESCO. (2006). Article 3 – Human dignity and human rights. 1. Human dignity, human rights and fundamental freedoms are to be fully respected. 2. The interests and welfare of the individual should have priority over the sole interest of science or society.

⁴⁸ UNESCO. (2006). Article 14, Subsection 2 highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, progress in science and technology should advance

- 11. It should be obvious that such a 'bottom-up' policy option holds out sustainable end-point benefits for tackling pandemic virus infections especially when compared to a <u>sole</u> reliance on novel and experimental inoculations of unknown safety and efficacy.
- 12. A pandemic virus is likely to try to evolve variant adaptations that outwit components used in the inoculations resulting in a virus re-gaining footholds in those that have had inoculations (the Israel example).
- 13. A bottom-up policy option for tackling pandemic viruses also has the benefit of empowering individuals to take command of their own bodies in a sensible way that has many other health benefits that offers a highly desirable benefit of much-lowered demand of state sickness services on most other disease-treatment fronts. The comparative benefit of pursuit of a 'bottom-up' health initiative for important matters of social cohesion, mental health and confidence and trust by people in their machinery-of-government should be obvious.
- 14. Legislative initiatives in New Zealand (including this latest Bill) seem to be focussed on pushing experimental inoculations to the active exclusion of bottom-up initiatives. The thrust of present legislative initiatives continues to produce massive economic and social harm to people; to polarise society; to take away peoples' rights; and to use state powers and instruments to both coerce and force a policy onto people that government is supposed to protect.
- 15. There has been no evidence made available that such a bottom-up policy option has either been identified let alone given due weight in a transparent policy formulation process used for the taking of statutory powers.
- 16. Rather, the evidence publicly available suggests that an inoculation policy was adopted exclusively as a basis for taking statutory emergency powers of which this current Bill is an example.^{49 50}
- 17. Policy decisions made by an administration that do not identify arguably primary policy options with compelling end-points, spawn public suspicion of caprice and arbitrariness and are inimical to the principle of open justice and the rule of law. ⁵¹ Davison CJ proclaimed it a public responsibility of both courts and administrative decision-makers to provide reasons.⁵²
- 18. It would appear that the present policy framework that informs the taking of statutory powers disregards personal health care (PHC) relevant considerations.⁵³
- 19. It is clear that the approach that has been taken to policy making as a basis for taking legislative powers, that affects citizens' rights is lacking any compelling statement of reasons to justify the taking of such powers.⁵⁴
- 20. Decision-makers bear an obligation to show candour in their reasoning and processes. They must weigh relevant considerations openly and transparently or risk a finding of no weight being accorded to those reasoning processes.⁵⁵

⁴⁹ Ministry of Health 2021. Regulatory Impact Statement Legislative improvements to support the public health response to COVID-19. Undated https://www.health.govt.nz/system/files/documents/information-release/ris_legislative_improvements_to_support_the_public_health_response_to_covid-19.pdf

⁵⁰ MBIE. Regulatory Impact Statement: Coversheet: Legislative Framework for Managed Isolation and Quarantine Undated. https://www.mbie.govt.nz/dmsdocument/17052-regulatory-impact-statement-legislative-improvements-to-support-the-public-health-response-to-covid-19

⁵¹ Joseph, P.A. Constitutional and Administrative Law in New Zealand, 3rd Ed., Thomson Brookers, 2007. p.985 ⁵² Potter v NZ Milk Board [1983] NZLR 620 at 624 per Davison CJ (HC).

⁵³ Anisminic Ltd v Foreign Compensation Commission [1969] 2 AC 147 per Lord Reid (HL)

⁵⁴ Lewis v Wilson & Horton Ltd [2000] 3 NZLR 546 at 567 (CA)

⁵⁵ Leiataua v Minister of Immigration. 26/11/03 , Durie J, HC Wellington CIV-2003-485-742, at para 45.

- 21. It would appear that policy decision-makers have made a reviewable error through not giving proper weight to important options and considerations.⁵⁶ Decision-makers must not disable themselves from considering information relevant to their statutory function.⁵⁷
- 22. In summary, it seems that the policy framework ignores fundamental principles of constitutional and administrative law.
- 23. It is in that context that we suggest your Select Committee should review the requirement for and the provisions included in this Bill.

D. RELEVANT CONSIDERATIONS

- 24. The COVID-19 Public Health Response Amendment Bill (No 2) strengthens powers, including increasing infringement penalties. Regulatory impact statements have failed to address as a relevant consideration, the fluid state of science in relation to risk and COVID-19.
- 25. Ignorance and exclusion of these relevant considerations risk absurdities in law. The COVID-19 Public Health Response Amendment Bill (No 2) is overly punitive, inconsistent with existing legislation and unjustified.
- 26. Measures in the Bill appear to not only restrict human rights, they appear inconsistent with overarching principles for management of infectious diseases, as stated in the Health Act which requires that individuals are protected and that measures are proportionate to the health risk.
- 27. There is little scientific evidence to support measures to restrict the movement of individuals.^{58 59 60 61} For example, there is little scientific evidence that nonpharmaceutical interventions (lockdowns) restricting movement contributed substantially to bending the curve of new cases in England, France, Germany, Iran, Italy, the Netherlands, Spain or the United States in early 2020.⁶²
- 28. The measures greatly risk impacting lower-income groups disproportionately. The New Zealand Public Health and Disability Act 2000 requires that measures taken by officials must 'reduce health disparities.'
- 29. The strengthening of powers and orders have been undertaken in isolation of increased evidence that the public health approach requires top-down and bottom-up measures, which include paying attention to the dignity of the individual.
- 30. This submission draws attention to the following mandatory and relevant considerations that:
 - a. The case fatality rate does not warrant measures that increasingly contravene human rights, including the right to health. Current measures are arbitrary and unjustified when the international data on risk of hospitalisation and death is taken into account;

⁵⁶BCNC v Broadcasting Tribunal [1986] 2 NZLR 620 at 634 per McMullin J (CA)

⁵⁷ Minister for Aboriginal Affairs v Peko-Wallsend Ltd [1986] 162 CLR 24 (HCA)

⁵⁸ Duhon et al.. (2021). The impact of non-pharmaceutical interventions, demographic, social, and climatic factors on the initial growth rate of COVID-19: A cross-country study. Science of The Total Environment, 760, 144325.

⁵⁹ Fraiman et al. The majority of the variation in COVID-19 rates between nations is explained by median age, obesity rate, and island status. medRxiv preprint https://doi.org/10.1101/2021.06.14.21258886

⁶⁰ Savaris et al. Stay-at-home policy is a case of exception fallacy: an internet-based ecological study. Scientific reports, (2021) 11(1), 1-13.

⁶¹ Chin et al. Effect Estimates of COVID-19 Non-Pharmaceutical Interventions are Non-Robust and Highly Model-Dependent. Journal of

Clinical Epidemiology (2021)

⁶² Bendavid et al 2021. Assessing mandatory stay-at-home and business closure effects on the spread of COVID-19. Eur J Clin Invest. 2021;51:e13484.

- b. mRNA vaccines confer limited and short-term protection;
- c. All medical interventions carry risks and mRNA COVID-19 vaccination is not without risk;
- d. The sweeping of healthy young people and children into a generic, 'one-size-fits all' vaccination approach ignores the data that demonstrates this group is at low risk;
- e. Clear data demonstrates that natural immunity confers greater protection than current vaccination strategies and that healthy people with natural immunity have broad protection to multiple variants;
- f. No steps have been taken to reduce vulnerability through appropriate health-based measures to prevent the immune systems of vulnerable groups.
- 31. We consider that the proposed bill carries with it significant and detrimental legal, social, economic and political implications. The potential legislation will be discriminatory and disproportionately harm low-income populations and particularly place Māori and Pasifika populations at risk.

(A) The Health Act 1956.

3A Function of Ministry in relation to public health: 'improving, promoting, and protecting public health'.

Part 3 Infectious and notifiable diseases Part 3A Management of infectious diseases: Subpart 1— Overarching principles

92C Respect for individuals

(1) An individual must be treated with respect for the dignity of the individual when any functions, duties, or powers are exercised or performed in relation to him or her under this Part.

(2) The person exercising or performing the functions, duties, or powers must take into account any known special circumstances or vulnerabilities of the individual, to the extent that the protection of public health permits this to be done.

92F, the Principle of proportionality. Where:

Measures applied to an individual under this Part must—

(a) be proportionate to the public health risk sought to be prevented, minimised, or managed; and

(b) not be made or taken in an arbitrary manner.

(B) the purpose of the New Zealand Public Health and Disability Act 2000:

(3) (1) (b) to reduce health disparities by improving the health outcomes of Māori and other population groups.

32. Any additional legislative actions to enforce isolation, apply penalties and regulate in such a manner which produces a coercive action requiring vaccination is against the protection of human rights is unjustified based on the current data.

- 33. According to government data, as of October 9, 28 people have died from COVID-19 and 4169 cases have been recorded.⁶³ New Zealand's case fatality rate (the number of deaths divided by the number of cases) based on official WHO figures cautiously may be observed to be 0.7%.
- 34. COVID-19 is not the bubonic plague. Age is the largest risk factor for severe or fatal COVID-19. Compared to a 20-year-old, a 65-year-old individual in the United States has a 90x higher risk of death from COVID-19, and an individual 75 years old has a 2003 higher risk of death. Children under 13 years of age generally have mild or no symptoms. Children make SARS-CoV-2 antibody responses distinct from adults. Where infected children develop the MIS-C syndrome, there are successful treatments.⁶⁴ A recent study looking at hospitalisations of adolescents reported no deaths across the group.⁶⁵
- 35. Systemic poverty and structural racism has resulted in a disproportionate weighting in risk to Māori and Pasifika populations.⁶⁶
- 36. COVID-19 is a notifiable⁶⁷ and quarantinable⁶⁸ disease. There is an absence of interpretation that can clarify to what degree an infectious disease is 'infectious' or 'quarantinable' in the legislation. This legal grey area creates a space for inappropriate and coercive measures that are ignorant to the degree of risk for different population sectors.
- 37. The virus Sars-Cov-2 produces symptoms in certain individuals, and it is these symptoms, as a disease progression, that are known as Covid-19. The principal cause of death among COVID-19 patients arises from an uncontrolled inflammatory cascade a cytokine storm which produces acute respiratory distress syndrome (ARDS), multiple organ dysfunction syndrome (MODS), and microvascular thrombosis. ^{69 70}
- 38. From an early stage it was recognised that those at most risk and most likely to be symptomatic would be the elderly and individuals with multiple chronic health conditions particularly obesity related and heart-related conditions.^{71 72} Diabetes, hypertension, stroke, and ischemic heart disease are risks, as well as the risk of blood clotting. Scientists have recognised the importance of recognising and treating these conditions to prevent the inflammatory cytokine cascade and thrombotic events.^{73 74} Thrombosis is such an enormous problem that scientists have referred to COVID-19 as a thromboinflammatory disease.⁷⁵

⁶³ World Health Organization. New Zealand situation January 3 – October 8 2021.

https://covid19.who.int/region/wpro/country/nz

⁶⁴ Sette & Crotty. Adaptive immunity to SARS-CoV-2 and COVID-19. Cell (2021) 184:861-880

⁶⁵ Havers et al. Hospitalization of Adolescents Aged 12–17 Years with Laboratory-Confirmed COVID-19 — COVID-NET, 14 States, March 1, 2020–April 24, 2021MMRW. 70:23;851-857

⁶⁶ Steyn et al 2021. Structural inequities and systemic racism. medRxiv preprint doi: 10.1101/2020.12.25.20248427;

⁶⁷ Health Act Schedule 1 Part 1 Section B

⁶⁸ Health Act Schedule 1 Part 3

⁶⁹ Wang 2021. A potential association between immunosenescence and high COVID-19 related mortality among elderly patients with cardiovascular diseases. Immunity & Ageing 18:25

⁷⁰ Ibrahim et al. The characteristics of SARS-CoV-2-positive children who presented to Australian hospitals during 2020: a PREDICT network study. MJA 215:5 6 September (2021)

⁷¹ Moore et al 2021 Modelling optimal vaccination strategy for SARS-CoV-2 in the UK

⁷² Malas 2020 Thromboembolism risk of COVID-19 is high and associated with a higher risk of mortality: A systematic review and meta-analysis. Arthritis & Rheumatology. Doi 10.1002/art.41285

 ⁷³ Ruocco et al. Mortality Risk Assessment Using CHA(2)DS(2)-VASc Scores in Patients Hospitalized With Coronavirus Disease 2019 Infection. The American Journal of Cardiology. (2020) https://doi.org/10.1016/j.amjcard.2020.09.029
 ⁷⁴ Mahajan et al. COVID-19-Associated Systemic Thromboembolism: A Case Report and Review of the Literature. Cardiorenal Medicine (2020) 10:462-469

⁷⁵ Gasecka et al. Thrombotic Complications in Patients with COVID-19: Pathophysiological Mechanisms, Diagnosis, and Treatment. Cardiovascular Drugs and Therapy (2021) 35:215–229

- 39. From the Spanish flu onwards, it has been very clear that disadvantaged populations are most at risk of bad outcomes in viral pandemics. As a virus progresses through the population, healthier individuals with better nutrient levels from better quality diets are more likely to be asymptomatic, while less healthy individuals, often on low incomes, or who receive subsistence benefits, are more at risk of being symptomatic because of obesity, a disease of poverty and associated poor diets.^{76 77}
- 40. This legislation has been enacted prior to public availability of rapid antigen self-testing kits (RETs). These are becoming available. The New Zealand public have in general co-operated with distancing and measures to protect elderly and vulnerable populations. RETs reduce ignorance relating to infection status and this ensures that family members and communities can act accordingly to protect vulnerable groups. The legislation is silent on the public supply of these kits which can continue the public co-operation and which also promote trust. RETs should be government funded to ensure that all income groups have equal access.⁷⁸
- 41. This is because the Bill and the COVID-19 response is dismissive and evasive of pervasive and persistent 'dilemmas' that specifically relate to the *public health risk, the substantial risk of serious harm that 1 or more individuals pose to the health or safety of 1 or more other persons*⁷⁹ and the 'the *nature of the infectious disease, including, without limitation, the transmissibility and mode of transmission of the infectious disease*'.

RELEVANT CONSIDERATIONS: CASE FATALITY RATE

- 42. Countries such as Canada, the United Kingdom and the USA can be used to estimate risk in New Zealand because of similar average ages and obesity rates. New Zealand's testing rate is similar to Germany and the Netherlands at around 730 tests per 1000 people. The USA, Australia and Canada have tested at a higher rate.⁸⁰ New Zealand's level of obesity, a major determinant for health risk, is similar to Canada and less than the USA and United Kingdom.⁸¹ New Zealand's median age, 37 is on par with the USA, Australia and China, while Canada and the UK have an older median age, 40.⁸²
- 43. Global case fatality rates appear to be declining.^{83 84} The case fatality rate (CFR) (the number of deaths divided by the number of cases) is strongly associated with median age of the population and the level of obesity. The global Public Health England data in July, 2021, shows that the CFR is somewhere between 0.2% and 2.8%. with the Delta case fatality rate is 0.2%.⁸⁵ New Zealand's CFR, based on official WHO figures cautiously may be observed to be .7%. As of October 9, 28 people have died from COVID-19 and 4169 cases have been recorded. There appears to be a declining trend in the global

⁷⁹ Health Act 1956. (2) Interpretation. Public health risk (a)

⁸² The average age in global comparison. WorldData.info https://www.worlddata.info/average-age.php

⁷⁶ Korakis et al. Obesity and COVID-19: immune and metabolic derangement as a possible link to adverse clinical outcomes. Am J Physiol Endocrinol Metab. (2020) 1;319(1):E105-E109.

⁷⁷ Michalakis & Ilias 2020. SARS-CoV-2 infection and obesity: Common inflammatory and metabolic aspects. Diabetes & Metabolic Syndrome: Clinical Research & Reviews. 14:469-471

⁷⁸ Schwartz et al. Rapid antigen screening of asymptomatic people as a public health tool to combat COVID-19. CMAJ March 29, 2021 193 (13) E449-E452; DOI: https://doi.org/10.1503/cmaj.210100

⁸⁰ Our World in Data <u>https://ourworldindata.org/grapher/full-list-cumulative-total-tests-per-thousand-map October 8,</u> 2021.

⁸¹ Our World in Data. https://ourworldindata.org/obesity

⁸³ Hasan et al 2021. The Global Case-Fatality Rate of COVID-19 Has Been Declining Since May 2020. Am. J. Trop. Med. Hyg.(2021) 104(6):2176–2184

⁸⁴ Fan et al 2021. Decreased Case Fatality Rate of COVID-19 in the Second Wave: a study in 53 countries. Transbound Emerg Dis. (2021)68(2):213-215. doi: 10.1111/tbed.13819.

⁸⁵ Public Health England. SARS-CoV-2 variants of concern and variants under investigation in England Technical briefing 18. 9 July 2021.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001358/Variant s_of_Concern_VOC_Technical_Briefing_18.pdf

CFR.⁸⁶ When case fatality rate is adjusted for age, radical differences appear. A review of the case fatality rate for hospitalised adult patients demonstrated that once hospitalised, patients under 50 had a 3% chance of death, while patients over 50 had a 19% chance of morbidity.⁸⁷

44. For New Zealand, who has had more protected borders, this is good news. While our vaccination rates are comparatively low, they are still higher than rates of countries such as the U.K. who did not commence vaccination until December 2020.⁸⁸

RELEVANT CONSIDERATIONS: LIMITED EFFECTIVENESS OF mRNA VACCINES

- 45. There is no evidence that vaccination can contain the epidemic.⁸⁹ Policy claims that justify restrictions on human rights or that risk interfering with privacy.
- 46. The clinical trials for mRNA vaccines were not designed to assess whether COVID-19 vaccines prevented infection with or transmission of Sars-Cov-2.⁹⁰
- 47. The duration of vaccine protection conferred by the mRNA vaccine is between 3-6 months.⁹¹
- 48. Similar viral loads may be carried by vaccinated and unvaccinated people.^{92 93 94}
- 49. A recent study 'demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity'.⁹⁵

⁸⁶ Fan et al 2021. Decreased Case Fatality Rate of COVID-19 in the Second Wave: a study in 53 countries. Transbound Emerg Dis. (2021)68(2):213-215. doi: 10.1111/tbed.13819.

⁸⁷ Alimohamadi et al. Case fatality rate of COVID-19: a systematic review and meta-analysis. J Prev Med Hyg. 2021 Jun; 62(2): E311–E320.

⁸⁸ BBC December 8 2020. Covid-19 vaccine: First person receives Pfizer jab in UK. https://www.bbc.com/news/uk-55227325

⁸⁹ Ibrahim et al. The characteristics of SARS-CoV-2-positive children who presented to Australian hospitals during 2020: a PREDICT network study. MJA 215:5 6 September (2021)

⁹⁰ Doshi 2020. Will covid-19 vaccines save lives? Current trials aren't designed to tell us. BMJ 2020 371 doi 10.1136/bmj.m4037

⁹¹ Tartof et al. Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA: a retrospective cohort study. October 4 (2021). <u>https://doi.org/10.1016/S0140-6736(21)02183-8</u>.

⁹² Griffin S. 2021. Covid-19: Fully vaccinated people can carry as much delta virus as unvaccinated people, data indicate. BMJ 374:2074: <u>http://dx.doi.org/10.1136/bmj.n2074</u>; published 19 August 2021.

 ⁹³ Acharya et al. No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups Infected with SARS-CoV-2 Delta Variant. medRxiv Preprint (2021) 10.1101/2021.09.28.21264262
 ⁹⁴ Riemersma et al. Vaccinated and unvaccinated individuals have similar viral loads in communities with a high prevalence of the SARS-CoV-2 delta variant. medRxiv preprint (2021)

⁹⁵ Gazit et al. Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections. medRxiv preprint. 10.1101/2021.08.24.21262415

- 50. Pervasive uncertainties include the risk of waning and breakthrough infections following vaccination. Breakthrough from fully vaccinated individuals has been recorded in Vietnam⁹⁶ Israel^{97 98 99}, the U.S.A¹⁰⁰ ^{101 102}.
- 51. A recent San Francisco study stated that 'fully vaccinated were more likely than unvaccinated persons to be infected by variants carrying mutations associated with decreased antibody neutralization...and that ... Differences in viral loads were non-significant between unvaccinated and fully vaccinated persons overall. The authors findings suggested that 'vaccine breakthrough cases are preferentially caused by circulating antibody-resistant SARS-CoV-2 variants, and that symptomatic breakthrough infections may potentially transmit COVID-19 as efficiently as unvaccinated infections, regardless of the infecting lineage.'¹⁰³
- 52. In New Zealand breakthrough cases have occurred in Katikati¹⁰⁴, at Auckland Airport¹⁰⁵ and at Auckland hospital.¹⁰⁶
- 53. mRNA vaccines are based on focused immunity that target a single viral spike protein.¹⁰⁷
- 54. Naturally acquired natural immunity confers equal or better protection than available estimates on vaccine efficacy. Natural immunity, appears realistic for most individuals.¹⁰⁸ In order to acquire robust responses individuals do not need to experience a severe infection.¹⁰⁹
- 55. Naturally infected people produce a broad range of antibody responses which produce an overarching structural response that is effective against emerging variants of concern. Their antibodies cross-neutralising emerging variants 'with high potency'.¹¹⁰

⁹⁶ Chau et al. An observational study of breakthrough SARS-CoV-2 Delta variant infections among vaccinated healthcare workers in Vietnam. EClinicalMedicine (2021) 41:101143

⁹⁷ Shitrit et al. Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021. Euro Surveill. 2021;26(39):pii=2100822. https://doi.org/10.2807/1560-

^{7917.}ES.2021.26.39.2100822

⁹⁸ Gazit et al. Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections. medRxiv preprint. 10.1101/2021.08.24.21262415

⁹⁹ Levine-Tiefenbrun et al. Viral loads of Delta-variant SARS-CoV2 breakthrough infections following vaccination and booster with the BNT162b2 vaccine. medRxiv preprint (2021) 10.1101/2021.08.29.21262798;

¹⁰⁰ Brown et al. Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021. MMWR 20:31;1059-1062

¹⁰¹ Farinholt et al. Transmission event of SARS-CoV-2 Delta variant reveals multiple vaccine breakthrough infections. medRxiv (2021)

¹⁰² Servillita et al. Predominance of antibody-resistant SARS-CoV-2 variants in vaccine breakthrough cases from the San Francisco Bay Area, California. (2021) 10.1101/2021.08.19.21262139

¹⁰³ Servillita et al. Predominance of antibody-resistant SARS-CoV-2 variants in vaccine breakthrough cases from the San Francisco Bay Area, California. (2021) 10.1101/2021.08.19.21262139

¹⁰⁴ MoH. Positive COVID-19 case in the Bay of Plenty. October 9, 2021. https://www.health.govt.nz/newsmedia/media-releases/positive-covid-19-case-bay-plenty

¹⁰⁵ NZ Herald. Covid 19 coronavirus: Worker at Auckland Airport tests positive. April, 20 2021.

¹⁰⁶ Otago Daily Times. Four new Delta Covid cases; nurse tests positive. August 18, 2021.

¹⁰⁷ Brouqui et al 2021. COVID-19 re-infection. Eur J Clin Invest. 2021;51:e13537.

¹⁰⁸ Dan et al., Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection. Science (2021) Science 371: eabf406

¹⁰⁹ Nielsen et al. SARS-CoV-2 elicits robust adaptive immune responses regardless of disease severity. EBioMedicine 68:103410, https://doi.org/10.1016/j.ebiom.2021.103410; published June 4, 2021.

¹¹⁰ Wang et al. Ultrapotent antibodies against diverse and highly transmissible SARS-CoV-2 variants. Science 373:eabh1766 (2021)

- 56. As Cho and colleagues note 'individual memory antibodies selected over time by natural infection have greater potency and breadth than antibodies elicited by vaccination'.¹¹¹
- 57. Antibody combinations reduce the generation of escape variants and people with antibodies following natural infection have a broader range of antibodies. Natural immunity confers broader protection than immunity via mRNA inoculation.¹¹²
- 58. The evidence that while Delta is more contagious, but that the risk to young people and children reflects a similar profile to early data. Where increases have been reported¹¹³ they are small in comparison to risk from car accident, heart disease and other health risks. U.K. case fatality rates for delta indicate that delta is no more severe than earlier Sars-Cov-2 variants.¹¹⁴
- 59. Vaccination after infection may not produce sufficient benefit to justify the intervention.¹¹⁵
- 60. It is not known exactly when a vaccine's effectiveness will weaken against Delta.¹¹⁶
- 61. Breakthrough events can occur shortly after inoculation.¹¹⁷

RELEVANT CONSIDERATIONS: mRNA VACCINES ARE NOT WITHOUT RISK

- 62. Healthy children and young adults are at particularly low risk for bad outcomes from Sars-Cov-2 infection.^{118 119} Their low-risk status was recognised at an early stage in the COVID-19 pandemic.¹²⁰ Adolescents are also at low risk of harm.¹²¹
- 63. Children with obesity and associated, often diet-related health conditions are more at risk of experiencing adverse harm from Sars-Cov-2 infection and can be recommended for innoculation^{122 123} in addition to dietary and treatments that improve immune status

¹¹¹ Cho et al. Anti-SARS-CoV-2 receptor binding domain antibody evolution after mRNA vaccination. doi: 10.1038/s41586-021-04060-7

¹¹² Wang et al. Ultrapotent antibodies against diverse and highly transmissible SARS-CoV-2 variants. Science 373:eabh1766 (2021)

¹¹³ Fisman DN & Tuite AR. Evaluation of the relative virulence of novel SARS-CoV-2 variants: a retrospective cohort study in Ontario, Canada. : CMAJ (2021) October doi: 10.1503/cmaj.211248

¹¹⁴ Public Health England. SARS-CoV-2 variants of concern and variants under investigation in England Technical briefing 18. 9 July 2021.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001358/Variant s_of_Concern_VOC_Technical_Briefing_18.pdf

¹¹⁵ Shrestha et al. Necessity of COVID-19 Vaccination in Previously Infected Individuals: A Retrospective Cohort Study. medRxiv preprint https://doi.org/10.1101/2021.06.01.21258176

¹¹⁶ Levine-Tiefenbrun et al. Viral loads of Delta-variant SARS-CoV2 breakthrough infections following vaccination and booster with the BNT162b2 vaccine. medRxiv preprint (2021) 10.1101/2021.08.29.21262798

¹¹⁷ Hacisuleyman et al. Vaccine Breakthrough Infections with SARS-CoV-2 Variants. NEJM. 2021. 384:23

¹¹⁸ Bhopal et al. Children and young people remain at low risk of COVID-19 mortality. Lancet (2021) /10.1016/S2352-4642(21)00066-3

 ¹¹⁹ Yilmaz et al 2021. Does Covid- 19 in children have a milder course than Influenza? Int J Clin Pract. 2021;75:e14466.
 ¹²⁰ Smith et al. Deaths in Children and Young People in England following SARS-CoV-2 infection during the first

pandemic year: a national study using linked mandatory child death reporting data. Research Square (2021)

¹²¹ Havers et al. Hospitalization of Adolescents Aged 12–17 Years with Laboratory-Confirmed COVID-19 — COVID-NET, 14 States, March 1, 2020–April 24, (2021) MMWR 70:23;851-857

¹²² Harwood et al. Which children and young people are at higher risk of severe disease and death after SARS-CoV-2 infection: a systematic review and individual patient meta-analysis. medRxiv preprint (2021) 10.1101/2021.06.30.212597

¹²³ Mertens & Peñalvo. The Burden of Malnutrition and Fatal COVID-19: A Global Burden of Disease Analysis.(2021) Frontiers in Nutrition. 7:619850 doi https://doi.org/10.3389/fnut.2020.619850

- 64. Recently, a New York Times article drew attention to the fact that many daily activities, such as travelling in a car, pose more risk to the average child than infection with Sars-Cov-2.¹²⁴
- 65. With their low-risk status, young people and children may be *more at risk* from vaccine harm. While this difference is slight, it can be compared alongside the unknown health risks from prospective ongoing booster regimes, which have not been studied in long term trials.
- 66. In New Zealand, deaths reported following Comirnity vaccination are recorded at 68.125
- 67. While Medsafe can question the veracity of the data, there is also an extensive body of scientific data drawing attention to the pervasive problem of the under-reporting of side-effects.¹²⁶
- 68. In comparison, there is strong evidence that the mRNA vaccine carries risk of side effects.^{127 128 129}
- 69. Recently Sweden and Denmark have paused vaccination for the under 20-year-old group.¹³⁰
- 70. It is apparent that those who have been naturally infected, and then been inoculated may be at more risk of adverse events.
- 71. Vaccine failure and waning is associated with age and immunosuppression.^{131 132 133}

RELEVANT CONSIDERATIONS: BOTTOM-UP HEALTH CARE

- 72. Poverty and dietary insufficiency is closely associated with risk from Sars-Cov-2 infection.¹³⁴
- 73. It is no longer legally, ethically or scientifically acceptable that public health measures rely exclusively on vaccination and distancing activities.¹³⁵
- 74. Those most at risk of vaccine failure, including waning and breakthrough infections may likely be the elderly as well as Māori and Pasifika low-income populations. Low-income is directly linked to dietary

https://doi.org/10.1101/2021.09.09.21263342

 ¹²⁴ Leonhardt June 18. Kids, Covid & Delta. https://www.nytimes.com/2021/06/18/briefing/kids-covid-and-delta.html
 ¹²⁵ Medsafe. Adverse events following immunisation with COVID-19 vaccines: Safety Report #29 – 18 September 2021.
 Published 6 October. https://www.medsafe.govt.nz/COVID-19/safety-report-29.asp#death

¹²⁶ E.g. Martin & Lucas 2021. Reporting adverse drug events to the Therapeutic Goods Administration. Australian Prescriber. 2021

¹²⁷ Bozkurt 2021. Myocarditis With COVID-19 mRNA Vaccines. Circulation. 2021;144:471–484.

¹²⁸ Lane & Shakir 2021. Reports of myocarditis and pericarditis following mRNA COVID-19 vaccines: A review of spontaneously reported data from the UK, Europe, and the US. medRxiv preprint doi:

¹²⁹ Pepe et al 2021. Myocarditis, Pericarditis and Cardiomyopathy After COVID-19 Vaccination. Heart, Lung & Circulation. 30:1425-1429 https://doi.org/10.1016/j.hlc.2021.07.011

¹³⁰ Reuters October 7 2021. Sweden, Denmark pause Moderna COVID-19 vaccine for younger age groups. https://www.reuters.com/business/healthcare-pharmaceuticals/sweden-pauses-use-moderna-covid-vaccine-citesrare-side-effects-2021-10-06/

¹³¹ Bajaj 2021 Aging, Immunity, and COVID-19: How Age Influences the Host Immune Response to Coronavirus Infections? https://doi.org/10.3389/fphys.2020.571416

 ¹³² Kimball et al 2021. Influenza Vaccine Failure Associated With Age and Immunosuppression. J Inf Dis 224:2;288-293
 ¹³³ Wang 2021. A potential association between immunosenescence and high COVID-19 related mortality among elderly patients with cardiovascular diseases. Immunity & Ageing 18:25

¹³⁴ Mertens & Peñalvo. The Burden of Malnutrition and Fatal COVID-19: A Global Burden of Disease Analysis.(2021) Frontiers in Nutrition. 7:619850 doi https://doi.org/10.3389/fnut.2020.619850

¹³⁵ Marik et al. A scoping review of the pathophysiology of COVID-19. International Journal of Immunopathology and Pharmacology

⁽²⁰²¹⁾ Volume 35: 1–16.

insufficiency.¹³⁶ Food insecurity is far too common and has been exacerbated by the pandemic.¹³⁷ ¹³⁸ ¹³⁹ ¹⁴⁰ Dietary inadequacy is directly connected to risk for obesity, diabetes and other metabolic diseases. Patients with these diseases are more likely to have low – immunosuppressed - immune systems.

- 75. As an example, low vitamin D levels are associated with a poor outcome following infection.^{141 142 143 144} Adjunctive treatment with vitamin D likely improves outcome.^{145 146 147} Yet Māori and Pasifika have some of the highest level of vitamin D deficiency in New Zealand.^{148 149}
- 76. This bill, if enacted into legislation would disproportionately and adversely impact Māori and Pasifika. Based on the scientific evidence, groups with weaker immune systems are more likely to experience waning and breakthrough infections. These groups are likely to receive disproportionate and unfairly scrutiny under the Act, and their vaccine status may be regarded sceptically and questioned.

RELEVANT CONSIDERATIONS: OBLIGATIONS TO PROMOTE HEALTH EQUITY

- 77. The Health Act recognises that medicines are important to prevent the occurrence of an infectious quarantinable disease.¹⁵⁰ However no steps have been taken to ensure low-income high-risk groups have access to preventable, prophylactic medicines and adjunctive nutritional treatments¹⁵¹ that reduce the potential for hospitalisations or death.
- 78. We recognise that potentially punitive legislation is already in place that ignores the potential for natural immunity, ignores the potential for individual vulnerability to the mRNA vaccine and ignores the potential for vaccines to wane.¹⁵²

income and neoliberalism. New Zealand Sociology 35:1;123-152

¹⁵¹ Inclusive of nutrients, as adjunctive nutraceuticals

¹³⁶ Patel et al 2020. Poverty, inequality and COVID-19: the forgotten vulnerable. Public Health.183: 110–111

¹³⁷ Graham et al 2018. Hiding in plain sight: experiences of food insecurity and rationing in New Zealand. Food, Culture & Society. 21:3;384-401

¹³⁸ Ministry of Health. 2019. Household Food Insecurity Among Children in New Zealand. Wellington: Ministry of Health.

¹³⁹ Reynolds et al 2020. Food and vulnerability in Aotearoa/New Zealand: A review and theoretical reframing of food insecurity,

¹⁴⁰ Neuwelt-Kearns et al 2021 The realities and aspirations of people experiencing food insecurity in Tāmaki Makaurau. Kōtuitui: New Zealand Journal of Social Sciences Online. DOI: 10.1080/1177083X.2021.1951779

 ¹⁴¹ Shah et al. Low vitamin D levels and prognosis in a COVID-19 pediatric population: a systematic review. QJM (2021)
 ¹⁴² Merzon 2020 Low plasma 25(OH) vitamin D level is associated with increased risk of COVID-19 infection: an Israeli population-based study. FEBS Journal 287:17

¹⁴³ Dror et al 2021. Pre-infection 25-hydroxyvitamin D3 levels and association with severity of COVID-19 illness. medRxiv

¹⁴⁴ Vasheghani et al 2021. The relationship between serum 25-hydroxyvitamin D levels and the severity of COVID-19 disease and its mortality. Scientific Reports 11:17594. | https://doi.org/10.1038/s41598-021-97017-9

¹⁴⁵ Lakkireddy et al 2021. Impact of daily high dose oral vitamin D therapy on the inflammatory markers in patients with COVID 19 disease. Scientific Reports. 11:10641

¹⁴⁶ Peng et al 2021. Immunological Aspects of SARS-CoV-2 Infection and the Putative Beneficial Role of Vitamin-D. Int. J. Mol. Sci. 2021, 22, 5251. https://doi.org/10.3390/ijms22105251

¹⁴⁷ Yisak et al 2021. Effects of Vitamin D on COVID-19 Infection and Prognosis: A Systematic Review. Risk Management and Healthcare Policy 14:31-38

¹⁴⁸ Cairncross et al 2017. Predictors of vitamin D status in New Zealand preschool children. Maternal & Child Nutrition (2017), 13, e12340

¹⁴⁹ Delshad et al 2019. Wintertime Vitamin D status and its related risk factors among children living in Auckland, New Zealand. NZMJ 132:1504

¹⁵⁰ Health Act 74C. Priorities for Medicines (6) medicine means any substance used or capable of being used to prevent, treat, or palliate a disease, or the symptoms or effects of a disease.

¹⁵² COVID-19 Public Health Response (Vaccinations) Order 2021. 7A notes a suitably qualified health practitioner can deem it inappropriate for the person to be vaccinated, and the person has been registered. These requirements may be difficult to fulfil for certain groups.

- 79. The current government approach appears severely deficient, with an overweighted focus on population control and isolation, and an underweighted focus on protecting vulnerable populations from hospitalisation and death.
- 80. At home access to multi-target anti-viral and immunoprotective treatments can be provided to high-risk groups to prevent hospitalisation and death.¹⁵³ ¹⁵⁴ ¹⁵⁵
- 81. In addition to hospital use, prophylactic at home access to vitamin D, vitamin C and safe antiviral medication may be consistent with the principle of mātauranga Māori. Treatment protocols can be targeted to personal need, and they acknowledge the problem of dietary deficiency prevalent in many Maori.
- 82. Both dietary nutrients and safe repurposed antiviral medications have a long history of use with side effects that are rare. The problems of adverse interactions between generic repurposed medications and existing medications can be more easily targeted and recognised by consulting practitioners.^{156 157}
- 83. There is adequate literature supporting the implementation of multi-target therapies that have potential to reduce inequities in immune-status that promote adverse outcomes, including hospitalisation and death. Both repurposed antiviral treatments and nutritional supplements have a long history of safe use.¹⁵⁸ ¹⁵⁹ ¹⁶⁰
- 84. The public health response has focussed on vaccination and non-pharmaceutical measures including masking, quarantine and social distancing. These are without doubt integral to the COVID-19 response. However, the public health response has not taken greater steps in the public interest since December 2019 to improve health outcomes. Substantial ignorance continues to remain regarding the risk profile of the population as there has been a reluctance of Cabinet and Ministry of Health officials to:
 - a. Explain the lower risk to those under 60 who do not have associated health conditions
 - b. Explain the very low risk to young $people^{161}$ and children.¹⁶²
 - c. Provide adequate treatments that will improve immune health and reduce risk to at risk elderly and multimorbid populations, particularly in low-income groups
 - d. provided rapid antigen screening measures to reduce public fear and increase knowledge.
 - e. Recognise the seasonal influence of viral pandemics and the relation to vitamin D levels.

 ¹⁵³ McCullough et al. Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. Am J Med. (2021) 134(1): 16–22.

 ¹⁵⁴ Derwand et al. COVID-19 outpatients: early risk-stratified treatment with zinc plus low-dose hydroxychloroquine and azithromycin: a retrospective case series study. International Journal of Antimicrobial Agents (2020) 56, 106214.
 ¹⁵⁵ Anuk et al 2020. The Relation Between Trace Element Status (Zinc, Copper, Magnesium) and Clinical Outcomes in COVID-19 Infection During Pregnancy. Biological Trace Element Research 199;3608–3617

¹⁵⁶ Kory et al 2021. Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19. Am J Ther. 2021 May-Jun; 28(3): e299–e318

¹⁵⁷ McCullough et al. Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). Reviews in Cardiovascular Medicine (2020) 21:4: 517-530 DOI:

^{10.31083/}j.rcm.2020.04.264

¹⁵⁸ McCullough et al. Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). Reviews in Cardiovascular Medicine (2020) 21:4: 517-530 DOI: 10.31083/j.rcm.2020.04.264

¹⁵⁹ Coelho-Ravagnani 2021. Dietary Recommendations During the COVID-19 Pandemic: an Extract. Komp Nutr Diet 2021;1:3–7 DOI: 10.1159/000513449

¹⁶⁰ Costagliola et al. Could nutritional supplements act as therapeutic adjuvants in COVID-19? Italian Journal of Pediatrics. 47:32 https://doi.org/10.1186/s13052-021-00990-0

¹⁶¹ Havers et al. Hospitalization of Adolescents Aged 12–17 Years with Laboratory-Confirmed COVID-19 — COVID-NET, 14 States, March 1, 2020–April 24, 2021MMRW. 70:23;851- 857

¹⁶² Bhopal et al. Children and young people remain at low risk of COVID-19 mortality. Lancet (2021) /10.1016/S2352-4642(21)00066-3

E. RESPONSE TO THE CURRENT BILL

85. The foundations for this Bill and its predecessor are fundamentally unlawful. This legislation should not therefore be passed. In particular we submit that:

- a. Clause 4. The extension of emergency legislation to be removed from the Bill
- b. Clause 5. No extended definition of the infringement fee
- c. **Clause 7.** Sections (11) (a) and (c) are far to broad and unspecified (which risks arbitrariness) as to conform with maxims of accountability and transparency. The degree to which Sars-Cov-2 is pervasive across the population is completely unknown. To create legislation which assumes this is known, is unfounded and unjust. Existing protections have been sufficient, and the virus will be becoming increasingly endemic in the population. Coronaviruses are pervasive and detections of Sars-Cov-2 wild and variant viruses have been detected across a broad range of biological life, from wild animals to waste-streams. The section encourages potentially selective and unaccountable arbitrariness that do not reflect scientific evidence and risk. (4) is anticompetitive and with full awareness that a broad range of anti-viral, anti-thrombotic and immune-protective treatments are required, would potentially be contrary to the protection of public health.
- d. **Clause 9.** Narrowing the scope of exemptions Section 12 (1) is ungrounded. Firstly, the risk from thrombotic events and other risks to vulnerable populations continues to be uncertain; secondly (and related to the first point) there no clear evidence concerning the degree to which vaccines prevent transmission and infection.
- e. **Clause 10 (b).** The delegation of discretion to any third party is unjustified and not in accordance with principles of public law.
- f. **Clause 12.** Extension of powers to third parties (relating to road closure, restriction of access to public places and stopping vehicles) should not be granted. Good governance and protection of the public interest requires transparency and third parties unnecessarily obfuscate a straight line of responsibility in what can be politically, socially, economically and culturally difficult circumstances.
- g. Clause 13&14. Increased infringement and other fines will disproportionately affect lowincome populations. This perpetuates existing inequalities in the population. Instead, generous and free provision to these groups – who have demonstrated the most respect for existing health protective measures – with RETs – and assurance of adequate cover and job security if these groups stay home from work due to symptoms – can substitute harmful and what will increasingly appear to be racist pecuniary measures.
- h. **Clause 23.** Penalties cannot become more pecuniary. Increased financial costs in terms of fines and penalties will result in a disproportionate burden on Maori and Pasifika who are more likely to be at risk from infection, breakthrough infection and vaccine waning due to compromised immune systems.
- i. **Clause 25.** Good legislation and regulations require a clear line of sight for the people governed in order to promote trust. This Section is unnecessary. Incorporation of Section 33B carries with it a risk of arbitrary lower order regulations and guidelines and consequential unfounded activities and regulatory measures that are likely to compromise goodwill and public trust. The tenet of this bill - which does not reflect the scientific literature on risk (including vaccine

efficacy, natural immunity and the process by which a virus becomes endemic across populations), - creates concern that consequent regulation will erode human rights, and particularly the rights of vulnerable groups, including children.

OBIGATION TO IMPROVE, PROMOTE & PROTECT HEALTH

- 86. PSGR respectfully requests that related officials, the Health Select Committee and the drafters of this bill, take steps to address the worrying direction of government that appears unable to recognise and respond with strategic and respectful flexibility to the individual vulnerabilities of the New Zealand public.
- 87. We hope that this submission will increase the potential for protective public health measures to be taken that recognise that vaccination can never be the 'silver bullet' treatment that can best assure the health and safety of the New Zealand population.
- 88. This submission emphasises:
 - a. The elderly, and low-income groups Māori and Pasifika have particular vulnerability;
 - b. Children and young adults have low vulnerability and scientifically greater public health benefits are likely to be achieved by permitting these groups to achieve natural immunity;
 - c. Risk profiles are highly variable and that the state should not be taking coercive action to ensure blanket inoculation from nRNA COVID-19 vaccines.
- 89. This Bill produces absurdities that are likely to contribute to public health harms:
 - a. The potential lawful detention of healthy asymptomatic populations inclusive of household members who have prior natural immunity and are less likely to carry high viral loads
 - b. The evidence that lockdowns and pecuniary steps will disproportionately harm disadvantaged households with precarious access to resources.¹⁶³
 - c. The evidence that vaccination may compromise the potential for a healthy individual to acquire natural immunity rather than shorter term immunity from vaccination
 - d. The potential for young adults and children who are not at risk of adverse COVID-19 to experience adverse health effects, including mental illness.^{164 165 166}
- 90. There is increasing evidence that the public health policy approach has been disinclined to publicly communicate uncertainties, including the potential for vaccines to wane; for side effects to occur, for mRNA vaccines to be vulnerable to breakthrough infections.
- 91. These persistent issues, represented in the scientific literature demonstrate that any future government incentives to introduce mandatory vaccination or associated passports null and void as such measures

¹⁶³ Czymara et al. Cause for concerns: gender inequality in experiencing the COVID-19 lockdown in Germany. European

Societies, DOI: 10.1080/14616696.2020.1808692

¹⁶⁴ Patel et al 2020. Poverty, inequality and COVID-19: the forgotten vulnerable. Public Health.183: 110–111.

¹⁶⁵ Fegert et al. Challenges and burden of the Coronavirus 2019 (COVID-19) pandemic for child and adolescent mental health: a narrative review to highlight clinical and research needs in the acute phase and the long return to normality. Child Adolesc Psychiatry Ment Health (2020) 14:20

¹⁶⁶ Luijten et al 2021. The impact of lockdown during the COVID-19 pandemic on mental and social health of children and adolescents. Quality of Life Research volume 30, pages2795–2804 (2021)

impose human health risks, unduly compromise human rights and do not achieve desired end-points of the obligation of public officials to improve, promote and protect human health.

- 92. With current persistent limitations of mRNA vaccines, we request that measures will be taken to ensure equitable access to adequate anti-viral and immunoprotective and home-based medical and nutritional therapies, and ensure a broad spectrum of medical and nutritional treatments are available for hospitalisation produces profound and sustained inequities for low-income groups, and in particular Māori and Pasifika.
- 93. Recent scientific evidence demonstrating that the delta variant infects the unvaccinated and the vaccinated at similar rates¹⁶⁷ ¹⁶⁸ and is likely to present similar risks of infection should have already been factored into government policy. ¹⁶⁹ ¹⁷⁰ On this basis vaccination mandates announced 10th October 2021 should be immediately revoked, as they cannot be scientifically justified and will create great hardship to the public by removing essential workers from the workforce and provide no benefit.
- 94. Recommending vaccination to children and young people on the basis of *reducing transmission*, can not be justified and should be immediately halted. ^{171 172} In regards to vaccinating healthy children for their personal benefit, there is insufficient evidence of benefit to justify the known and as yet unknown risks of vaccination,¹⁷³ particularly as natural immunity confers long-term protective benefits.^{174 175 176}

95. Associate professor at the University of California, Vinay Prasad has recently written of how democracy ends, and how policy, legislation and culture shifts towards totalitarianism. He suggests that '*The key lesson of the coronavirus pandemic is not that the fall of democracy is inevitable, but rather that our policy preferences, and polarization, have set the stage for a series of events where it is possible democracy falls.*¹⁷⁷ He outlined core trends which currently exist, which may pave the way towards totalitarianism:

- The use of strong force, including military force, to combat a respiratory virus;
- Public acceptance of restrictions on movement and commerce in the face of respiratory pandemic, with many calls for greater restrictions to be applied

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breakthrough infections. medRxiv preprint. 10.1101/2021.08.24.21262415
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¹⁶⁷ Riemersma et al. Vaccinated and unvaccinated individuals have similar viral loads in communities with a high prevalence of the SARS-CoV-2 delta variant. medRxiv preprint (2021)

 ¹⁶⁸ Acharya et al. No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and
 Symptomatic Groups Infected with SARS-CoV-2 Delta Variant. medRxiv Preprint (2021) 10.1101/2021.09.28.21264262
 ¹⁶⁹ Gazit et al. Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus

¹⁷⁰ Public Health England. SARS-CoV-2 variants of concern and variants under investigation in England Technical briefing 18. 9 July 2021.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001358/Variant s_of_Concern_VOC_Technical_Briefing_18.pdf

¹⁷¹ Servillita et al. Predominance of antibody-resistant SARS-CoV-2 variants in vaccine breakthrough cases from the San Francisco Bay Area, California. (2021) 10.1101/2021.08.19.21262139

¹⁷² E.g. Dougherty et al. SARS-CoV-2 B.1.617.2 (Delta) Variant COVID-19 Outbreak Associated with a Gymnastics Facility — Oklahoma, April–May (2021) MMWR 70:28:1004-1007

¹⁷³ Marshall et al. Symptomatic Acute Myocarditis in Seven Adolescents Following Pfizer-BioNTech COVID- 19 Vaccination. Pediatrics. 2021; doi: 10.1542/peds.2021-052478

¹⁷⁴ Bhopal et al. Children and young people remain at low risk of COVID-19 mortality. Lancet (2021) /10.1016/S2352-4642(21)00066-3

¹⁷⁵ Yilmaz et al 2021. Does Covid- 19 in children have a milder course than Influenza? Int J Clin Pract. 2021;75:e14466. ¹⁷⁶ Doulberis et al. Does COVID-19 Vaccination Warrant the Classical Principle *"ofelein i mi vlaptin"*? Medicina 2021,

^{57, 253.} https://doi.org/10.3390/medicina57030253

¹⁷⁷ Prasad, V. Blog How Democracy Ends. October 3, 2021.

- media presentation of vignettes or anecdotes about overwhelmed hospitals or the untimely death of a young person, without acknowledging the denominator or comparing the risk to other risks we accept.
- The rise of social media corporations means that public dialog increasingly occurs in spaces that can be regulated.
- Increasing acceptance of the regulation and censorship of information
- Cultural emphasis that valorises safety as a virtue above all
- The implications of current measures for future democracy. Caution is warranted as the party that favours stronger application of force during the COVID19 pandemic is vulnerable to misuse of force for a respiratory virus from the counterparty in the future.

CONCLUSION: LEGAL IMPLICATIONS

Measured against the legal parameters and principles referred to at the commencement of this Submission it is clear that the policy framework that has generated both this Bill and its related preceding legislation is grossly faulted when measured against the requirements of constitutional and administrative law in New Zealand; and/or measured against existing legislation; and/or when measured against NZ Bill of Rights; and/or when measured against the United Nations New Zealand undertakings in various documents relating to medical experimentation and human rights.

It is arguably unconscionable for this House to pass this Bill when it should be plain to all Members of this House - and to members of the public who may apply reason to these matters that the present policy direction is <u>not</u> in the public interest; it is not aligned with the economic interest of New Zealand; it is grossly deficient, if not absurd, in terms of delivering reliable endpoints in New Zealand public health; it is not a reliable model for government future and effective management of pandemics; and it does not protect the individual person and their fundamental rights.

It should be noted that the primary duty of government is to protect *the person*; and at law that consideration trumps any claimed and generalised 'public health' policy agenda.¹⁷⁸

Measured for compliance with the 'principle of proportionality', it is plain that policy-makers have given disproportionate weight to a single option (inoculations) that is so great that it cannot be rationally supported – and is therefore unreasonable.

Such is the context and conclusion of our evaluation of this proposed Bill.

End of PSGR's October 11, Submission.

¹⁷⁸ UNESCO Article 3, Subsection 2. The interests and welfare of the individual should have priority over the sole interest of science or society.

[4] EVIDENCE ON SAFETY IN 2025

From commencement of testing by the manufacturer, proven processes were discarded. The BNT162b2 safety and toxicological trials were truncated, participants were not representative of the population and so groups with multimorbidities were poorly represented, and the trials of pregnant women and children were unfit for use as these populations were not sufficiently represented.

People with complex underlying medical conditions were most at risk of hospitalisation and death following SARS-Cov-2 infection¹⁷⁹, and vaccine-conferred immunity in these may have been limited or negligible. There is increasing evidence that officials conflated deaths to infer that the cause of the death was due to infection from SARS-CoV-2 when the infection may have been co-present, or a PCR was simply highlighting viral particles post-infection. A 2025 paper¹⁸⁰ recently highlighted that attribution of death to COVID-19 may have been artificially inflated:

We reviewed 530 in-hospital deaths, classified as COVID-19 deaths (52.4% males; mean age 81.7 \pm 11.1 years). We categorized 290 (54.7%) deaths as attributable or related to COVID-19 and in 240 (45.3%) deaths unrelated to COVID-19 In multivariable analysis The two groups differed significantly in age (83.6 \pm 9.8 vs. 79.9 \pm 11.8, p = 0.016), immunosuppression history (11% vs. 18.8%, p = 0.027), history of liver disease (1.4% vs. 8.4%, p = 0.047) and the presence of COVID-19 symptoms (p < 0.001).

Complex health conditions including diabetes can suffer from high levels of inflammation, and this puts them at risk of other diseases including cancer. Repeated injections may have promoted inflammation in the body. This may be one of the drivers of cancer rates post-Covid.

Post-Covid a study was published showing that injected pregnant women experienced a higher rate of adverse events including significantly higher rate of abortions, oligohydramnios (24.4%), abnormal placentas (size and location), 103 (42.7%) abnormal fetal growth, 122 (53.7%) problems breastfeeding, blood pressure problems, and more cases of malaise, headaches, chest pain, breathing problems, and sleep problems than unvaccinated women, and adverse event rates increased with boosters.¹⁸¹

There was no funding channels for this form of research in New Zealand.

Manufacturers were well aware of the potential for contamination, yet there was no transparent testing of batches for contamination.

The financial conflicts of interest in many of the groups promoting vaccines as safe and effective were often undeclared. The U.S. Centres for Disease Control (CDC) was often cited as an authority, however the CDC has ownership interests in at least 56 vaccine patents and buys and distributes \$4.6 billion in vaccines annually.¹⁸² In 2003 the CDC filed a patent on a SARS coronavirus isolated from humans (Patent No. 7776251). The National Institutes of Health holds the patent to the spike protein which is licenced to

¹⁷⁹ Kompaniyets L, Pennington AF, Goodman AB, Rosenblum HG, Belay B, Ko JY, et al. Underlying Medical Conditions and Severe Illness Among 540,667 Adults Hospitalized With COVID-19, March 2020–March 2021. Prev Chronic Dis 2021;18:210123. DOI: https://doi.org/10.5888/ pcd18.210123

¹⁸⁰ Basoulis, D., Logioti, K., Papaodyssea, I. et al. Deaths "due to" COVID-19 and deaths "with" COVID-19 during the Omicron variant surge, among hospitalized patients in seven tertiary-care hospitals, Athens, Greece. Sci Rep 15, 13728 (2025). https://doi.org/10.1038/s41598-025-98834-y

¹⁸¹ Amer AA, Amer SA, Badokhon A, Hammad SM, Wasfy MA, Khan M, Ateyah Al-Harbi T, Alobaid SQ, Eskander G, Abdel-Azeem A, Alshowair A, Ramadan MS. Exploring COVID-19 vaccine adverse events among pregnant women: a cross-sectional study, 2022. Ther Adv Vaccines Immunother. 2024 Oct 5;12:25151355241285594. doi: 10.1177/25151355241285594. PMID: 39376246; PMCID: PMC11457191.

¹⁸² Kennedy RFK Jr. The Real Anthony Fauci. 2021. Skyhorse Publishing.

Moderna. Agency scientists then collect annual royalties from vaccine sales. Similarly, the Bill and Melinda Gates Foundation (BMGF) invests in vaccines and medical drugs and was a primary funder of the Pirbright Institute which owns Coronavirus Patents (Europe) EP3172319A1 and (United States) US10130701B2.

Five months prior to the start of the pandemic, Anthony Fauci, who had investments in mRNA technology, presented at the Milken Institute 'Making Influenza History: The quest for a universal vaccine, and discussed how to get the global public to accept mRNA universal vaccines. Prior to public knowledge about the pandemic, Anthony Fauci and NIAID signed a vaccine agreement for mRNA. The BMGF sponsored Event 201 was a hypothetical event on a coronavirus epidemic, 3 months before the COVID-19 pandemic commenced, and about the same time the Wuhan Military games were underway in Wuhan China.

Genotoxicity and carcinogenicity tests were excluded due to the loophole of being mischaracterised as a vaccine.

The Covid trials did not evaluate whether the Pfizer BNT162b2 vaccine prevented hospitalisation and death in older and high risk people. The trials did not evaluate whether the BNT162b2 prevented the spread of infection.¹⁸³ These were the endpoints that most people believed would have led to the release and mandating of a previously untested biologic gene therapy.

Instead of standard 3-year trials, the FDA permitted Pfizer to terminate the BNT162B2 study after 6 months, and then offered the vaccine to the placebo recipients, muddying the trial.¹⁸⁴

There was no transparent and published testing in New Zealand to assess the extent of spike protein produced by age, gender and health or multimorbid status or by immunocompromised groups, despite the fact that this was a biologic drug that would send the biological instructions to the cells to reproduce a spike protein. There was no testing to assess the length of time that a body would reproduce spike protein. There was no testing to assess the inflammatory potential of the spike protein, ¹⁸⁵ either in healthy population groups, or in heavily boostered populations.

As of 2024, there was evidence that if people were hospitalized for COVID and vaccinated with the COVID vaccine, they were nearly twice as likely to die than those who were hospitalized for COVID and not vaccinated.¹⁸⁶

There was no 'proven process' because this biologic injection had never been injected into human populations before.

The Pfizer New Medicine Application stated that¹⁸⁷:

COVID-19 Vaccine (BioNTech code number BNT162b2, Pfizer code number PF-07302048).

https://doi.org/10.1161/circ.144.suppl_1.10712

¹⁸³ Bhattacharya J, Kulldorff (2025) The Covid Vaccine Trials: Failures in Design and Interpretation. *History of Public Health*. Doi: 10.70542/rcj-japh-art-lx5ggg

¹⁸⁴ ClinicalTrials.gov Study to describe the Safety, Tolerability Immunogenicity and Efficacy of RNA Vaccine Candidates in Healthy Individuals. April 30, 2020. https://clinicaltrials.gov/ct2/show/NCT04368728

¹⁸⁵ E.g. Gundry 2021 Abstract 10712: Observational Findings of PULS Cardiac Test Findings for Inflammatory Markers in Patients Receiving mRNA Vaccines. Circulation Volume 144, Number Suppl_1

¹⁸⁶ Adhikari B, Bednash JS, Horowitz JC, Rubinstein MP and Vlasova AN (2024) Brief research report: impact of vaccination on antibody responses and mortality from severe COVID-19. Front. Immunol. 15:1325243. doi: 10.3389/fimmu.2024.1325243

¹⁸⁷ Information can be found in the Official Information Act request h202106950: All docs discoverable by Crown Nga Kaitiaki Tuku Iho includes risk benefit response.

The RNA-based vaccine encodes a viral antigen which is expressed by the vaccine recipient and can elicit protective immune responses. Unlike live attenuated vaccines, RNA vaccines do not carry risks associated with infection. RNA-based vaccines are manufactured by a cell-free in vitro transcription process, which allows easy and rapid production and the prospect of producing high numbers of vaccine doses within a shorter time period than could be traditionally achieved with conventional vaccine approaches.

The public were misled by the claim of '95% efficacy' as it was not communicated that efficacy merely meant a short-term reduction in infection. Covid continued to circulate and it was very clearly recognised that the 'vaccine' waned very quickly after injection.

Vaccine efficacy for the primary endpoint against confirmed COVID-19 occurring **at least 7 days after the second dose** was 95.0% with 8 COVID-19 cases in the vaccine group compared to 162 COVID-19 cases in the placebo group. ¹⁸⁸

Peak viral loads in vaccinated and unvaccinated individuals were known by October 2021 to be insufficiently different. The greater predictor for viral load was more likely related to age and health status.¹⁸⁹

The problem of 'leaky vaccines' industry jargon for partially effective products which are intended to prevent infection, replication and spread of disease is well understood. Pfizer and BioNTech would have been well aware of this problem.

New Zealand scientists communicated that *BNT162b2* would lead to population level immunity and they downplayed the role of herd immunity. New Zealand scientists never assessed the scientific literature to transparently evaluate the different evidence on immunity from natural infection versus immunity from BNT162b2 injection.

The modelling groups were not public health epidemiologists and epidemiologists drawing attention to the important role of herd immunity faced barriers to media access. The modelling groups downplayed and ignored the important role of herd immunity in bringing any pandemic to a close. From 2020-2023 studies persistently demonstrated the broader benefits that arise from natural immunity. This public health knowledge that was known but set aside by officials continues to be reaffirmed in the literature.

The government failed to conduct rolling surveys and to transparently report on immunity in the population from prior infection (symptomatic and asymptomatic). Prevalence studies reliant solely on serological assays likely underestimate the extent of community exposure to the virus and the role of the innate immune response such as the extent of Type I interferon SARS-CoV-2-specific T cells could have been studied from an early stage, but this work was not undertaken in New Zealand.¹⁹⁰ ¹⁹¹ It's now apparent that

¹⁸⁸Vaccines and Related Biological Products Advisory Committee Meeting December 10, 2020

FDA Briefing Document Pfizer-BioNTech COVID-19 Vaccine https://www.fda.gov/media/144245/download ¹⁸⁹ Singanayagam et al (2021) October. Community transmission and viral load kinetics of the SARS-CoV-2 delta

⁽B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study https://doi.org/10.1016/S1473-3099(21)00648-4

¹⁹⁰ Grifoni et al (2020) Targets of T Cell Responses to SARS-CoV-2 Coronavirus in Humans with COVID-19 Disease and Unexposed Individuals. Cell 181, 1489–1501, https://doi.org/10.1016/j.cell.2020.05.015

¹⁹¹ Le Bert, N., Samandari, T. Silent battles: immune responses in asymptomatic SARS-CoV-2 infection. Cell Mol Immunol 21, 159–170 (2024). https://doi.org/10.1038/s41423-024-01127-z

even the common cold may have provided a degree of infection.¹⁹² If people understood the rate of natural immunity in the population, they would not have accepted the pre-purchased Pfizer injections. This failure snowballed into a failure to appreciate the extent of chronic exposure in vaccinated and boostered groups from the spike protein.

Greater transparency regarding prior infection to confirm herd immunity as well as whether at-risk people had already been infected would have reduced fear, as once immunity was obtained there was little chance that person was at risk of hospitalisation and death from SARS-Cov-2.¹⁹³

Vaccine mandates for people with superior infection-acquired immunity persisted. Unethically, highly exposed groups that historically are recognised to quickly gain natural immunity – medical, ambulance and frontline workers and teachers, were not permitted to be tested for natural immunity and were forced to consent to ongoing booster injection, in order to keep their jobs.

Mandates have been found to have negatively affected the wellbeing of these groups.¹⁹⁴

The New Zealand government failed to be transparent and honest when a death was driven by an illness other than COVID-19.¹⁹⁵ Basic risk, for example, vulnerability of the aged and infirm to influenza, has long been understood. While the data for influenza disappeared between 2020-2023, it appears that influenza on average, may present a greater risk than COVID-19.¹⁹⁶ The real problem with virus-associated death in the elderly is due to the aging of their immune systems (immunosenescence).¹⁹⁷ Yet the vulnerability of the aged and infirm to COVID-19 as an approximate risk was not articulated by the Ministry of Health.

Funding was available for 'Long Covid' yet official documents nor the New Zealand media were frank about the overlap between adverse events from the vaccine and 'Long Covid'. It is increasingly apparent that many vaccine-related side-effect syndromes could be mistaken by the medical fraternity for infection-related disease syndromes.¹⁹⁸

The government had no Delta plan. There was no evidence based document which looked at infection case or fatality rate by age, gender and health or multimorbidity status. The government stated:²⁰⁰

¹⁹² Majdoubi A, Michalski C, O'Connell SE, et al. A majority of uninfected adults show preexisting antibody reactivity against SARS-CoV-2. JCI Insight. 2021 Apr 22;6(8):e146316. doi: 10.1172/jci.insight.146316. PMID: 33720905; PMCID: PMC8119195.

¹⁹³ Chin et al 2022. Protection against Omicron from Vaccination and Previous Infection in a Prison System. N Engl J Med 2022;387:1770-82. DOI: 10.1056/NEJMoa2207082

¹⁹⁴ Chaufan C. Hemsing N and Moncrieffe R. COVID-19 vaccination decisions and impacts of vaccine mandates: a cross sectional survey of healthcare workers in Ontario, Canada. *Journal of Public Health and Emergency* (2024), Online First, https://jphe.amegroups.org/article/view/10313

¹⁹⁵ For example. Kompaniyets L, Pennington AF, Goodman AB, Rosenblum HG, Belay B, Ko JY, et al. Underlying Medical Conditions and Severe Illness Among 540,667 Adults Hospitalized With COVID-19, March 2020–March 2021. Prev Chronic Dis 2021;18:210123. DOI: https://doi.org/10.5888/ pcd18.210123

¹⁹⁶ Xie Y, Choi T, Al-Aly Z. Risk of Death in Patients Hospitalized for COVID-19 vs Seasonal Influenza in Fall-Winter 2022-2023. JAMA. 2023;329(19):1697–1699. doi:10.1001/jama.2023.5348

¹⁹⁷ Liu, Z., Liang, Q., Ren, Y. et al. Immunosenescence: molecular mechanisms and diseases. Sig Transduct Target Ther 8, 200 (2023). https://doi.org/10.1038/s41392-023-01451-2

¹⁹⁸ Scholkmann and May (2023) COVID-19, post-acute COVID-19 syndrome (PACS, "long COVID") and post-COVID-19 vaccination syndrome (PCVS, "post-COVIDvac-syndrome"): Similarities and differences

https://pmc.ncbi.nlm.nih.gov/articles/PMC10154064/pdf/main.pdf

 ¹⁹⁹ Bhattacharjee B, Lu P, Monteiro S, Tabachnikova et al (2025). Immunological and Antigenic Signatures Associated with Chronic Illnesses after COVID-19 Vaccination post-vaccination syndrome (PVS). medRxiv Preprint, February 18, 2025. Doi: 10.1101/2025.02.18.25322379 https://www.medrxiv.org/content/10.1101/2025.02.18.25322379v1
 ²⁰⁰ Ministry of Health (20 September 2021) Official Information Act request H202110943

The Ministry has conducted scenario planning to encompass different aspects of our response to be ready for a Delta variant outbreak. This has included continuous improvements in surveillance testing, contact tracing, vaccination, border control and MIQ, and being able to surge our capacity in these areas as required.

Overall, our approach is a more defensive, cautious and conservative one because of the higher level of risk which the Delta variant presents to New Zealand. The New Zealand experience of managing COVID-19 has taught us that capacity is not a steady state measurement. Our approach to response management is to adjust as an outbreak evolves, and capacity is utilised where it will most effectively minimise the risk of onward transmission.

However, any concept of 'risk' was not articulated with respect to risk of hospitalisation and death by age and risk status. As the above language demonstrates, the government was exclusively concerned about transmission.

The scientific studies which had been used to bolster and justify the injection campaign failed to control for population growth rates over time.²⁰¹

As New Zealand basic science research to assess health and disease risks from environmental factors have been eliminated through policy changes, there could be no research to identify unknown or offtarget harms that might have been driven by the BNT162b2 biologic.

The risk from ongoing exposure, particularly from the spike protein, extends from heart risks, to harm to the microbiome,²⁰² to risk of neurological disorders.^{203 204 205}

It was only later that the public became aware that the trial samples were produced using a different manufacturing technology (Process 1) from the BNT162b2 that was injected into the New Zealand population (Process 2).

Consistency of product could never be assured, from the size of lipid nanoparticles to the amount of mRNA in each batch. Levels of contamination in some batches were orders of magnitude above a level that could be defined as accidental and dismissed as safe. ^{206 207} We discussed the problem of contamination in our paper on the Ministry of Business, Innovation and Employments current science system reform, in order to

 ²⁰¹ John Gibson (2024) Cumulative excess deaths in New Zealand in the COVID-19 era: biases from ignoring changes in population growth rates, New Zealand Economic Papers, 58:1, 95-106, DOI: 10.1080/00779954.2024.2314770
 ²⁰² Rubio Casillas (2024) Could the Spike Protein Derived from mRNA Vaccines Negatively Impact Beneficial Bacteria in the Gut? https://www.mdpi.com/2673-8112/4/9/97

²⁰³ Jee Hoon Roh, Inha Jung, Yunsun Suh, Min-Ho Kim, A potential association between COVID-19 vaccination and development of Alzheimer's disease, QJM: An International Journal of Medicine, 2024;, hcae103, doi: 10.1093/qjmed/hcae103

 ²⁰⁴ Kim, H.J., Kim, MH., Choi, M.G. et al. Psychiatric adverse events following COVID-19 vaccination: a population-based cohort study in Seoul, South Korea. Mol Psychiatry (2024). https://doi.org/10.1038/s41380-024-02627-0
 ²⁰⁵ Rong, Zhouyi et al. Persistence of spike protein at the skull-meninges-brain axis may contribute to the neurological sequelae of COVID-19

Cell Host & Microbe, Volume 32, Issue 12, 2112 - 2130.e10

²⁰⁶ Quantitative Multiplex Real-Time PCR analysis of Moderna (Spikevax) and Pfizer (BNT162b2) vaccines Sona Pekova, MD, PhD. TILIA LABORATORIES s.r.o. Laboratory for molecular diagnostics Pchery, Czech Republic https://www.10letters.org/CzechResearch.pdf

²⁰⁷ Igya rto BZ and Qin Z (2024) The mRNA-LNP vaccines – the good, the bad and the ugly?. Front. Immunol. 15:1336906. doi: 10.3389/fimmu.2024.1336906 Contamination

draw attention to how regulators failed during COVID-19, bowing to political pressure to expedite the vaccine. The section²⁰⁸ is reproduced here:

Contamination Ignored: Case Study: The NZ EPA's deficient approach to approving Pfizer's genetic tech.

During Covid, 2021-2024, the New Zealand government was exclusively dependent upon data from Pfizer and data from other regulatory agencies to identify risk-based pathways from the mRNA gene therapy, an experimental and completely new technology. Collegial regulatory agencies also depended on Pfizer's data to assure to the public that the mRNA gene therapy was safe and effective. It was difficult for people to report adverse events to Medsafe, and to access financial assistance from the Accident Compensation Corporation. The mainstream media actively criticised people who were trying to highlight the potential risk of the experimental technology and did not cover reports of adverse events.

What follows is abhorrent, but true. During Covid, scientists were not funded to research risks^{209 210} from RNA drugs and mRNA vaccines. New Zealand's health research policy doesn't permit it.²¹¹

Approval for the mRNA injection was granted after a single Zealand Environmental Protection Authority (NZEPA) scientist swiftly drafted the NZEPA's Staff Assessment report²¹² on the mRNA genetic component of the BNT162B2 injection. The technology was specifically designed to enter human cells and replicate. The lipid nanoparticles were the transfection agents, and enabled the technology to evade normal body defence systems. The paper was then forwarded to the Committee, two people who did not have expertise in biologic drugs and mRNA risk.²¹³ The report was dated February 2, 2021, the same date that the provisional consent approval was granted.²¹⁴

The basis of NZEPA's claim mirrored Pfizer's position, which emphasised strict adherence to the language in the Hazardous Substances and New Organisms Act (HSNO Act). Because the *produced organism* doesn't replicate, it will not be categorised as a genetically modified organism. The NZEPA scientist used the Oxford English dictionary to attempt to untangle the precise meaning of the word 'organism' and 'genetic element' in the Hazardous Substances and New Organisms Act.

The resemblance between instructions designed to replicate, and a produced organism that replicates, was not addressed by NZEPA staff with full consideration of the greater purpose of the HSNO Act which is to protect the health and safety of people. The NZEPA scientist did not outline that the intended function of the BNT162B2 mRNA technology resulted in a biological function that resembled the replicating activity of

²¹¹ Bruning, J. 2022. University of Auckland Master of Arts (sociology). Thesis. Innovation and Ignorance: How Innovation Funding Cultures Disincentivise Endocrine Disruption Research.

https://researchspace.auckland.ac.nz/handle/2292/57929

²⁰⁸ PSGR (2025) When powerful agencies hijack democratic systems. Part II: The case of science system reform. Chapter 9.(c). Bruning, J.R.. Physicians & Scientists for Global Responsibility New Zealand. April 2025. ISBN 978-1-0670678-1-6

²⁰⁹ Igyarto BZ and Qin Z (2024) The mRNA-LNP vaccines – the good, the bad and the ugly? Front. Immunol. 15:1336906. doi: 10.3389/fimmu.2024.1336906 Contamination

²¹⁰ Bhattacharya J and Kulldorff M. (2025). The Covid Vaccine Trials: Failures in Design and Interpretation.1:1 *Journal of the Academy of Public Health*. https://doi.org/10.70542/rcj-japh-art-lx5ggg

 ²¹² NZ EPA (February 3, 2021) Staff Assessment Report. Advice to the Decision-making Committee on APP204176:
 Pfizer SARS-CoV-2 vaccine BNT162b2 (COMIRNATYTM) Dr Kerry Laing and Dr Julie Everett-Hincks.

https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP204176/APP204176-Staff-Assessment-Report.pdf ²¹³ NZEPA. (February 11, 2021). Decision. Determination of whether or not any organism is a new organism under section 26 of the Hazardous Substances and New Organisms Act 1996 (the Act). Consideration date 4 February 2021

https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP204176/APP204176-Decision.pdf ²¹⁴ See discussion: Bruning J. (July 25, 2023). How did our NZEPA fail to recognise that BNT162b2 [mRNA] was a GMO? https://jrbruning.substack.com/p/how-did-our-nzepa-fail-to-recognise

an organism. The mRNA technology operated as a blueprint, to transport and encode a gene into the cell, where it could use the cell's machinery to produce unlimited quantities of the modified spike protein. This same EPA scientist did not address the ethical overlap

This NZEPA paper did not consider any potential of the mRNA to drive systemic risks which could arise from the release of unrestricted quantities of a spike protein that was scientifically known for its inflammatory potential, that was coded for by synthetic modified RNA, from human cells into the body for an unknown timespan.

The paper failed to address toxic co-formulants that were integral to the success of the mRNA technology. Encapsulating lipid nanoparticles would evade the body's normal detection system, enabling potentially contaminated, synthetic, modified RNA to enter human cells and then produce unregulated quantities of the SARS-CoV-2 spike (S) protein. Also not considered was (a) the issue of persistence from the unregulated production of spike protein; (b) the potential for the mRNA product to be transferred into the genome and become heritable; or (c) that contaminating foreign plasmid DNA could also be incorporated into the genome. Contamination has long been a challenge in biologic drug development.^{215 216 217}

Pfizer and Moderna were expected to declare all open reading frames (ORFs), any sequence of bases that could potentially encode a protein, including unexpected ORFs. This information should have identified all functional components of each bacterial plasmid's DNA.

The New Zealand public were injected with the gene edited BNT162b2 solution made via Process 2²¹⁸. However, the outcome of the Process 2 trials and tests on only 250 participants was never published. It is now evident that batches made under Process 2 were contaminated with plasmid DNA fragments.²¹⁹ Contamination is a recognised risk²²⁰ and manufacturers have skirted this problem by utilising a differently manufactured product for premarket assessment. Furthermore, laboratory studies did not consider the risk from lipid-nanoparticle encapsulation of mRNA and DNA, which facilitates entry to the cell.

A further very concerning contaminant in the vaccine mixture includes the intact promoter and enhancer elements from Simian virus 40 (SV40) which comprises 72 base pairs. The SV40 promoter sequence, only 50 base pairs long, is very effective at nuclear targeting.²²¹ Pfizer did not declare that SV40 promoter (eukaryotic enhancer) elements were used in batch processing. Note, this is a promotor region or element, not the entire viral sequence. This promoter element assists DNA to cross the nuclear membrane in order

²¹⁹ Kammerer U, Schulz V, Steger K.(2024) BioNTech RNA-Based COVID-19 Injections Contain Large Amounts of Residual DNA Including An SV40 Promoter/Enhancer Sequence. *Public Health Policy Journal*

large-amounts-of-residual-dna-including-an-sv40-promoter-enhancer-sequence/

 ²¹⁵ McCarty, N.S., Graham, A.E., Studená, L. et al. Multiplexed CRISPR technologies for gene editing and transcriptional regulation. *Nat Commun* 11, 1281 (2020). https://doi.org/10.1038/s41467-020-15053-x
 ²¹⁶ Barone, P.W., Wiebe, M.E., Leung, J.C. et al. Viral contamination in biologic manufacture and implications for emerging therapies. *Nat Biotechnol* 38, 563–572 (2020). https://doi.org/10.1038/s41587-020-0507-2

²¹⁷ Glass, Z, Lee M, Li Y, Xu Q. (2018). Engineering the Delivery System for CRISPR-Based Genome Editing. *Trends in Biotechnology*, 36:2;173-185. Doi: 10.1016/j.tibtech.2017.11.006

²¹⁸ Guetzkow J, Levi R (2023). Rapid response to: Covid-19: Researchers face wait for patient level data from Pfizer and Moderna vaccine trials. *BMJ* 2022;378:o1731, doi: 10.1136/bmj.o1731

https://publichealthpolicyjournal.com/biontech-rna-based-covid-19-injections-contain-interval and the second sec

 ²²⁰ Janghorban, M., Kazemi, S., Tormon, R., Ngaju, P., & Pandey, R. (2023). Methods and Analysis of Biological Contaminants in the Biomanufacturing Industry. *Chemosensors*, 11(5), 298. doi: 10.3390/chemosensors11050298
 ²²¹ Young JL, Benoit JN, Dean DA. Effect of a DNA nuclear targeting sequence on gene transfer and expression of plasmids in the intact vasculature. *Gene Ther*. 2003 Aug;10(17):1465-70. doi: 10.1038/sj.gt.3302021. PMID: 12900761; PMCID: PMC4150867.

to increase the likelihood of integration. Regulators claim that the sequence is inactive, without a functional role.²²²

Unregulated cell growth presents a cancer risk. The polyomavirus simian virus 40 (SV40) is a potent DNA tumour-inducing virus, or, in other words,

'a known oncogenic DNA virus which induces primary brain and bone cancers, malignant mesothelioma, and lymphomas in laboratory animals'.

In 2004 scientists suggested that SV40 could be considered a 'declared human pathogen'.²²³ Professor Angus Dalgliesh, an oncologist from the University of London, has described how SV40 is used as a tumour growth promoter on rodents, enabling laboratory researchers to test the efficacy of chemotherapy.

The oncogenic potential of SV40 was discovered by National Institutes of Health scientist Dr Bernice Eddy in 1960, and studies continue to elucidate pathways of potential oncogenesis. Eddy had earlier discovered that the previously claimed inactivated vaccine manufactured by Cutter Laboratories, instead contained a live poliovirus that was found to paralyse test monkeys. The contaminated Sabin polio vaccine stocks were not recalled, and the harmful product remained on the market even after the oncogenic potential had been identified. ^{224 225}

Insertional mutagenesis is an unavoidable consequence of the transposition of genetic material and scientists have always understood that this action carries the risk of oncogenesis (cancer).²²⁶ In April 2023, genomics expert Dr Kevin McKernan and colleagues detected SV40 in Covid-19 vials,²²⁷ and presented these findings to the Covid-19 Vaccine Contamination to the FDA VRBPAC Advisory Committee. The preprint of this paper has had more than 19,000 downloads.

Eight laboratories globally, have detected high levels of DNA contamination in Covid-19 vaccines.²²⁸ Most recently, in March 2025, Czech clinical biochemist and molecular geneticist Dr Soňa Peková detected residual DNA in both Pfizer and Moderna vaccines at levels up to 100 times higher than regulatory limits.²²⁹ Peková noted that there were amounts of DNA in the tested solution that was quantitatively comparable to the amounts of the active mRNA.

²²² See E.g. U.K. Government.

https://assets.publishing.service.gov.uk/media/669e40cdce1fd0da7b592a11/FW_FOI_24_212_final_redaction.pdf ²²³ Vilchez RA, Butel JS (2004) Emergent Human Pathogen Simian Virus 40 and Its Role in Cancer. *Clin Microbiol Rev.* 2004 Jul;17(3):495–508. doi: 10.1128/CMR.17.3.495-508.2004

²²⁴ Institute of Medicine (US) Immunization Safety Review Committee. Immunization Safety Review: SV40 Contamination of Polio Vaccine and Cancer. Stratton K, Almario DA, McCormick MC, editors. Washington (DC): National Academies Press (US); 2002. PMID: 25057632.

²²⁵ Šenigl F, Soikkeli AI, Prost S, Schatz DG, Slavková M, Hejnar J, Alinikula J. The SV40 virus enhancer functions as a somatic hypermutation-targeting element with potential tumorigenic activity. *Tumour Virus Res.* 2024 Dec;18:200293. doi: 10.1016/j.tvr.2024.200293.

²²⁶ Sadelain M. 2004. Insertional oncogenesis in gene therapy: how much of a risk? Nature Gene Therapy 11,569-573.

²²⁷ McKernan K, Helbert Y, Kane LT, McLaughlin S. (2023). Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose. *OSF Preprints*. https://doi.org/10.31219/osf.io/b9t7m

²²⁸ Demasi M (March 18, 2025). New evidence of DNA contamination in mRNA vaccines – too big to ignore. https://blog.maryannedemasi.com/p/new-evidence-of-dna-contamination

²²⁹ Peková S (March 8, 2025). Quantitative Multiplex Real-Time PCR analysis of Moderna (Spikevax) and Pfizer (BNT162b2) vaccines. TILIA LABORATORIES s.r.o. Laboratory for molecular diagnostics Pchery, Czech Republic https://www.10letters.org/CzechResearch.pdf

SV40 is not the only potential oncogenic pathway.²³⁰

This raises the question: if the NZEPA were adhering to their constitutional purpose of protecting health and safety, why wouldn't they, or any other government department, consider a broader concept of risk from a biological drug that includes the potential for laboratory-based or process-based contamination from a new technology?

The New Zealand government has failed²³¹ to disclose the extraordinary range of adverse events that were communicated by Pfizer to the U.S. Federal Drug Agency in February 2021 and that should have been communicated to all countries that had signed contracts with Pfizer.²³² Trials show that the COVID-19 gene therapy has had more deaths in the treatment group than the placebo group.²³³ The Covid-19 commissioners have been presented with an extensive array of evidence that a percentage of the New Zealand public has been harmed, or in some cases killed, as a result of this gene therapy, and that the government has gone to great lengths to suppress that information.

The New Zealand public were misled in many ways, including that the BNT162B2 biologic drug was a vaccine. Pfizer's trial endpoints did not satisfy the requirements of a traditional vaccine, for preventing disease, and preventing the transmission of the disease. Instead, Pfizer's primary endpoints relied upon lowering symptoms in a two week period.

In 2025 New Zealand scientists were funded \$70 million to scale up research on RNA drugs and mRNA vaccines.^{234 235} Independent funding is still unavailable for New Zealand scientists to research risks from RNA and mRNA biologic drugs, including the BNT162B2 gene therapy.

[5] PSGR RECOMMENDATIONS FOR AN ALLEGED PUBLIC HEALTH EMERGENCY

PSGR understand that the Royal Commissioners have not requested that people send in recommendations. However, if we may, we briefly list below some issues that the Commissioners may consider:

- 1. Reinstate: public health ethics and make informed consent non-violable.
- 2. Highlight: The illegality of silencing academics and doctors.
- 3. Reinstate: Epidemiological understanding of movement, progression, and the decline of an infectious disease and remove pathogenicity (transmissibility) as a main reason for declaration of an emergency event. Instead, an emergency event can be identified from the evidence for hospitalisation and death following infection. This data must be updated on an ongoing basis, using trusted, methods-based

https://fyi.org.nz/request/22327/response/84763/attach/4/H2023022884%20Response%20letter.pdf ²³² Pfizer Worldwide Safety Report.(April 2021) 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports, by February 2021. https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf

²³⁴ University of Auckland (2023). The story behind New Zealand's mRNA platform

https://www.auckland.ac.nz/en/news/2023/10/03/story-behind-mrna-platform.html

²³⁰ Valdes Angues R, Perea Bustos Y. SARS-CoV-2 Vaccination and the Multi-Hit Hypothesis of Oncogenesis. *Cureus*. 2023 Dec 17;15(12):e50703. doi: 10.7759/cureus.50703. PMID: 38234925; PMCID: PMC10792266.

²³¹ James C. (May 8, 2023) Official Information Act request to Medsafe. No.22327.

²³³ Thomas, S.J. et al. (2021). Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine. NEJM. 385, 1761-1773 (Pfizer) https://doi.org/10.1056/NEJMoa2110345 Adverse Events Page 6.

²³⁵ Malaghan Institute (2024) https://www.malaghan.org.nz/research-and-expertise/research-platforms/rna-technology/

conventions to ensure that the data is consistent over time with full recognition that the potential for any infectious disease outbreak to cause death will peak and then decline.

- 4. Reinstate herd immunity as a key factor in a population reaching immunity from an infectious disease, and require that in any future event that confirmation of natural immunity is central to pandemic response, and that this information is continually and consistently updated.
- 5. Recognise that all key goals of the Ministry of Health involve medical drugs or speed of treatment, and that prevention and protection of health through nutrition is a not a high level goal.
- 6. Reinstate/reeducate: public law (constitutional and administrative law) education for officials:
 - i. Good process transparency, accountability.
 - ii. Relevant considerations what is a relevant consideration for policy development?
 - iii. Duty to consult must not be to parties biased to a single intervention.
 - iv. Basis of evidence the scientific evidence must be systematically updated
 - v. Bias/impartiality agencies who sign contracts with corporations should not control funding for science, modelling, data production etc.
- 7. Consult with: Philip Joseph, Andrew Butler, Andrew Geddis, Geoffrey Palmer on reinstating public law in government and academia and tightening democratic and constitutional protections for the people of New Zealand.
- 8. Revive research in constitutional and administrative law
- 9. Expand: Precautionary principle into general law as per the European Union.
- 10. Promote scientific freedom: Pandemic declarations may only be trusted if scientists are independent from political agencies and Ministries. Freedom of scientific enquiry basic science research must be funded over time so that in an emergency event scientists can research with no concern for scientific freedom and of political or professional licensure.
 - i. Nutrition and education for public health.
 - ii. Basis of government recommendations must be able to be criticised.
 - iii. Risk from biolabs/gain-of-function.
 - iv. Role of protection of public health complex disease aetiology.
- 11. Understand: freedom for basic scientific research increases our capacity to talk about uncertainty and risk and identify uncertainty and risk. It supports interconnectivity between scientists and researchers and will support resilience across scientific issues as they arise. This research has been supressed and only narrowly granted to pre-approved projects.²³⁶
- 12. Recommend pathways and funding for: social science, philosophy and public health research so that discussion on ethics, bioethics, freedom, informed consent and so on, may become a part of common lexicon.

²³⁶ PSGR (2025) When powerful agencies hijack democratic systems. Part II: The case of science system reform. Bruning, J.R.. Physicians & Scientists for Global Responsibility New Zealand. April 2025. ISBN 978-1-0670678-1-6

- 13. Emphasise: The importance of the traditional role of clinical experience in dealing with complex symptom presentation of individual patients. That this is honoured and respected. That education, discussion and collegial professional relations with doctors and public health professionals is nurtured in funded, open conferences and seminars to discuss complex overlapping chronic and communicable presentations and the freedom of treatment options, including nutrition, for experts across all related fields.
- 14. Engender a language for reversing disease and biohacking: The practical and ethical questionable response of introducing new drugs to displace the foundational role of the immune system, supporting complex medical/nutritional responses to any infectious disease event. The over-reliance on corporation supplied randomised control trials (RCTs) for drug approvals, and the failure to understand that many treatments are low risk, and therefore do not need an RCT but can be assessed through a weight of evidence in the scientific literature.
 - Second line response: Repurposed drugs with a known safety profile
 - New, relatively untested drugs/vaccines as a third line position when other treatments have been demonstrated scientifically to be insufficient. That their use be voluntary following fully informed consent and never mandated.
- 15. Recognise: That the setting aside of the Bill of Rights was a likely consequence of our long-standing suppression of public good science and enabled officials to narrow their minds to the goal of global vaccine coverage. This also underpinned the conservatism of the courts who were reluctant to weigh the expertise of global scientists outside of the Ministry of Health experts and who were not able to judge the risk from the BNT162b2 intervention for the average healthy person.
- 16. Query: New Zealand ratified the ICCPR²³⁷ on 28 December 1978. Did the COVID-19 response comply with the ICCPR obligations and derogations if the direct threat of hospitalisation and death to the people of New Zealand is interpreted as the *threat to the nations' life'*, instead of case counts, infectivity and selectively chosen information? Was COVID-19 a demonstrable health threat to the everyday New Zealander from 2020 onwards, or was the justification for lockdowns and mandates based on the infectivity of a coronavirus that primarily targeted the infirm and elderly, much like seasonal influenza?

We thank the Commissioners for this opportunity.

²³⁷ International Covenant on Civil and Political Rights. https://www.ohchr.org/en/instrumentsmechanisms/instruments/international-covenant-civil-and-political-rights

APPENDIX

Appendix (i) ORDERS MADE FOLLOWING ROYAL ASSENT OF THE COVID-19 RESPONSE AMENDMENT NO.2 BILL

October 25 2021. Ll2021/94 Order. Amendments include expansion of affected workers to include healthcare workers, prison staff, and 'Workers over the age of 12 years who carry out work at or for an affected education service (including as a volunteer or an unpaid worker)' including home- based education and care service. Workers must have first injection by close of 15 November 2021; and second injection by January 1, 2022.

<u>19 November 2021: Royal Assent granted for COVID-19 Public Health Response Amendment Bill (No 2)</u> updated with the No.2 amendment. (Bill 68-2). (2021 No 48).

<u>20 November 2021: COVID-19 Public Health Response Act 2020 updated</u> to reflect the amendment (2021 No 48). At this stage this primary Act does not mention vaccines.

23 November: COVID-19 Response (Vaccinations) Legislation Bill released, Minister in Charge Chris Hipkins. No public consultation.

'The amendments in this omnibus bill make vaccination a more prominent part of New Zealand's COVID-19 response framework.'

25 November: COVID-19 Response (Vaccinations) Legislation Act 2021. (2021/51) Received Royal assent on November 25.

<u>26 November: COVID-19 Public Health Response Act 2020 updated</u> to incorporate new obligations as per the COVID-19 Response (Vaccinations) Legislation Act 2021. This primary Act now mentions vaccines/vaccination 157 times.

From thereon in, Orders would be released extending the powers to require vaccination:

<u>November 29 2021 Order (LI2021/94)</u> Redefined vaccine to Pfizer/BioNTech COVID-19 vaccine. Schedule 3 which contained the list of approved vaccines/vaccinations was significantly expanded.

<u>December 1 2021 Order (LI2021/94)</u> Inserted Clause 9A Director-General may authorise affected persons not fully vaccinated to carry out certain work; Clause 11A Duties of relevant PCBUs of affected persons belonging to groups specified in Part 7, item 8.2 of Part 8, or Part 9 of Schedule 2: vaccination records. Clause 12A Power of Minister to grant exemptions

<u>December 3 2021 Order (LI2021/94)</u> New definitions: close-proximity business or service; CVC (COVID-19 vaccination certificate); food and drink business or service; gym; permitted event; tertiary education premises; tertiary education provider.

December 4 2021 Order (LI2021/94) Categorized infringement offences (low/medium/high).

<u>December 16, 2021 Order (LI2021/94)</u> Amended Clause 10(1AAA) to include staff members of corrections prisons. Changed name Part 10 to Groups in relation to settings where CVC may be required for persons to enter place or receive service.

January 1, 2022 Order (LI2021/94) Exemptions revoked for people working in essential supply chains and the essential operations of corrections prisons.

January 23, 2022 Order (L12021/94) Expanded purpose and definitions to include booster doses for over 18year-olds. Schedule 1 Part 8 inserted to require booster doses. For workers in part 1-7 of Schedule 2 before 15 February 2022; Part 8 or 9 before 1 March 2022; and then booster doses are required every 183 days (6 months).

<u>February 14, 2022 Order (LI2021/94)</u> Amended Clause 15, removing Schedule 2 Part 7 affected persons groups in the health and disability sector. Inserted 15A to require affected persons received a booster dose before 25 February.

March 25 2022 Order (LI2021/94) Amended to expand of Schedule 3 list of vaccines.

April 4, 2022 Order (LI2021/94) Amended to revoke fire services and education personnel.

Appendix (ii) Updated approach to the Sequencing Framework for COVID-19 vaccines.

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Authorised for lodgement:

Hon Chris Hipkins Minister for COVID-19 Response

Hon Andrew Little Minister of Health

In Confidence

Office of the Minister for COVID-19 Response

Office of the Minister of Health

Cabinet

Updated approach to the Sequencing Framework for COVID-19 vaccines

Proposal

1 This paper seeks agreement to the updated Sequencing Framework, following on from Cabinet's discussions on 1 March 2021. The Sequencing Framework will, uid the initial focus for the COVID-19 Immunisation Programme.

Relation to government priorities

2 New Zealand's ability to recover from the COVID-19 paids initiatequires obtaining safe and effective vaccines to implement our preferred memorisation programme at the earliest possible time. The Sequencing Framework will guide the use of COVID-19 vaccines to support the COVID-19 Elimination Strategy, in order to ensure that everyone continues to be protected as the COVID-19 Immunisation Programme is rolled out.

Executive Summary

- The COVID-19 Vaccine and Imauna 3 on Programme aims to vaccinate as many COVID-19 Elimination Strategy. Vaccinations are people as possible to support the er and managed isolation and quarantine (MIQ) well underway for bò. workforces. Vaccinat. ns we also begin for their household contacts from 8 March, Auckland We will next be shifting our focus to frontline (nonstarting in Sout orkers who could potentially be exposed to COVID-19 while border) health Tie providing
- 4 Bas due to the paper to Cubinet and Ministerial discussions following the advice in the paper to Cubinet and March 2021, we propose a number of updates to the next groups for focus in the Sequencing Framework. These changes will streamline the approach so that we can move to nationwide rollout for older people and other at-risk groups somer.

On this basis, Tier 2 (b) would be focused on:

- 5.1 Frontline healthcare workers who may expose people, who are more at risk of severe health outcomes, to COVID-19
- 5.2 Certain groups living in settings or locations that are "high risk", including:

Please note, some numbers within this document are indicative and should be considered point in time estimates. They are refined on an ongoing basis following Cabinet decisions.

- 5.2.1 older people and people with relevant health conditions in the Counties Manukau District Health Board (DHB) district;
- 5.2.2 people in long-term residential care where a high proportion of residents are at-risk of severe health outcomes if they contract COVID-19 (such as aged residential care); and
- 5.2.3 older people living in a whānau environment in hard to reach places, and their household. This is because they face a similar risk to those in aged residential care. This group will be supported by Māori and Pacific providers, and we recommend an initial allocation of 40,000 courses to Māori and Pacific providers to distribute.
- 6 Subsequently, we propose that Tier 3 would be focused on the following at-r groups nationwide:
 - 6.1 Tier 3 (a) people aged 75 years and above
 - 6.2 Tier 3 (b) people aged 65 years to 74 years
 - 6.3 Tier 3 (c) disabled people and people with relevant univerlying health conditions.
- 7 The COVID- 19 Immunisation Programme will parties with sudori and Pacific providers to deliver vaccinations in their communities. They will be provided with vaccine supplies from Tier 2(b) onwards. This is to ensure they are resourced to meet their needs of the communities. In addition, we will support them to meet vaccination demand beyond their enrolled populations, such as through targeted investments into related capital infrastructure, workshe conability and general readiness for delivering vaccinations.
- 8 It is expected that the Sequencing Framework will be used as a broad guide for delivery focus, and we propose that providers will have flexibility to adjust their approach to maximum uptake and minimise wastage. This includes directing them to adopt a whānau control approach during Tier 2 (b) and Tier 3.

Background

On 1 March 2021 Callinet received an update on the Sequencing Framework and endorsed the groups included in Tier 2(a)...

The CHID-19 Immunisation Sequencing Framework guides our focus where ccine supplies are limited.

Cabinet has previously endorsed the proposed approach for Tier 1 of the Sequencing Framework, which is tightly focused on border and MIQ workers who are covered under the COVID-19 Public Health Response (Required Testing) Order 2020 (the Testing Order), and their household contacts [CAB-21-MIN-001 refers]. People in Tier 1 are at the greatest risk of infection and transmission because of their proximity to cases coming through the border, so vaccination can be an additional safeguard for them and their wider community.

- 11 Vaccinations are well underway for these workers and will begin for their household contacts from 8 March 2021, starting in South Auckland.
- 12 Note we are currently working through changes to the Testing Order, which broadens the definition on who is included within Tier 1(a).
- 13 On 1 March 2021, we reported back to Cabinet with an update on the Sequencing Framework. Cabinet agreed that that Tier 2 (a) should be frontline (non-border) health workers potentially exposed to COVID-19 while providing care [CAB-21-MIN-0040 refers]. This group includes an estimated 57,000 staff¹ who are at the frontline and directly interacting with patients such as GPs, nurses, pharmacists and people working in our testing centres.

...and we now seek agreement to the subsequent groups included in the Server Framework

- 14 Cabinet invited Ministers to report back with further advice on the Sequencini Framework. This paper responds to this invitation and seeks continue in the will be included in the Sequencing Framework.
- 15 Fundamentally, the COVID-19 Immunisation Programments keypart of our COVID-19 Elimination Strategy, as it will help to manage the impact of COVID-19 on our communities and response systems by:
 - 15.1 protecting people from the potential harm of contracting COVID-19;
 - 15.2 potentially reducing the risk of transmission in the community; and
 - 15.3 supporting the health system creatiness and resilience if there is an outbreak, both by vaccinating certain beatin workers early and by vaccinating the groups most at risk of severe lines of they contract COVID-19.

Analysis

We have streamlined and Security Framework to help us move to a national rollout as quickly as possible

16 Our tear of twomillion has been fundamental to our response to COVID-19, and we want to be able to provide the opportunity for all New Zealanders to be vaccinated as scon as possible. We have purchased enough COVID-19 vaccines for everyone to have access over time. However, while supplies are initially limited there is a need to target specific population groups and communities who are at increased risk.



This includes older people and people with other health conditions that put them atrisk of serious illness from COVID-19.

Given this, we have streamlined the Sequencing Framework to be more tightly focused on those most at-risk. The changes since the version considered by Cabinet on 1 March 2021 are:

¹Note these numbers are approximate and are constantly being refined as we work with delivery partners.

- 18.1 streamlining the workforces that will receive early access to the COVID-19 vaccine, focusing more tightly on frontline health workforces
- 18.2 refining who is considered to live in "high risk" settings or locations, including providing early access for certain at-risk groups in the Counties Manukau DHB district
- 18.3 simplifying Tier 3 of the Sequencing Framework to focus on people progressively based on their risk of severe health outcomes.
- 19 On this basis, the expansion of the COVID-19 Immunisation Programme would be phased to focus on the following at-risk groups after Tier 2 (a):

Tier 2 (b)

- 19.1 Frontline healthcare workers who may expose more vulnerable excovID-19
- 19.2 People living in settings or locations that are "high sisk" if te
 - 19.2.1 the likelihood of exposure and/or transmissio
 - 19.2.2 the likelihood that residents will experience evere health outcomes if they contract COVID-19.

Tier 3

- 19.3 Tier 3(a) people aged 75 years and as
- 19.4 Tier 3 (b) people aged 6 years to 74 year
- 19.5 Tier 3 (c) disabled people and people with relevant underlying health conditions.
- 20 A more detailed outline of who we propose to include in each Tier is provided at the **Appendix One Appendix Two** illustrates the indicative COVID-19 Vaccine Rollout Plan, noting that it will need to be updated following Cabinet decisions.
- 21 Below we direct your advice on the updated Sequencing Framework changes in more detail, below who else would be included in Tier 2 (b) alongside people in longtern restrential care where a high proportion of residents are at risk of severe health outcomes if they contract COVID-19.

i en that people in South Auckland are at a high risk of exposure, we recommend cluding at-risk people living there in Tier 2(b)

Tier 2(b) is focused on people who are living in settings where there is a high risk of transmission and there are residents at risk of severe health outcomes if they contract COVID-19. Likewise, we know that there are communities whose residents face an increased risk of being exposed to COVID-19.

- 23 Counties Manukau has recently experienced a number of COVID-19 cases and has a high proportion of Māori and Pacific people (16 percent and 22 percent respectively), as well as a significant Asian population. These cases reflect that a significant proportion of the MIQ workforce is living in South Auckland. This puts their at-risk population at an increased risk of harm from COVID-19, and has flow-on implications to their social, cultural and economic wellbeing.
- Given this, we recommend that Tier 2(b) includes anyone in the Counties Manukau DHB diverse who is aged 65 years or has a relevant underlying health condition. Counties Manukau DHB will work with its Māori and Pacific providers to help identify and reach the relevant population groups.
- 25 Planning is underway to enable wider community wide rollout in the Counties nanuke. THB district (i.e., to people not included in Tier 3 or Tier 2(b)) as soon as possible, and potentially alongside the Tier 3 rollout. We will report back to Cabinet on this as planning progresses.

We will partner with Māori and Pacific providers to help reach these tork hand maximise uptake of COVID-19 vaccination...

- All providers are responsible for the immunisation of the Maon and Aucific people in their community. However, we know that Māori and Pacific providers will be cacific for maximising uptake and achieving equitable coverage for Māori and Pacific people. The hold upta relationships with the whānau they serve and are acutely aware of the disparities that whānau in their community experience across all outcomes and services, including health, education and employment. These providers can:
 - 26.1 leverage strategic relationships to quick draw on capability in the community
 - 26.2 rapidly increase the capacity of realth and social services to provide localised whānaucentred support
 - 26.3 mobilise services and where whānau gather (i.e. temporary clinics such as marae, churches, workplaces) and lived i.e. home, residential care, shelters), and bring whānau into services (i.e. providing, transport o clinics), and
 - 26.4 dative strengths-based communications to individuals and whānau, with critical feedback loors to inform changes to the national response.
- 27 The COVID-19 Immunisation Programme will partner with Māori and Pacific providers so that they can deliver tailored and targeted approaches to their communities as part of the wider community inflout.



We expect that Māori and Pacific providers may extend their reach to beyond their enrolled population. This will mean that there will need to be a process for them to access additional vaccines (when available) if their allocation runs out and they have identified further demand. Officials are working to take account of this through distribution planning and operational guidelines. 29 To support these partnerships, the Ministry will work through what direct investment is needed to help build provider infrastructure and workforce capability. This presents an opportunity for Māori and Pacific provider development that is likely to have a lasting impact beyond the COVID-19 vaccination programme.

...including through providing supplies of COVID-19 vaccines for Tier 2(b) and beyond

- 30 One mechanism for partnering with Māori and Pacific providers is through providing dedicated OVID-19 vaccine supplies to reach at-risk people living in the community.
- 31 We propose that for Tier 2(b) there is an allocation of an initial 40,000 courses to these partners, to support them to reaching older people living in whānau environments in hard to reach paces ather than aged residential care. Note that depending on delivery schedules, and the needed of the Māori and Pacific providers, we would expect this allocation to be smoothed over a pumber of veeks.
- 32 This process of providing dedicated COVID-19 vaccine supplies to Maori and Proific providers will continue into Tier 3, as we need to support providers to build the momentum early to maximise uptake in their communities.

Tier 3 would see us move to nationwide rollout for older people disabled people and people with relevant health conditions

- 33 We know that the risk of a person experiencing severe illness, hospitalisations and death if they contract COVD-19 increases significantly with are. It has been estimated that those aged 65 years and older have a five-fold increase in risk of severe health outcomes, and this increases with age.
- 34 Tier 2(b) already includes older people by ing in high-risk settings. Following this, we propose that Tier 3 first focuses on older people nationwide.
- 35 Subsequently, it would focul on other groups who also have an increased risk of severe health outcomes. There is evid use that certain conditions increase risk, such as coronary heart disease, hypertension, stroke, tabetes, chronic obstructive pulmonary disease/chronic respiratory conditional disease, cancer and pregnancy.
- 36 Discort phone generally have poorer health and wellbeing than non-disabled people and some fare even worst, particularly tangata whaikaha (Maori disabled people), Pacific disabled people and people with an intellectual / learning disability. There is limited specific evidence around the level of risk acced by disabled people more generally in respect of COVID-19, noting however that disabled people may be more likely to have one of the underlying health conditions mentioned above.
- p 3, N
 - Nonetheless, we consider that it is reasonable to expect that many disabled people may be at an increased risk, particularly if they are supported in their home by a number of support workers or carers. As such, we propose that disabled people are included in Tier 3(c) alongside people with relevant underlying health conditions.

- 38 As we move into the national rollout we will consider existing mechanisms like the High Use Health Card which may allow us to deliver the vaccine in a structured manner to pre-identified cohorts.
- 39 This will allow us to leverage existing mechanisms that approximate some relevant risk factors to ensure high integrity identification and clear communication with those individuals in the cohort.

To support the Elimination Strategy, we aim to vaccinate as many people as possible at pace and will provide flexibility to providers

- 40 To support the Elimination Strategy by helping us to manage the potential impact or COVID 19, we need to vaccinate as many people as possible, as soon as possible. Initially white supplies are limited we need to have a focus on at-risk populations and communities. This proves focusing on maximising uptake rather than maintaining vaccine stockpiles.
- 41 We consider that the Sequencing Framework should not be treat a constitute ligibility criteria for who can receive the COVID-19 vaccine. It is intended to guide the particular focus for the Immunisation Programme at a given point in time.

This would include discretion to immunise whānau members and others as appropriate

- 42 Given this, we propose that DHBs and all other proviners are directed to adopt a whānau-centred approach during Tier 2 (b) and Tier 3. This world mean that they can use discretion to immunise whānau members of older people, disabled people and people with relevant underlying health conditions when they accompany then to the expointment, considering factors such as whether:
 - 42.1 the whanau member/s are are softhe person presenting for the vaccination;
 - 42.2 they have sumcient dosps of vaccine available at the site to meet expected demand until new deliveres arrive;
 - 42.3 the whatau or famely member faces barriers to access or is in a population group that may have difficultus in accessing the health system (including Māori, Pacific peoples, disabled people, ranbot communities²³⁸, ethnic minorities and people in remote regions); and/or

eleare other risk factors in the household, such as overcrowding or a multi- generational ng arrangement.

also propose providing flexibility to providers about how to allocate the vaccine based on what they know of their community to maximise uptake and minimise wastage. For example, it may be appropriate to vaccinate as many people as possible at once in small rural communities. Likewise, if a provider has leftover supply, they

²³⁸ It is not expected that whānau members would be asked to share this information with the vaccinator to receive access to the COVID-19 vaccine, rather the provider can use their discretion based on what they know of the whānau and their access to healthcare in the past (given that people in the rainbow community are more likely to experience inequitable access to healthcare).

could use it to vaccinate other people identified as at-risk (even if they are not within the current focus group). This is because risk is a spectrum, and we do not want to:

- 43.1 wait for everyone in a category to be vaccinated before pushing into the next group identified, as this could cause delays and a loss of momentum
- 43.2 contribute to any wastage of the vaccine, which has a short shelf-life of five days once defrosted.

Financial Implications

44 The financial implications arising directly from the proposals in this paper will be met within the existing appropriation of Implementing the COVID-19 Vaccine Strategy Multi Category Appropriation until December 2021.

Legislative Implications

45 There are no legislative implications resulting from the proposals.

Population Implications

- 46 The COVID-19 Immunisation Strategy has been developed to enable best use of COVID-19 vaccines to support the immediate health response to COVID-19 in New Zealand and the Pacific. Delivering on the COVID-19 Immunisation Strate v may contribute to the full cultural, social and economic recovery from COVID-19.
- 47 This can benefit population groups that have experienced disproportionate cultural, social and economic harm. For example, some groups are nore likely to experience difficulty in returning to employment and subsequent economic hardship over the long-term, such as disabled people, Māori, Pacific peoples and young people who nave recently entered the labour market.
- 48 In addition, risk of negative nexts effects of COVID-19, including death, could disproportionately affect older people and people with relevant underlying conditions. Disabled people, Māori and Pacific peoples are more likely to experience these impacts, as they have higher rates of underlying health conditions and co-morbidities. Those who live in crowded housing, especially Māori and Pacific peoples for example, living in an intergenerational arrangement, or those who work in particular roles such as ford a security, are also likely to be more at risk of transmission.

Human R shts



previously advised, vaccines may be targeted earlier to certain people or populations when supplies are limited as per the Sequencing Framework. However, it is important to note that we have purchased enough vaccines for every person in New Zealand. All people are equally deserving of care, but certain risk characteristics and the initial limited supply will justify prioritisation of vaccine delivery.

50 Vaccines may be targeted earlier to certain persons or groups of persons when supplies are limited. This means individuals may receive a COVID-19 vaccine sooner who may also have a disability or health condition, be a certain age, sex, ethnicity, or family status. If this differential treatment occurs it will be based on particular risks faced by these people, as well as promoting equitable outcomes.

- 51 This raises possible issues around discrimination under section 19 of the New Zealand Bill of Rights Act 1993 and section 21 of the Human Rights Act 1993 by potentially prioritising access to specified groups. This response is proportionate and based on evidence and decision-making frameworks underpinned by the principle of equity, with any discrimination in favour of people at greater risk. As such, it is demonstrably justified in a free and democratic society in accordance with section 5 of the Bill of Rights Act.
- 52 Note that if specific at-risk groups are not included within the Sequencing Framework but are at an equivalent risk of harm to those who are, this may raise human rights concerns that the Government is not working to actively and equitably protect there from harm.

Consultation

- 53 The Ministry of Health advised The Treasury, Te Puni Kōkiri, Te Anawha, the Office of Ethnic Communities, Corrections, and the Ministries of Folgin Affairs and Trade, Pacific Peoples, Business Innovation and Employment, Indice and Primary Industries that this paper was being prepared.
- 54 Due to the tight drafting timeframes, formal consultation with other agencies on this paper was not possible.

Communications

- 55 Following your decisions on this paper on sials will update current content on the Unite against COVID-19 and Ministry of flealth websites promptly. Work is also underway to build an online to it to bely people to understand where they fit into the Sequencing Framework and when they are likely to receive their vaccine.
- 56 Previous public corr bunketions identified particular workforces as being in a particular Tier, some on whom will now instead receive access to the COVID-19 vaccine when we move to national rollout for everyone in New Zealand. Following Cabinet decisions, officials will proactively update the affected sectors on any changes to when they are likely to be able to be vaccinated.

Proactive Renas

to proactively release this Cabinet Paper (within 30 working days) with dactions as appropriate under the Official Information Act 1982.

55

Recommendations

6

The Minister for COVID-19 Response, the Minister of Health and the Associate Ministers of Health recommend that Cabinet:

- 1 Note that vaccinations are well underway for the Border and Managed Isolation and Quarantine workforces, and will begin for their household contacts from 8 March 2021, starting in South Auckland.
- 2 Note that Cabinet previously agreed that the next focus is Tier 2 (a), which includes frontline (non-border) health workers potentially exposed to COVID-19 while providing care [CAB-21-MIN-00400 refers]
- 3 Note that individuals can be at increased risk of severe health outcomes from control 19 due to their age and/or or an underlying health condition or disability
- 4 Note that this risk is increased for at-risk people living in high-risk settings locations, such as residential care settings or Counties Manukau
- 5 Agree that after rolling out to people included in Tier 2 (a), that the following groups are included in Tier 2 (b):
 - 5.1 Frontline healthcare workers who may expose people at risk of severe health outcomes to COVID-19 (as outlined in **Appendix one**)
 - 5.2 Certain groups living in settings or locations that are "high risk", including:
 - 5.2.1 people aged 65 years and at see and people with relevant health conditions (as specific in **Appendix One**) in the Counties Manukau DHB district.
 - 5.2.2 people in long-term residential care where a high proportion of residents a par-risk of severe health outcomes if they contract of 71D-9 (as specified in **Appendix One**); and
 - 5.2.3 an allocation of 40,000 courses to Māori and Pacific providers to distribute to older people living in whānau environment in hard to leach places, and their household
 - Agr Chat liers would be focused on the following groups:
 - r 3 (a) people aged 75 years and above
 - Tier 3 (b) people aged 65 years to 74 years
 - 6.3 Tier 3 (c) disabled people and people with relevant underlying health conditions (as specified in **Appendix One**)
- 7 **Note** the attached indicative COVID-19 Vaccine Rollout Plan, which will be updated following Cabinet decisions on sequencing

- 8 Agree to direct DHBs and other providers to adopt a whānau -centred approach during Tier 2 (b) and Tier 3
- 9 Note that the Ministry will partner with Māori and Pacific providers to deliver vaccinations in their communities, who will be provided with ongoing vaccine allocations from Tier 2 (b) onwards
- 10 Note that the Ministry will work with Māori and Pacific providers to suppor t them to meet vaccination demand beyond their enrolled populations, including through targeted investments to build provider infrastructure and workforce capability
- 11 Agree that providers, while using the Sequencing Framework to guide their delivery focus, will have flexibility to adjust their approach as required to maximise uptake and minimise wastage
- 12 Note following your decisions in this paper, officials will work with the Vaccine Ministers' offices on updated communications.

Authorised for lodgement

Hon Chris Hipkins

Minister for COVID -19 Response

Hon Andrew Littl

ster o

Health

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Appendix One: L	Jpdates to the Sequencing Framework Tier d	definitions (changes in red)	
SUB-TIER	POPULATION COHORT	DEFINITION	Π
TIER ONE: THE BO	DRDER AND MIQ		
Tier 1(a)	Border workforce, all workers recorded on the official Border Register as per the Required Testing Order. (~7,700 people)	 "Affected persons" at a New Zealand border (airport or marine port) as defined by the COVID-19 Public Health Response (Required Testing) Order 2020. Includes only the workforce that qualify for routine COVID testing as recorded on the official Border Register within the following categories: Aircrew members who spend more than 15 minutes in an enclosed space (plane or ship) and qualify based on the border order Airside government official Border Register within the following categories: Airside BDHB workers Airside DHB workers Airside cleaners Airside cleaners Cither aladicide cleaners Airside cleaners Cither ansport torfrom affected ship Workers who interacting with international passengers Biolis, stevedores working onfaround, and people who board affected ship Workers who interact with people required to be in isolation Health workers providing COVID-19 testing services to these sites. 	
	MIQ workforce (~4,900 people)	 "Affected persons" at a New Zealand border (airport or marine port) as defined by the COVID-19 Public Health Response (Required Testing) Order 2020. Includes only the workforce that qualify for routine COVID testing as recorded on the official Border Register within the following categories: This includes: All MIQ workers (including all New Zealand Defence Force (NZDF) eligible for rotation to MIQ) MIQ healthcare workers including medical, nursing and support staff who provide services to these facilities Workers who transport to/from MIQ. 	s S
Tier 1(b)	Household contacts of the eligible border and MIQ workforce (~40,000 people)	Any person who usually resides in a household or household-like setting with (a border or MIQ worker as set out above), regardless of whether they are related or unrelated people; this will include people who may reside part-time in the household including children and partners not permanently resident in the household.	5
TIER TWO: FRONT	TLINE WORKFORCES AND AT-RISK PEOPLE LIVING I	IN HIGH-RISK SETTINGS	
Tier 2 (a)	Frontline (non-border) healthcare workers potentially exposed to COVID-19 whilst providing care. (~57,000 people)	 The frontline healthcare workforce in service delivery settings where possible cases will seek healthcare and there is no ability to screen for COVID-19 before the interaction occurs. It includes only staff who are at the front line <u>interacting directly with patients</u> in: COVID-19 testing (aking samples and laboratory analysis) Administering COVID-19 testing (aking samples and laboratory analysis) Administering COVID-19 testing (aking samples and laboratory analysis) Moministering COVID-19 testing (aking samples and laboratory analysis) Administering COVID-19 testing (aking samples and laboratory analysis) Administering COVID-19 testing (aking samples and laboratory analysis) Administering COVID-19 vacinations Adm	0
		To Contact tracing personnel required to respond to prevent community transmission	

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 The frontline healthcare workforce working in healthcare service delivery settings interacting with patients/clients. Frontline healthcare workers interacting with patients: Inpatient, ambulatory and outpatient publicly funded hospital services including community staff and diagnostics All long-term residential care frontline workers, including aged residential care. Corrections (staff at custodial and community-based residences), disability, Oranga Tamariki (including Youth Justice), mental health and addictions, group-based transitional residences for homeless people, and hospice careworker Home care support workers including aged care and disability support Community and home-based services including with-based services, mental health All other primary care not included in Tier 2 (a) Community and home-based services including with-based services, mental health All other primary care not including outreach immunisation staff Community public health teams, including with-based services, mental health Community public health teams, including with-based services, mental health Community public health teams, including with-based services, mental health All NGO and community-based services including with-based services, mental health Community public health teams, including workers or the purpose of vaccination programmes NZDF staff who may be involved in overseas deployments for the purpose of vaccination programmes 	 Any person who usually resides in a long-term residential care setting, including (approximately ~57,000 people): Aged Residential Care (~35,000 people) Disability Residential Support Services (~7,700 people) Disability Residential Support Services (~7,700 people) Carage Tamariki, including Youth Justice (up to 100 people) Mental health and addictions (~9,800 people) Group-based transitional residences for homeless people (~4,000 people based on the number of transitional housing places, though actual number is likely be lower) Approximately 40,000 courses allocated to Mãori and Pacific providers to reach older people (and their households and carers) living within a whānau environmin hard to reach places (this is approximately equivalent to the number of Mãori and Pacific people over 70 years of age, and the allocation for aged residential care). Any person in the Counties Manukau DHB district who: is over the age of 65 years (~70,000 people), or is over the age of 65 years (~70,000 people), or is under 65 years oid but has a felevant underlying health condition that puts them at risk of severe disease from COVID-19 infection* (indicative estimateis ~67,000 people). 	SK OF SEVERE ILLNESS FROM COVID-19	People who are 75 years or older (~317,000 people) ⁴ People who are 65 years - 74 years (~432,000 people)	People with relevant underlying health conditions* and disabled people under 65 years of age (very approximate estimate due to potential double counting is 730,000 – 1.3 million people). *This includes coronary heart disease, hypertension, stroke, diabetes, chronic obstructive pulmonary disease/chronic respiratory conditions, kidney disease and carcer. While it is not a health condition, pregnant people will also be included in this Tier.	
Frontline healthcare workers who may expose more vulnerable people to COVID-19 (~183,000 people)	At-risk people living in settings with a high risk of transmission or exposure to COVID-19 (234,000 people)	ZEALAND PUBLIC WHO ARE AT AN ELEVATED RI	Older people nationwide (not already covered in Tier 2(b))	People with comorbidities nationwide aged under 65 years	
Tier 2 (b)		TIER THREE: NEW	Tier 3 (a) Tier 3 (b)	Tier 3 (c)	

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This redacted page, theoretically shows the plans for Tier 4 – wherein 2 million people would be injected with the BNT162b2 Pfizer vaccine.

