COVID-19 IN NEW ZEALAND.

ETHICS & THE SETTING ASIDE OF NORMATIVE PRINCIPLES.

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Contents

This discussion paper draws attention to the setting aside of ethical obligations in law, and moral dilemmas over the COVID-19 pandemic, of 2020-2022. I suggest that in the absence of such considerations, a weakening of democratic and ethical norms occurred, excluding important processes that would guard against bias and promote transparency and accountability in decision-making.

Broader consideration processes were replaced by arguably narrow and technocratic rule-making and decision-making processes in favour of the drug sponsor. These processes 'stretched the rules' to get the novel drug accepted, while failing to put in place processes of knowledge triangulation (using the peer reviewed literature) to ensure the claims of industry could be verified. The favouring of confidentiality of clinical data of a new biological entity, for a novel, high risk drug which has not yet finished clinical trials, for which the manufacturer has indemnity, is possibly the most egregious example of these processes.

The technical approach has created conditions that has placed the greatest risk burden on healthy young people, for which mandates and rights restrictions potentially produce the greatest harm over the longer term.

Together, the systematic evasion of process and the failure to enshrine democratic and public health principles at high level throughout the pandemic, have resulted in an erosion of protective norms that keep civil society safe; protect democracy life and promote trust in government. Such activities directly contradict and place a barrier to, the ability of the Ministry of Health to protect and promote health and erode trust. The processes were at odds with principles of administrative and public law,[1] and contradicted the Cabinet Manual.[2]

The issues at play establish a worrying precedent for future activities where officials and elected members develop policy and law that has potential to restrict human rights, including the human right to health, with scant disregard for higher level principles.

I propose that mandatory considerations in law should encompass the overriding statutory obligation of Ministry of Health officials to protect health; and similarly ensure infectious disease management reflects principles enshrined in the Health Act which are in place to ensure that actions are proportionate and do not contravene democratic and public health norms.

[1] BACKGROUND

1.1. Shifts in determination of pandemic status in 2009 decoupled risk for a high case fatality rate for the generally healthy, as a requirement to declare pandemic status. This situated prevention of *infection* framed as primary risk.

1.2. The public associated declaration of pandemic status with population level case fatality rate.

1.3. This mismatch, manufactured consent for global lockdowns and the acceptance of a novel technology that fundamentally differed from legacy vaccine technology.

1.4. By March 2020, epidemiologist Professor John Ioannidis confirmed that death risk was highly stratified,
'with over 1000-fold variability between children and elderly nursing home residents. 4,27,28 Median age of death with COVID-19 typically tracks average life expectancy in high-income countries.'[3]

1.5. New Zealand researchers did not tend to cite Ioannidis' work, yet he is one of the most widely cited epidemiologists in the world. By June 2020, Ioannidis and colleagues had confirmed that:

> People <65 years old have very small risks of COVID-19 death even in pandemic epicenters and deaths for people <65 years without underlying predisposing conditions are remarkably uncommon. [4]

1.6. Many have struggled to approximate the risk of death, Ioannidis equated risk with a risk commonly recognised, that of driving a car:

> The highest daily risk of COVID-19 death (in New Jersey) corresponds roughly to the risk of dying in a traffic accident while travelling daily from Manhattan to Washington, DC round trip for these 99 days of COVID-19 fatalities-period. [5]

1.7. By March 2021the infection fatality rate (based on 1.5-2 billion infections) was extremely low, approximately 0.15%.[6]

1.8. However, the facts of the matter were ignored by the Attorney General, David Parker, in his production of the overriding legislation, the May COVID-19 Public Health Response Bill.[7]

1.8.1. The enacted legislation then informed all consequent legislation, rule-making, and shepherded the processes by which judicial reasoning would take place, and how facts and evidence would be considered.

1.8.2. Parker was well aware that the secondary or delegated legislation would have all the powers of primary legislation, as he had overseen the new Legislation Act and Secondary Legislation Acts.[8]

1.8.3. This overnight COVID-19 Public Health Response Bill failed to incorporate the principles of infectious disease management enshrined in the Health Act 1956. [9]

1.8.4. The Ministries over-riding obligation to act proportionally to the risk and to *protect* the health of the generally healthy was set aside.

1.9. The legislation and consequent orders, emphasised risk from *infection transmission*, without imposing an over-riding obligation on Ministers and officials to protect health.

1.10. These policy shifts established the preconditions to adopt utilitarian policies to impose a novel technology on the generally healthy population, including children and young people.

1.11. Public message framing promoting fear of infection from early 2020.The focus on infectivity not age and health-based stratified risk, shepherded public compliance.

1.12. Research confirms that emotional responses over-ride socio-political considerations to produce compliant behaviour in citizens. In a 2021 UK study, fear of COVID-19 was identified as the major functionable variable that ensured compliance, and that 'measures of fear and anxiety symptoms were stronger predictors than moral and political orientation'. [10] Lord Sumpton has stated that in the UK, fear 'was deliberately stoked to justify decisions made on the hoof and based on questionable advice.'[11]

1.13. The statutory 'gap'- an ethical 'black hole' did not require officials were not required to consider the ethical and moral dilemma of the consequence of their policies on the generally healthy, including young people and children.

1.13.1. Scientific evidence which underpinned safety and efficacy claims were based on the following data: (1) Clinical trial data supplied by Pfizer; (2) Data from collegial regulators (who also prioritise clinical trial data to guide policy-making); and (3) Modelling studies undertaken by institutions funded by the Department of Premier and Cabinet (DPMC).[12]

1.13.2. Excluded from information gathering were obligatory reviews of the peer reviewed literature.

1.13.3. All informational intelligence was supplied by institutions who were expressly dedicated to broad community wide measures rather than risk-based measures. DPMC and Ministry of Health (MoH) policy hinged upon an 'elimination' plan; and traffic light system, designed to drive vaccination levels to over 90%.[13]

1.13.4. The elimination plan hinged on release of a commercial vaccine. The public were largely unaware that the mechanisms of the technology were fundamentally different to historic vaccines.[14]

1.13.5. The potential for negative efficacy, where the vaccine would produce more harm than it prevented, was never considered. Indeed, governments have avoided releasing or discussing contradictory data.[15] [16] [17] [18]

1.14. This 'scientific elite' repeatedly failed to consider the novelty and uncertainty of the safety and efficacy of the mRNA gene technology outside of Pfizer clinical trial data. They avoided issues that might contradict their argument, such as the low death risk, the capacity for coronaviruses to rapidly mutate, and the role of natural immunity in prevention of hospitalisation and death.

1.15. Submissions to Select Committees, affidavits to judicial review, and evidence to Ministers from experts and the lay public before global mandates, repeatedly underscored the fact that the generally healthy were not at risk. Officials and the judiciary repeatedly dismissed this information.

1.16. Utilitarian and collectivist policies over-rode established principles of autonomy and informed consent that counter the power of the state in often complex health environments.

1.17. Principles of autonomy/ informed consent reflect democratic norms to promote two-way trust (i.e. as a fiduciary relationship). This also promotes individual responsibility.

[2] ETHICALLY - IS THE HEALTH ACT PARAMOUNT?

2. Humanity has a long history of avoiding bringing attention to the ethical mismatch, when lower order rules contradict higher level principles.

2.1. Actions taken 2020-2022 appear to contradict long established norms enshrined in the Health Act 1956, requiring that Ministry officials act to improve, promote, and protect public health.

2.2. The Medicines Act is considered the relevant statutory scheme.

2.3. However, the Medicines Act is administered by the Ministry of Health. Officials' powers are derived through the Health Act 1956. The overarching obligation of the Ministry of Health is to engage in operations/activities that have the function of improving, promoting, and protecting public health.[19]

2.4. Should obligations in the Health Act guide consideration of activities undertaken within the auspices of the Medicines Act?

2.5. Provisional consent granted based on the evidence of medical or scientific merits supplied by the manufacturer. With consideration that in order to protect health, activities should not be limited to evidence provided from a manufacturer of a pharmaceutical substance; from collegial regulators, and from modelling funded by the institutions who signed the contract for supply of the injectable.

2.6. Ethically, there is an obligation to consider the evidence more broadly.

2.6.1. The Cabinet Manual requires that officials: 'inform Ministers promptly of matters of significance within their portfolio responsibilities, particularly where these matters may be controversial or may become the subject of public debate.'[20] [21]

2.7. The background is a relevant consideration to the case at hand, as Ministers and officials overseeing New Zealand's COVID-19 response have used the powers secured through the production of a small number of Acts of Parliament with scarce public input.[22]

2.7.1. Bills Digests which accompanied relevant Bills, at no stage analysed risk of hospitalisation and death and weight the consequences of lockdowns for the broader population who were never at risk of hospitalisation and death.

2.7.2. Following the production of these Acts, dozens, if not hundreds of Orders have been produced without scrutiny to establish whether these interventions would reduce hospitalisation and death.

2.7.3. At no stage was a bioethics panel[23] convened to weigh the ethics of compulsory vaccination and masking, and it is unlikely that bioethics panels have been convened to analyse the ethics of vaccinating young children with a novel mRNA injectable.

2.7.4. Instead, the issue of infectivity, transmission of SARS-CoV-2 became to raison d'être for all legislation.

2.7.4.1. The Legislation Act and Secondary Legislation Act were in place and ensured that the Minister for COVID-19 response could quickly produce Orders.[24]

2.8. A Minister is entitled to weigh each matter individually, provided has considered all the factors.

2.8.1. The Medicines Act confers protection of confidential supporting information about innovative medicines.

2.9. This produces a contradiction – the statutory obligation does not confer an obligation to consider the published scientific literature – yet the bulk of data are hidden from the public. How can the state promise transparency and accountability?

[3] THE HEALTH ACT 1956. EXCLUDED IN 2020: PRINCIPLES OF INFECTIOUS DISEASE

3. From early 2020, established principles to be taken into account for the management of infectious diseases, long enshrined in the Health Act 1956 were side-lined and ignored.

3.1. The following principles[25] have been excluded from David Parker's overarching COVID-19 legislation: 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.[26] [27] [28]

3.2. In New Zealand 2020-2022, despite substantial quantities of data supplied from applicants to court proceedings over the past 2 years, judicial decision-making struggled to balance the information supplied by the public, which has been drawn from the published and peer reviewed literature, with clinical trial data and regulatory data supplied by officials.

3.3. From an early stage, elderly and multimorbid groups were at greatest risk due to weak immune systems, and it was the biological response (as vulnerability or resilience) of the body that produced or prevented a complex cascade of disease responses. [29]

3.4. From 2020 it was understood that, rather like acquired immunodeficiency syndrome (AIDS), an individual response following infection by SARS-CoV-2, necessitated complex early treatment to manage disease as it presented in the individual. [30] [31] (See discussion part 9).

3.4.1. As with HIV/AIDs public activity played a strong role in shifting the dialogue towards management and early treatment approaches.

3.4.2. Ethical and legal dilemmas presenting in 2020-2020 mirror much of the controversy observed with HIV/AIDs. Brandt, writing in the NEJM observed: 'The AIDS epidemic demanded the recognition of basic human rights. Early on, lawyers, bioethicists, and policymakers debated the conditions under which traditional civil liberties could be abrogated to protect the public from the threat of infection. Such formulations reflected traditional approaches to public health and the "police powers" of the state, including mandatory testing, isolation, detention, and quarantine.[32]

3.5. A fiduciary relationship demands optimum transparency and accountability. Mandates and rights limiting restrictions are rendered unethical when democratic norms are not upheld. For example, when clinical trials remain unfinished, a technology is 'high risk', and company data is kept secret.

3.6. Informed consent was distorted by the government's continued 'safe and effective' claim which undermined the public's capacity to weigh options and conduct their own risk-benefit analysis.[33]

3.7. The effect produces a moral hazard, whereby the vaccine recipient is required to accept the physical, social and economic risk, which may be short or long term for which it may be difficult to establish a clear causative link. As with exposure to any medicine, identification of risk is often uncertain, complex and nebulous. This produces barriers to justice when an individual is harmed.

3.8. Failure to consider the such nuances can be observed in Ian Town's *Completed summary of evidence of COVID-19, transmission risk and vaccination in 5–11-year-olds*[34] -

3.8.1. Identifying harm in a child from a medical intervention is more difficult than identifying harm in an adult.[35]

3.8.2. Where Town integrates published literature, there is no evidence of methodological surveillance. Prima facie, the content appears designed to support an argument for vaccination.

3.8.3. Town's report does not traverse broader issues of risk. This includes neurological, inflammatory, allergenic. Much evidence associates risk with the persistence of the synthetically produced spike protein in the body that may persist for months.[36]

3.8.4. The numbers needed to treat (NNT) discussion is based on earlier Delta data;

3.8.5. Town ignores the potential for infection via the nasopharynx.

3.9. Judicial decisions struggle to place weight on affidavits supplied by individuals with extensive expertise in the matter at hand.

3.9.1. For example, the judicial decision in MKD and Seven Others v the Minister of Health[37], Justice Gendall considers the referral by Medsafe's evaluation team of the Provisional Consent application for the Paediatric Vaccine to the Medicines Assessment Advisory Committee (MAAC).

3.9.2. Justice Gendall notes that MAAC is headed by a diabetes specialist, Dr Paul Tomlinson, and advises that the MAAC panel includes broad expertise, but does not confirm that any members have expertise in cardiology.

3.9.3. Justice Gendall lists the data supplied to the MAAC:

> [18] To assist in their consideration, members of MAAC were provided with:
>
> (a) Pfizer's medicine application dossier;
> (b) Medsafe's final evaluation report and associated data;
> (c) Medsafe's paper to the Medicines Adverse Reactions Committee (an advisory body to Medsafe) regarding proposed updates to Pfizer's risk management plan (RMP) for the vaccine for those 12 years and older;
> (d) a presentation from the United States Center for Disease Control on COVID-19 epidemiology in children aged five to 11;
> (e) a Medsafe presentation on myocarditis; and
> (f) a report to Te Rōpū Whakamana i te Tiriti o Waitangi | the Waitangi Tribunal prepared by six eminent New Zealand clinicians and academics who had been asked to give expert evidence about the anticipated impact on Māori children and their whānau of the Government's planned shift to the COVID-19 Protection Framework (the "traffic light system").

3.9.4. Justice Gendall's deliberations do not focus on the gap in consideration, the failure of the MAAC to receive reviews (as informational intelligence) that consider cost-benefit to children,

which might include assessments considering the likelihood of an adverse event, including hospitalisation and death, in contrast to the risk of hospitalisation and death following exposure to the Omicron variant.

3.9.5. Justice Gendall does not consider a predominant issue of concern, the potential risk to heart function. None of the expert committee appear to have authoritative expertise in this field.

3.9.6. It is my understanding that the applicants forwarded an affidavit from Dr Peter McCullough. McCullough has published over 600 peer reviewed articles in his area of expertise. He has an H index of 95. He is the top ranked expert in this field.

3.9.7. Members of the MAAC were not privy to such high-ranking expertise, and Medsafe and the Ministry of Health do not conduct comprehensive reviews to balance risk as identified across the published literature.[38]

3.10. The provisional approval for paediatric use of the novel mRNA injectable was secured without review of the peer reviewed literature to balance (triangulate) claims of efficacy and safety by the manufacturer. This is not a statutory obligation as per the Medicines Act – so it wasn't done.

[4] ETHICAL AND MORAL PRINCIPLES

4. Bioethical principles assist health professionals and public policymakers to recognize moral dilemmas in health care and biomedical research and provide a compass, principles and moral rules with which to navigate through these dilemmas. Maintaining principles and demonstrating they are adhered to promotes trust in the governors by the governed.[39]

4.1. However, morally difficult situations have arisen over the pandemic, possibly the most divisive and ethically questionable dilemma has surrounded the role of modelling studies in declaring that the population at large, and particularly high transmitting age groups (young adults and adolescents) should be vaccinated in order to protect at-risk older adults.[40] [41] The precedent used was influenza.[42] No clinical trials studied the potential for the mRNA gene therapy to prevent transmission of infection – there was no clinical evidence of meaningful prevent of transmission.[43]

4.2. Officials have a responsibility to improve and promote health, and they have a responsibility to 'remove from policy debate programs that are unethical, whether because of insufficient data, clearly discriminatory procedures, or unjustified limitations on personal liberties.' [44]

4.3. Principles assist to direct panels to consider broader uncertainties and ethical dilemmas outside their areas of expertise, for 'while experts might have deep knowledge and insight in their own fields, their narrow perspectives can be poison for public policy.'[45]

4.4. The stoking of fear is associated with decreased physical and environmental wellbeing.[46] In 2020 it was understood that individuals that perceived the virus to be severe, had worse mental health outcomes.[47]

4.5. With these considerations in mind, four historic ethical principles[48] [49] guide governing decisions and promote the protection of health. They are broadly reflected in the Health Act 1956. They are accepted norms for health professionals, directed at the higher order purpose of maintaining and improving health.

4.5.1. Autonomy. Deliberated self-rule; 'the ability and tendency to think for oneself, to make decisions for oneself about the way one wishes to lead one's life based on that thinking, and

then to enact those decisions.'[50] Autonomy, as free will, intersects with a moral compass, human endeavour and the exercise of personal responsibility. 'Respect for autonomy is an important moral constraining principle, both on paternalistic clinical beneficence, and on paternalistic global beneficence.'

4.5.2. Non-maleficence – Has origins in the Hippocratic 'primum nil nocere'– first of all, do no harm.' Non-maleficence asserts that health professionals should take all steps to avoid and minimise harms (either through omission or commission). Dr. Julie Ponesse has argued that the actions of an individual in taking a vaccine with possible adverse effects, so that others are protected, violates this principle.[51]

4.5.3. Beneficence – Encompasses a 'moral obligation to act for the others' benefit, helping them to further their important and legitimate interests, often by preventing or removing possible harms.'[52] Beneficence is recognised as an imperfect obligation, requiring judgement so as to be in accord with a common morality or ethical norm. [53]

4.5.4. Justice – Justice demands equal opportunities, however there is an important nuance, as justice demands the fair distribution of health outcomes, or health equity.[54] 'Accounting for human heterogeneity is important: justice requires aiding people in proportion to their degree of disadvantage, according to Aristotle's proportionality principle. Additionally, health capability determinants vary across societies, and assessing health capability inequalities must account for these differences.'[55]

4.6. The principle of autonomy is considered the overarching principle, ensuring that a person may make informed voluntary choices for themselves, 'under the influence of as little bias, coercion, pressure or duress as possible[56]; it is also understood as 'first among equals' of the four ethical principles.[57]

4.7. The New Zealand Medical Association draw on these principles as a foundation for their Code of Ethics, which emphasises the maintenance of a trust relationship between doctor and patient.[58]

4.8. In New Zealand public health ethics encompass an obligation to adhere to the principles of te Tiriti o Waitangi and the special obligations to Māori to ensure equity and active protection.[59]

[5] PRINCIPLES DISESTABLISHED IN A PANDEMIC

5. New Zealand publications suggest that these long-established principles – especially that of individual autonomy – have been jettisoned by Ministers and officials during 2020-2022.[60] [61]

5.1. This has established a startling precedent for extensive medical coercion and lockdown policies. The pandemic was *never* associated with a high case fatality rate across all population groups.

5.2. 2020-2022 evidenced unprecedented and paradigm shifting approaches to governance in an emergency event. Coercive promotion urging vaccination in the generally healthy; injection of a novel technology which skipped many historic clinical trial processes.

5.3. These patterns suggest that without giving effect to autonomy, decisions by Ministers and officials can rapidly place large swathes of the population at substantial health risk, when they were not at risk previously.

5.4. Respect for autonomy places an ethical requirement that 'all eggs are not placed in one basket.' Human failure is real, and the scholars are already expressing concern that improperly regulated biotechnology presents a fundamental - and existential - health risk.[62]

[6] W.H.O. 'RISK TURN' AWAY FROM SEVERE DISEASE – TOWARDS 'INFECTIVITY'

6. Historic shifts by the World Health Organization (WHO) in 2009, established the preconditions for the pandemic declaration in March 2020 with relatively low death rates, which then informed the purpose of the Acts for the New Zealand response.

   6.1. However, an obligation that consideration of a pandemic would necessarily entail a high mortality rate was removed in 2009 when the World Health Organization (WHO) decoupled severe critical risk factors considered integral to the category of 'pandemic'. The WHO pandemic phase descriptions emphasised phase risk predicated on *viral outbreaks*.

      6.1.1. Requirements did not include a classification which would capture severe disease (as high case fatality rate in traditionally healthy populations) within the definition required before a pandemic could be announced was demonstrated to classify an influenza/respiratory infection as pandemic status to placing more emphasis on disruption to social and economic life.[63]

      6.1.2. Instead, the conventional health indicators of severity, case fatality rate, unusually severe morbidity, unexpected mortality pattern and unusual complications[64] were removed as a high-level recommendation. These indicators were repositioned as lower order considerations.[65]

   6.2. Therefore, the narrative that was established in 2009, that transmission of the virus, not potential death was the central risk factor to be managed.

   6.3. The WHO 2009 shifted the established the policy environment for 2020 global recommendations that were able to fundamentally ignored the ethical implications of interventions placed upon the generally healthy – as the primary risk issue became identified as transmission of infection.

   6.4. COVID-19 pandemic was declared on March 11, 2020 by the Director General of the World Health Organization, Dr Tedros Adhanom Ghebreyesus.[66] From the early stage it was recognised that the death rate following infection did not reflect the risk that was observed in earlier smallpox epidemics and during the Spanish Influenza.

   6.5. The fatality rate was always substantially different from diseases linked in the public consciousness, as being designated as high-risk events. Smallpox infection can result in a high death rate, variola minor with a case fatality rate of 1% and the more common variola major with a case fatality rate of 30%. Spanish Influenza resulted in high case fatality rates for relatively young people as well as the aged.[67] [68] The 1918 Spanish Influenza had an estimated case fatality rate of 2-3%; the 1957 Asian Flu under 0.2%, the Hong Kong Flu under 2%.

[7] PFIZER TRIAL DATA & REGULATORY DATA OVERRIDE PUBLISHED LITERATURE?

7. Decision makers must 'genuinely weigh matters that ought to be taken into account'.[69] Yet decision-makers and judicial decisions continue to expressly consider Pfizer data and regulatory information, while ignoring, downplaying and dismissing the peer reviewed literature.

   7.1. The state neglected to build in mechanisms that would triangulate industry claims of safety. Lord Sumpton has recently noted 'fundamental rule of government is not to make radical decisions without understanding the likely consequences.'

   7.2. Judicial decisions, Official Information Act requests and Cabinet minutes demonstrate that the machinery of government has placed the *greatest weight of evidence* on the data submitted by the

manufacturer Pfizer; as well as prioritising collegial offshore regulators who also predominantly base decision-making on clinical trial data supplied by the sponsor.

7.3. Judicial decisions, Official Information Act requests and Cabinet minutes demonstrate that at no time, have *methodological* reviews been undertaken of the great quantity of scientific evidence published in the peer reviewed literature.

7.4. New Zealand's Department of Premier and Cabinet funded modelling groups, working under the Te Pūnaha Matatini and later the COVID-19 Modelling[70] umbrella have consistently neglected to build in the known risk factors of waning and breakthrough, i.e. vaccine failure.

7.4.1. Coronaviruses historically mutate rapidly, and officials were aware of this.[71] [72] By mid-2021 waning and breakthrough events were regularly recorded in the peer reviewed literature. I presented this information to the Health Select Committee with a colleague in October 2021. Once Omicron was in play, waning and breakthrough events escalated.[73]

7.4.2. Young people and children are recognised 'vectors' for disease, with increased transmission rates across these communities. However, historically these communities are resilient and they play an important role in moving an infectious disease to endemic status. Such considerations appear not to be considered relevant.

7.4.3. The systemic uncertainty concerning the waning and breakthrough was excluded in all government communications. None of the deliberations on mandates included the potential for waning and breakthrough, despite the fact that coronaviruses mutate rapidly.

7.5. Internally produced adverse-event reporting data is historically bedevilled by under-reporting.[74] The failure to require mandatory adverse event reporting for new products which lack long term trial data has produced another knowledge gap.

7.6. Review of clinical trial data and offshore regulatory data have been claimed by officials to justify decisions and to provide evidence that statutory obligations have been undertaken with rigour.

7.7. I propose that such actions to avoid and steer clear of 'at arms' length' surveillance of the peer reviewed literature, demonstrate a fundamental governance failure at odds with principles of administrative and public law. Scrutiny and review of evidence in the peer reviewed literature arguably represents a mandatory consideration for which decision-makers must give due consideration for.

7.8. Vaccination for the benefit of others assumes a perfect situation where the injectable is presumed to have undergone extensive testing; that infection will not be transmitted following injection; that the virus will not rapidly mutate; and where the benefits outweigh the costs.

7.8.1. The technology releases instructions into the body to produce an antigen. The product encodes an inflammatory spike protein into the cells of the recipient that the manufacturer claims elicit a protective immune response. The current injectable encodes a spike protein that is effectively outdated, it is a synthetic replica of the original Wuhan wild type virus.

7.8.2. While historic vaccines imparted a limited quantity of an antigen into the body, the mRNA injectable (BNT162b2/tozinameran) contains the instructions for uncontrolled release of the antigen.

7.8.3. Issues of safety and efficacy of the new generation biotechnology and complex ethical issues were set aside; and no pathways outlined procedures to follow if the *decision-making* relating to

the products efficacy was imperfect. This was not a New Zealand phenomenon. Documents presented as policy advice frequently neglected to consider nuance and context.[75]

7.8.4. Due to rapid mutation, this would always be a highly dynamic environment. Locking in mandates not only demolishes public health norms of autonomy, ensure non-maleficence and ensure maximum health protection, but fails to build in sufficient flexibility to ensure the state is trusted, and cohesion is maintained when knowledge changes.[76]

7.8.5. Vaccine protectiveness against asymptomatic infection quickly declined, this information was understood by October 2021.[77] Prevention following mRNA vaccination declined most rapidly in the most at-risk groups and there is little evidence to support ongoing booster doses.[78]

7.8.6. Vaccine efficacy against symptomatic Omicron infection is modest and wanes rapidly in children and adolescents, and appears to have no predictable impact beyond 2 months.[79]

7.8.7. A Pfizer study of adolescents aged 12 to17 years found that vaccine effectiveness against Omicron related emergency department (ED) and urgent care (UC) was only 73% at 2 months and waned to 16% against Omicron at 6 months and beyond. Data looking at a third dose only considered protection to 19 days.[80] Boosters continue to have limited efficacy.[81]

7.8.8. Such poor efficacy must be balanced against risk that is not linear (i.e. people may be at risk of clotting or myocarditis, but of both harms). This might include risk of myocarditis, but also thrombosis/blood clots,[82] multisystem inflammatory syndrome,[83] and the impact of the spike protein to liver,[84] brain[85] and heart[8687] and immune system,[88] particularly if persistence is longer than anticipated.[89]

[8] NAVIGATING PERVASIVE UNCERTAINTY

8. The moral and ethical underpinning rationale for scrutiny of the peer reviewed literature by officials, should have been of the essence as the mRNA gene therapy was a novel, untested genetic technology:

8.1. The technology is a *biological entity*, a biologically active substance that had never before been released at scale. Medsafe recognises the injectable is a *higher risk* medicine.

8.2. Somewhat contradictorily, as a biological entity a data protection period applied for 5 years, preventing public access to industry trial data, and thereby industry claims of safety and efficacy.

8.3. Ministry officials signed contracts with the manufacturer for the supply of the BNT162b product based on Pfizers' own data. Through this act Ministry officials have demonstrated that they believe vaccine acceptance across communities, including paediatric communities, is desirable.

8.4. Earliest trial data demonstrated that the mRNA injectable did not exhibit the characteristics of a sterile vaccine, i.e. it did not prevent transmission of infection. The trial data showed that participants could still develop the symptoms associated with COVID-19. The earliest trial data tested the mRNA injectable, designed to reproduce a synthetic replica spike protein (original Wuhan wild virus) against circulating variants in 2020.

8.5. The approval is based on *immunisation* against COVID-19 – the presentation of symptoms – rather than prevention of infection from SARS-Cov-2. No serology testing has been required to assess pre-existing immunity. Serology testing is a conventional procedure undertaken in medical environments before staff receive mandatory vaccines to protect them against disease.

8.6. Pervasive uncertainty regarding duration of efficacy has persisted. Efficacy for regulators was primarily based on prevention of symptoms at 2 weeks post second dose.[90] The New Zealand public remain largely unaware that the provisional consent approval centres on reduction of respiratory virus symptoms 2 weeks post second dose.

8.7. The approval concerned an unprecedented pivot to *symptom suppression* which might easily be conflated with symptoms for any respiratory virus, including circulating coronaviruses and influenza. There was no accompanying requirement for serology testing, which would accurately verify the presence of SARS-Cov-2 in samples.

8.8. Pfizer benefitted from regulatory loopholes provided to traditional infectious disease preventing vaccines. Yet the novel technology is demonstrably *new generation technology*, Therefore, there were no requirements to:

8.8.1. Conduct genotoxicity and carcinogenicity trials.

8.8.2. Independently scrutinise the scientific literature to assess the potential for the injectable to promote inflammation, thrombosis/clotting, cancer, mitochondrial disruption, reactivation of latent viruses and mast cell activation syndrome.

8.8.3. Assess the length of time the Pfizer antigenic spike protein remained in the body.

8.8.4. Assess the combinatory toxicity of the lipid nanoparticles and the reproducing spike protein, and the other undisclosed ingredients (such as through biomarker tests on trial participants).

8.9. Coronaviruses readily mutate, and infection with coronaviruses are not associated with predictable durable immunity. The expectation that the generally healthy should be exposed regularly to an mRNA injectable in the hope that it might prevent an older at-risk population, for example if that mutation alters every 3-6 months, is unethical.

8.10. Infection chasing, in the current pandemic was posited to promote communitarian benefit and prevent hospitalisation.

8.11. The communitarian/utilitarian approach failed to consider absolute risk reduction and how risk altered as the coronavirus mutated. By time of release of the mRNA injectable in New Zealand, there was clear evidence that mutation was rapid and ongoing.

8.12. The machinery of government did not establish mechanisms which would impose an overriding obligation to judge *the absolute risk reduction*[91] *from the mRNA injectable (*BNT162b2/tozinameran); and to assess the impact on risk to those who are not at risk of hospitalisation and death from COVID-19 so that health would be protected for those not at risk of COVID-19.

8.13. Similarly, it was always recognised that vaccine efficacy would be limited in patients with comorbid conditions. Such patients present to doctors with complex and multifactorial conditions, and repurposed drugs with a long history of safe use more safely support comorbid patients with complex drug regimes.[92]

8.14. The injectable that contained the instructions to produce an inflammatory spike protein which could persist from weeks to months.[93] Subchronic harm from repeated boosters where the inflammatory protein might produce harm was not explored by local researchers

8.15. Onerous barriers to early treatment were put in place by officials. Unlike the gene therapy, the early treatments had a long history of safe use. The query concerned efficacy (a problem which plagued the vaccine).

8.15.1. The machinery of government did not establish mechanisms which would impose a greater obligation to review and judge the literature concerning *the absolute risk reduction from nutritional and medical early treatments*[94] with a long history of safe use without side effects. Those most at risk of harm from COVID-19 were also predominantly multimorbid and vulnerable to iatrogenic harm arising from polypharmacy.

8.15.2. Officials imposed barriers to identifying protective treatments by insisting on randomised control trials (RCTs) for proof of efficacy for drugs used in the treatment of COVID-19.[95]

8.15.3. RCTs are designed for the purpose of understanding the safety and efficacy of new and novel drugs for which there is no history of safe use in the target population.

8.15.4. Pharmaceutical companies do not establish RCT's for off-patent medications.

8.15.5. RCTs are an overly strict requirement and quite unnecessary to demonstrate efficacy.[96] Observational studies are an equally valid study design.

8.15.6. New Zealand health research funding bodies lack the scope to fund RCTs.

8.15.7. Banning and scapegoating of repurposed antiviral treatments artificially limited potential treatments and locked in the Pfizer injection as the dominant COVID-19 treatment.

8.16. The Bradford-Hill criteria[97] [98] can assist to identify harm from a medical treatment. The Bradford Hill criteria is a set of requirements, applied to assist with decision-making in order to provide adequate evidence of a causal relationship between two factors. It assists to navigate a scientific dilemma whereby it is relatively easy, in a scientific experiment to detect no scientific effect due to a myriad of reasons, but more difficult to detect subtle effects.[99]

8.16.1. Significant advances in technologies can assist to identify exposure-response relationships and disease causation. 'Advancements in genetics, molecular biology, toxicology, exposure science, and statistics have increased our analytical capabilities for exploring potential cause-and-effect relationships, and have resulted in a greater understanding of the complexity behind human disease onset and progression.'[100]

8.16.2. It is well known that technologies used generally in pharmaceutical and medical research are only slowly taken up in research to understand the processes by which anthropogenic factors including from pharmaceutical medications, increase risk for, or drive disease.[101]

8.16.3. In effect, the 'black box' between exposure and disease can now be explored. Researchers can actively 'assess exposure, internal dose, biologically effective dose, early biologic effect, altered structure/function, invasive cancer diagnosis, tumor metastasis and prognosis.'[102]

8.16.4. However, none of the clinical trial data publicly published, have demonstrated that the regulatory expectations have meaningfully kept pace with these laboratory developments.

8.16.5. No processes for pathology laboratories or the Chief Coroner have been developed to assist officials and the medical profession to identify dose and effect responses.

8.17. The immune responses required to designate drug efficacy may be 'off-target'. MRNA injectable gene therapies primarily elicit an immunoglobulin G (IgG) immune response, with lesser amounts of IgA.

8.17.1. Kaczmarek et al. noted[103]: 'The rationale behind vaccination is to provide every vaccinated person with protection against the SARS-CoV-2 virus. This protection is achieved by stimulating the immune system to produce antibodies against the virus and to develop lymphocytes that will retain memory and the ability to fight off the virus for a long time." However, since vaccination is given parenterally, IgG is the principal antibody class that is raised against the SARS-CoV-2 spike glycoprotein, not IgA, not IgA.[104]

8.17.2. The Clinical results provided by Pfizer to MBIE for Immunogenicity claimed the following protection: 'Antigen binding IgG and neutralising responses to vaccination were boosted by a second dose; neutralising immune responses measured 7 days after second dose of 30 µg BNT162b2 ranged from 1.7 to 4.6 times (18-55 yrs) or 1.1 to 2.2 times (65-85yrs) compared to that of individuals recovering from COVID-19.'

8.17.3. The exclusive focus on IgG resulted in the state failing to consider – as a mandatory consideration – the role of secretory IgA in barrier function at mucosal (the nasopharynx) sites. Injection in the arm does not extend to infection prevention in the nose and mouth.

8.17.4. The nasopharaynx is the most common entry point for infectious disease, yet the mRNA injectable does not produce mucosal IgA antibodies.[105] This is where massive viral replication occurs at an early stage.

8.17.5. The IgA 'blackbox' failure in regulatory approvals is a yet another symptom of a machinery of government that fails to review the scientific literature. The IgA blackbox may be closely related to the potential for the mandated vaccine to wane, and to encourage breakthrough infections.

8.17.6. It is entirely possible a child (or adult) could be vaccinated and still transmit infection.

[9] IMMUNOSUPPRESSED GROUPS BENEFIT FROM REPURPOSED DRUGS

9. COVID-19 early treatments are designed to ameliorate COVID-19 symptoms, including viral replication, inflammation and thrombotic effects.[106]

9.1. Immunosuppression can blunt vaccine responses, and vaccines can wane quickly.[107] [108]

9.1.1. Ironically many groups with autoimmune issues are prescribed generic antivirals as a prophylactic disease management strategy.

9.2. Provisional consent appears to be based on a promise of efficacy up to two weeks, and the mRNA injectable gene therapy might exercise short term antibody enhancement, but long term (i.e. greater than 8 weeks), efficacy cannot be assured.

9.3. As discussed in Part [4], the disease HIV/AIDs, with a complex aetiology, necessitated complex early treatments. This model is well understood across the public health community.

9.4. From an early stage repurposed drugs were selected for early treatment not only for their (for example) anti-viral or anti-inflammatory effect, but because they have a history of being 'well tolerated'.[109]

9.5. The spectrum encompasses individual tolerance, and takes into consideration the potential for drug-drug effects that may put patients at risk, as any risk factors are firmly established in the literature. Tolerance includes safe long term prophylactic prescription.

9.5.1. Ivermectin is repurposed for its multi-pathway, antiviral and anti-inflammatory effects. Observational studies show ivermectin is protective against severe COVID-19, reducing times to clinical recovery and rates of disease progression and mortality.[110]

9.5.1.1. The Ministry of Health/Pharmac predominantly relied on Cochrane Library RCTs as a primary rationale to exclude ivermectin.[111] [112] While they refer to other regulators, global regulators applied the same practice of favouring RCTs. The 2022 paper by Popp relied on a markedly narrow evidence base of 14 studies to claim no efficacy of IVM.[113]

9.5.2. Hydroxychloroquine (HCQ) is a guideline WHO drug, taken on a weekly basis as an outpatient treatment. [114] HCQ has been used for decades, primarily in tropical environments as a weekly treatment for the prevention and treatment of malaria. The prophylactic use of HCQ is safe, as is the use of HCQ alongside other prescribed medications.

9.5.2.1. New Zealand's March 2020 exclusion of HCQ coincided global shifts.[115] [116]

9.5.3. A substantial literature supports the protective antiviral role of HCQ in preventing the descent into severe COVID-19. As well as a strong safety record, HCQ may have better RCT outcomes than Remdesivir[117] which has an uncertain safety profile.[118] [119] Many RCTs have focussed on the capacity of HCQ once a patient is hospitalised. The New Zealand government includes Remdesivir in guideline treatment but removed HCQ in March 2020 from use as an off-label antiviral.[120]

9.5.4. Vitamin D remains outside the COVID-19 guidelines. Many submissions have been advanced to the government concerning the role of vitamin D to modulate the immune response to COVID-10.[121] Vitamin D is protective against lower respiratory tract infections, including pneumonia, a major risk factor in severe COVID-19).[122] Vitamin D exerts protective effects for those at risk of metabolic syndrome, which includes hyo hypertension, diabetes, cardiovascular diseases (CVDs), autoimmune diseases and cancer.[123]

[9] COMORBID COMPLEX HEALTH CONDITIONS

10. Poverty, dietary insufficiency, the role of obesity and metabolic stress does not appear to be broadly considered by officials and task forces.[124]

10.1. Consideration too should concern the fact that public health historically concentrated their efforts on alleviating poverty (low socio-economic status) as poverty – the social determinants of health - place people at greatest risk from both communicable and non-communicable disease. [125]

10.2. Those with multiple conditions, which are frequently associated with metabolic syndrome, obesity and poor diets were at greatest risk of hospitalisation and death.[126] The New Zealand government did not enact measures to increase access to healthy food for these groups.

[11] NEW ZEALAND – PREVENTION OF INFECTION AS KEY POLICY TARGET

11. The policy shifts in 2009 removed a high case fatality rate as a predicator for risk, pivoting policymakers to emphasise transmission risk. This step also removed the established risk factor that fatality rate would encompass mortality risk for the under 50 age group.

    11.1. The general public equated pandemic risk as a risk of severe illness and morbidity from early 2020.

    11.2. The trust and co-operation with interventions arose from a trust that severe hospitalisation and death was being prevented at scale.

    11.3. Yet it was New Zealand's high-level focus on infection and prevention of transmission, that presaged the secondary legislation (as Orders) free-for-all that imposed onerous restrictions on the generally healthy, who were never at risk of hospitalisation and death.

    11.4. This legislation has never required that as a primary obligation, that health is protected, and that measures would be proportional to risk. Such obligations have been enshrined in the Health Act 1956 since its introduction. There has been no discussion on the relative risk of children and the generally healthy population.

    11.5. Officials have a political and ethical obligation to inform Ministers of controversial matters. There has been no obligation conferred on officials to refer back to the scientific literature to judge (and triangulate against the claims of the manufacturer) the shifting cost-benefit relationship as the evidence mounted in the scientific literature.

    11.6. Deliberation throughout the pandemic has revolved around risk of infection, and this parameter has been applied to coerce the public into accepting an injectable that was approved on the basis of prevention of symptoms.

[6] EXPERTISE LOCK-INS

12. Throughout COVID-19 there has been little evidence that officials, Ministers and task groups placed weight on ethical or precautionary considerations in order to ensure that health was protected for the generally healthy.

    12.1. Public health emergencies can resemble a 'fog of war'. Decision-making in such arenas can become fraught, technocratic and divorced from ethical precedent. This is due not only to the authority of stakeholders who control the supply of information and have predetermined outcomes. Ethical failures occur when officials are required to process and judge large quantities of information; and social and human failings – including a natural reluctance to make a 'wrong decision' that might impact that officials' professional or social reputation may also impact ethical outcomes.

        12.1.1. Knowledges of groups arise from the cultures around them, reflecting the expertise, pragmatisms and political orientations of the institutions they associate with. Expert committees are more familiar with their disciplinary areas than the larger drivers of metabolic health and disease. This shapes their frame of reference.

12.1.2. Scientist peer groups develop their own 'social systems' norms and values which direct the group towards certain preferences. While consensus in science is the result of social processes of negotiation, peer group logics play a critical role in guiding what is acceptable for discourse and what is outside.[127] Thus, 'social groups create deviance by making the rules whose infraction constitutes deviance and then applying those rules to those people who deviate and labelling them as outsiders'.[128]

12.1.3. State funding for interdisciplinary and basic science has declined, while funding for IP associated medical innovation has increased. Privileging of applied research alters expertise, and how disease risk and uncertainty will be navigated. This has *medicalised* both the public health agencies and the research community. [129] [130] There are now less basic scientists, less polymaths who can draw attention to broad biological risk from new technologies. Our science policy and funding schemes do not permit this critical work.

12.1.4. Applied, technical perspectives can be weaponised to delay regulation of pollution or silence steps to remove a technology from the market. Technical arguments can promote ignorance and confusion concerning normative maxims of proportionality and public law ethical norms, which were historically designed to navigate complex, uncertain environments (open-ended systems).

12.1.5. The key high-level health system indicators for the Ministry of Health are medical rather than aimed at reducing complex metabolic disease. Vaccination rates are established as a high-level health system indicator. Medical/hospital targets across public health demonstrate that policymakers struggle to articulate complex issues relating to comorbidity, the drivers of communicable and non-communicable disease, and such issues as risk factors in pandemics.[131]

12.1.6. Thomas Kuhn's treatise demonstrating science's often natural turn to dogma, as elites control the narrative and engage in boundary work to prevent advances that challenge the status, demonstrates this well.[132] Kuhn also clearly had appreciated the tendency for elite groups to excise paradigm challenging, or morally uncomfortable concepts that

"A paradigm can, for that matter, even insulate the community from those socially important problems that are not reducible to puzzle form, because they cannot be stated in terms of the conceptual and instrumental tools the paradigm applies" (Kuhn, 1970, p. 37).

12.1.7. Such activities by elite groups, to retain uncomfortable, controversial or contractor information outside their 'scope' is a method of depoliticization. Often such issues are highly political simply because they are controversial or lack consensus.

[13] CONCLUSION.

13. It has long been recognised that protective principles will be set aside in times of war or emergency.

13.1. Democratic norms of transparency and accountability to ensure justice and the protection of human rights, are in place to prevent the shaping or stewarding of decisions to favour special interests; however, these are most vulnerable in times of crisis.

13.2. Government actions throughout COVID-19 have resulted in the setting aside of normative public health principles, and the downplaying of democratic norms of transparency and accountability that promote public trust by the governed in the governors.

13.3. From the earliest stage the drafted legislation[133] failed to take account and incorporate the principles of infectious disease management that was required to be considered by officials. No public consultation was permitted.

13.3.1. Ironically, the purpose of the inclusion of Part 3A in the Health Act, was specifically to require officials, as a mandatory consideration, to take account for the potential for an infectious disease to place individuals at different risk, and for early treatments to ameliorate risk.

13.3.2. Part 3A considered the fact that not all individuals might be at risk of severe disease and death from an infectious disease and as such, demanded a proportionate considered response by officials. [134]

13.4. Movements in science research funding have resulted in there being less basic science experts who can talk broadly about complex health risk. Funding has increasingly driven expertise in applied science and drug discovery rather than in the drivers of disease and harm.

13.5. Applications for regulatory review have drawn upon overseas experts, the absence of experts in New Zealand institutions have resulted in a diminished local cohort that could securely discuss risk.

13.6. Legislation changes (such as to broaden provisional consent to encompass the New Zealand population) persistently favoured the industry sponsor, eroding the protection previously offered when a drug was offered with incomplete trial data.

13.6.1. This directly contradicted higher-level Health Act principles.

13.7. The knowledge that the WHO could announce a pandemic that did not involve risk of severe disease or death to the general population, was not understood by the public at large. The role of functional fear of the viral infection was identified as an important variable in ensuring compliant behaviour.

13.8. Pervasive uncertainties continue to surround the safety and efficacy of an RNA-based vaccine that encodes a viral antigen which is expressed by the vaccine recipient. Risk continues to be downplayed by officials. The scientific literature continues to demonstrate complex interrelationships between the injectable and human biological responses.

13.9. Harmful effects of the injectable may persist for longer than claimed benefits. Efficacy was always based on clinical trials demonstrating 7-14 day prevention of symptoms, yet the antigenic spike protein can persist in the body for longer than the period of symptom suppression.

13.10. There is demonstrable evidence early treatment more effectively protects elderly, multimorbid and immunosuppressed groups from severe illness and hospitalisation.

13.11. Evidence from judicial decisions, from Official Information Act requests and Cabinet minutes continue to establish that no meaningful action has been undertaken to transparently and methodologically review the peer reviewed and published scientific literature in order to triangulate and judge industry claims of safety and efficacy as the pandemic event progressed.

13.12. Challenges concern the capacity for judges to ‘look upstream’ and consider the overriding function of the Ministry of Health, and the obligation to broadly protect health. Instead, judgements and consideration focuses on instrumental lower order guideline issues such as statutory provisions in the Medicines Act. Judges have struggled to weigh expert advice outside government Ministries.

ABOUT THE AUTHOR, J.R. BRUNING.

14. I am a sociologist with expertise in the bioethical implications of exposures to technologies and human health risk.

14.1. My work explores the processes and techniques deployed in policy development and regulatory decision-making and the tendency to retain higher level principles of protection outside the scope of consideration.

14.2. This encompasses the practice of exclusion of independent science required for public interest policy-making and deliberation during processes of authorisation and regulation of technologies.

14.3. This work draws attention to the importance of democratic norms of transparency and accountability in the stewarding of scientific information and evidence used in policy. Such action would ensure that scientific information, used in the development and rolling out of policy is held at arm's length from vested interests, and therefore has the greatest likelihood of reflecting the greater public interest. A common technique is for commercial in confidence (secrecy) claims to override disclosure in the public interest.

14.4. This focus arises from the truism that policy, society and democratic life in twenty-first century societies hinges upon the provenance of science to support and uphold policy.

14.5. A central theme of my research concerns the protection of children and young people and the scientific literature relating to the developmental origins of health and disease (DoHaD).

14.6. This work is important as the potential for harm to arise following exposures of a biological technology and/or pollutants is one of pervasive uncertainty and complexity. Human or environmental vulnerability is a factor of social, cultural historic and economic influences. In order to navigate difference and risk, principles of care act as umbrella concepts to guide officials.

14.7. I am a trustee for Physicians and Scientists for Global Responsibility New Zealand Charitable Trust. The Trusts' objectives focus on the education of risks relating to technologies including biotechnology; and the promotion of scientific research and public debate to traverse such risks.[135]

14.8. My Master of Arts, received from the University of Auckland,[136] explored health research and the barriers to researching the environmental origins of endocrine disruption and disease. The absence of funding schemes prevents development of scientific expertise relating to risk from anthropogenic exposures; limiting the capacity for society to steward technologies and pollutants.

14.9. In addition to co-authoring PSGR reports, I publish on TalkingRisk.NZ and on JRBruning.Substack.com. Throughout the 2020-2022 I have released discussion papers documenting the decision-making processes of policy-makers with a particular focus on the absence of methodological reviews of evidence in the peer reviewed literature as a basis for triangulation of knowledge in g/Government decision-making.[137] [138] [139]

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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.
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The COVID-19 Public Health Response Bill. No public consultation 1 day. Introduced May 12, Third reading and Royal Assent May 13 2020. Minister in Charge: Parker
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