Sue Grey Lawyer

31 March 2021

URGENT- OPEN LETTER

Prime Minister Jacinda Ardern
Ministers of COVID-19
Director-General of Health
Chris James- Group Manager Medsafe

cc Attorney-General David Parker
Solicitor-General Una Jagose
Health and Disability Commissioner

Dear Prime Minister, Attorney-General, Director-General of Health and Chris

RE PFIZER VACCINE "COMIRNATY" RE BREACHES OF MEDICINES ACT, MISLEADING AND DECEPTIVE CLAIMS and OTHER MATTERS

I represent a large number of New Zealanders who are extremely concerned about apparent legal breaches and misleading and deceptive representations in the provisional approval, promotion, marketing and roll out of the novel Pfizer mRNA and nanogel vaccine known as "Comirnaty" ("the Pfizer injection").

I write to formally put you on notice of some of the many apparent breaches of New Zealand law and of deficiencies and mis-representations which undermine fundamental rights of all New Zealanders to give fully informed consent to any medical procedure. The result is considerable risk for the Crown, for the public representatives involved and accordingly for the public of New Zealand.

In summary some of the most serious concerns are:

1. "Comirnaty" has only "provisional consent" in New Zealand under s23(1) of the Medicines Act. This means it can lawfully be used only "*for treatment of a limited number of patients*".

   Section 23(1) states: **Section 23 Minister may give provisional consent**

   (1) "*Notwithstanding sections 20 to 22, the Minister may, by notice in the Gazette, in accordance with this section, give his provisional consent to the sale or supply or use of a new medicine where he is of the opinion that it is desirable that the medicine be sold, supplied, or used on a restricted basis* ***for the treatment of a limited number of patients****.* [emp added]".

   This provisional consent is subject to 58 conditions which are set out in the relevant gazette notice[1].

   Media releases confirm the securing of "*over 10 million doses. That's enough for all of New Zealand"* and the NZ Government advertisement of its rollout plan "for the injection of all New Zealanders" (most of whom are healthy and at no immediate or significant risk from COVID-19). The proposed scale of use is well outside the scope and purpose of a s23(1)

[1] https://www.medsafe.govt.nz/COVID-19/Comirnaty-Gazette.pdf

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provisional consent. Further it is difficult to imagine how exposing healthy individuals to the risks inherent in any novel medication (and particularly one using novel technology that only recently started safety and efficacy trials) could possibly comply with any responsible risk/benefit assessment. The public interest in exposing frail and immuno-compromised individuals to an experimental new medicine with only provisional consent is even more questionable, as the safety trials were limited to healthy individuals. Surely a more precautionary approach can be adopted and New Zealanders can be protected in more orthodox ways, (rather than all in effect being guinea pigs in a world wide experiment), especially as there is no imminent threat from COVID-19 in New Zealand and so no urgency.

2. The agenda for the meeting of Medsafe's Medicines Assessment Advisory Committee on 2 February 2021 states that approval would be sought for provisional consent for Comirnaty as a **"prescription only"** medicine. Curiously the "prescription only" restriction is omitted from the subsequent gazette notice. It is unclear if this omission is an error or was deliberate.

   If the proposed "**prescription only**" classification was overlooked by Medsafe, the expert advisors and the responsible Ministers in error, please confirm how and when this will be rectified, including what steps will be taken to ensure that in future only health practitioners who are qualified to use prescription only medicines and familiar with Comirnaty, treat patients with this novel vaccine.

   If this was a deliberate omission, please urgently provide the evidence and assumptions relied on and the reasons why:

   a) this novel vaccination with only provisional consent was exempted from usual Medicines Act assessments and classification and
   b) why it has fewer restrictions on its use than many other far less novel and more tested vaccines, such as the MMR vaccine and influenza. I note that in the case of the influenza vaccine a documented process was followed before pharmacists with specialised training were authorised to give the influenza vaccine.
      Surely this type of delegation away from a medical practitioner is inappropriate in the case of the novel Pfizer vaccine where the New Zealand and international advisory data sheets identify numerous clinical decisions and medical judgment calls for doctors and patients, with limited if any supporting research[2].

3. The NZ government has engaged in a substantial media and publicity campaign involving PR advice, numerous press releases and advertisements in newspapers, TV and on the radio to market "the Pfizer vaccine". The claims includes representations that the Pfizer vaccine:

   a) Is "safe and effective".
   b) "It's safe. It has been approved by our own Medsafe experts..."
   c) "It's effective"
   d) "The more of us who get vaccinated the safer and stronger we will be"
   e) "It's free. The vaccine will be free for everyone in the country…"

4. In fact, there is no reliable evidence that this novel Pfizer vaccine is "safe" or "effective," at least not in the sense commonly understood by the public. To the public "safe and effective"

[2] https://medsafe.govt.nz/profs/class/ReclassificationOfVaccines.asp

means it will not cause any significant short or long-term harm to anyone who receives it, and it will prevent infection, symptoms and transmission. In relation to the claim that it is "free", while individuals may not be personally charged when they receive a vaccine, it comes at very considerable cost to New Zealand taxpayers, including payments and/or other consideration to Pfizer the details of which have been withheld from the public. In addition, documentation provided under the Official Information Act confirms that the Minister of Finance approved an ad hoc indemnity for the supplier (Pfizer), under the Public Finance Act, in September 2020 (indicating a lack of confidence by Pfizer in the safety of its own product), to induce Pfizer to supply to New Zealand. Further the public of New Zealand will at least indirectly fund any vaccine injury claims that are accepted by ACC. Individuals who are unable to get ACC cover, will bear their own costs for medical treatment and any loss of income.

Particulars:

a. Medsafe have given only "provisional consent" under s23(1). This is subject to 58 conditions. No information is available for the public or their advisors to assess compliance with these conditions. The advertised timing of rollout in the government's vaccination rollout plan means that most of these conditions will not be met until after the three of the four groups of adult New Zealanders identified in the plan have already been vaccinated.
b. Even full Medsafe approval does not warrant the "safety or efficacy" of a new medicine. Section 20(3) of the Medicines Act states:
"No consent given under this section shall be deemed to warrant the safety or efficacy of the medicine to which the consent relates".
It is accordingly misleading and deceptive for the government to suggest in its advertising that this Pfizer vaccine has Medsafe approval at all, let alone that Medsafe approval can be relied on to show this new vaccine is safe.
c. US clinical (safety) trials will not be completed until 2023;[3]
d. There have been no animal or human challenge studies for this vaccine despite serious safety problems being identified in animal challenge studies for previous experimental coronavirus vaccines;
e. The US clinical trials test only healthy individuals, whereas the people most at risk from Covid are those who are frail, and have underlying medical conditions or compromised immunity. There have been no independent safety trials on frail or immune suppressed people.
f. The Pfizer Vaccine is not FDA approved. It has only Emergency Use Authorisation in the USA. This is confirmed by the US FDA Data Safety Sheet[4]
g. The Pfizer vaccine has only Emergency Use Authorisation in the EU[5]
h. Pfizer itself clearly is not confident that Comirnaty is "safe and effective" as it required an indemnity from the New Zealand government before it would supply this product to New Zealand.

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[3] https://clinicaltrials.gov/ct2/show/NCT04368728

Official Title:	A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-C RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS
Actual Study Start Date :	April 29, 2020
Estimated Primary Completion Date :	August 3, 2021
Estimated Study Completion Date :	January 31, 2023

[4] https://www.fda.gov/media/144413/download

[5] https://www.ema.europa.eu/en/news/ema-recommends-first-covid-19-vaccine-authorisation-eu

i. This representation that this experimental vaccine is safe is particularly egregious taking into account that people trust and depend on the government to give factual and balanced information. Extra care is surely required because healthy people who are at no apparent risk from COVID-19 are being asked to accept an experimental barely tested vaccine that uses novel technology. The data sheet and clinical trials highlight the absence of research to establish safety for people who are already frail, ill or immunosuppressed (who are the very people most at risk if exposed to COVID-19), women who are pregnant, people on medications, people who have recently had other vaccines, and people with allergies. This representation of safety in the government advertisements is in direct conflict with the key documentation and is contrary to the warnings of many international experts, to the precautionary principle and to the fundamental tenant of medicine of "First Do No harm."

j. Re effectiveness- (i) Nobody knows how long the Pfizer vaccine will provide protection to those who are injected as no medium to long term research has been done; and (ii) as other government information states[6] "we don't yet know if it will stop you from catching and passing on the virus."

k. The claim "*when we roll up our sleeves we are helping to protect all of us"* creates the inference that the Pfizer vaccine will prevent the transmission of COVID-19 from one person to another. There is no evidence to support this claim. Even Pfizer itself does not claim that the vaccine prevents the transmission from one person to another. Some experts are concerned that the vaccine will create an additional threat to the community by creating more asymptomatic carriers who may spread a virus they don't know they have.

l. With past attempts at coronavirus vaccines serious problems emerged with animal challenge studies. With COVID-19 vaccine development there have been no animal challenge studies and human challenge studies are only just commencing[7].

m. The government advice is inconsistent with the best of the available evidence including the clinical trials. It appears that the phrase "Safe and effective" has been chosen as part of a PR "spin" campaign and is being given a meaning that is different from its common meaning, apparently to improve consumer acceptance of a novel and barely tested vaccine.

5. New Zealand law is clear that no medical treatment is mandatory. The government has confirmed this in Official Information responses. Consistent with this, the Health and Disabilities Act and its Code of Patient Care requires that all health and disability services must comply with certain minimum standards of patient care, including providing adequate information to patients so they can make informed decisions. The principle of "informed consent" is fundamental. This requires information about risks, benefits and uncertainties as well as alternatives, and also that decisions are freely made, without duress.

   This obligation on health care providers and this fundamental right of all patients who received treatment, is breached if information provided about a treatment is inadequate to identify risks, uncertainties or benefits and particularly if it is misleading or deceptive. The information on "informed consent" given out at the time of Co-vax is grossly deficient to facilitate informed consent, and is very superficial compared to information provided to recipients in other jurisdictions. Despite warning patients not to take the vaccine if they are allergic to any of its ingredients, the New Zealand patient information uses only the trade name of the active ingredient. This means ingredients included in the active ingredient such

[6] Getting Your COVID-19 vaccine: what to expect published by Ministry of Health

[7] https://blogs.bmj.com/bmj/2021/01/08/human-challenge-trials-of-covid-19-vaccines-still-have-much-to-teach-us/

as Polyethylene Glycol "PEG" which is known to cause allergies and potentially life threatening anaphylactic shock are not disclosed to prospective recipients.

6. The misleading information and public hype and pressure is inciting breaches of employment contracts. Employees have clear legal rights. They cannot be lawfully required to accept an experimental vaccine with only provisional consent and limited safety or efficacy testing, for a disease that most are highly unlikely to ever be exposed to, and which for healthy people has a very high recovery rate. It is difficult to imagine why any employer would demand this, especially when there is no evidence this vaccine prevents infection or transmission. Despite this, some employers are threatening employees with dismissal or reduced hours if they do not receive this experimental vaccine.

7. Similarly the Health and Safety at Work Act requires employers to identify and manage all risks. This must include the risk of adverse effects from receiving an experimental vaccine, and workplace stress for employees who are pressured to accept a vaccine that they oppose for medical, ethical or other reasons. Despite these clear obligations there are many reports of some employers threatening staff with dismissal or reduced hours if they do not accept the Pfizer vaccine. There will inevitably be health and safety claims against employers who required or encouraged employees to accept this experimental vaccine if they suffer vaccine injury. Claims of this type are already being discussed. In addition to the obvious human rights and employment breaches, this type of conduct is irrational in the absence of evidence that this vaccine prevents transmission.

8. There is significant risk of consequential harm due to reliance on misleading and unjustified assurances that the vaccine is approved by Medsafe and is safe and effective. Another example of this is the threat to the integrity of our bloodbank. This website at www.nzblood.co.nz states that no standdown is required for the Pfizer BioNTec vaccine as it is "approved by Medsafe". In fact it has only provisional consent for treatment of a limited number of patients. Clearly the consequences could be wide-ranging if our national blood supply becomes contaminated by novel mRNA.

9. The matters identified include apparently serious breaches of the Medicines Act, Fair Trading Act, the NZ Bill of Rights Act and public law principles of decision making. There are also apparent breaches of the fiduciary duties owed by our elected representatives to the public of New Zealand. The cumulative effect of the many breaches significantly reduces the level of protection for patients that was intended by the hierarchy and statutory scheme of Medicines Act. These risks to individuals and the community could have been avoided if the law, best practice well-established procedures for assessing medicines, and common sense had prevailed over hype.

10. The result is a serious threat to the rule of law, fundamental human rights of New Zealanders, public health and wellbeing and trust in government. There is also potentially very significant economic risk, especially if any of the warnings of international experts about this experimental vaccine triggering auto-immune or other adverse reactions are correct or if it facilitates the spread of COVID-19 by creating asymptomatic carriers.

11. My clients and the public of New Zealand expect and require an urgent response. This will likely need to include:

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a) an agreement the Crown will immediately suspend the vaccine rollout until the outstanding legal issues are addressed, and the law and statutory scheme for new medicines with provisional consent can be fully complied with. This means that Comirnaty should be treated as a prescription only medicine that can be used only to treat a limited number of patients;
b) an immediate end to the current misleading advertisements and corrective advertising to address misleading and deceptive claims that have already been made, and to facilitate fully informed consent for any future patients who might be offered Comirnaty; and
c) promotion of more orthodox ways the public can enhance their immunity and protect themselves against COVID-19 to promote individual empowerment. This will help people become more resilient and move on from this current climate of fear, propaganda and uncertainty, and start to reclaim individual sovereignty and optimism about the reinstatement of once well-established New Zealand freedoms, lifestyle and culture.

12. I would be very happy to discuss possible ways forward with you in a personal meeting, or by phone or email. In the first instance please email to acknowledge receipt and confirm your intentions.

13. If we cannot reach a satisfactory resolution, at least in principle, by 5 pm Tuesday 5th April, my clients have instructed me to file urgent proceedings seeking appropriate interim and final declarations and orders. We will then need to discuss a timeframe to facilitate these important questions being put before the court as a matter of urgency.

Thank you for your prompt action and attention.

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