Has the Crown really demonstrated that the limitation on the *Right to Decline Medical Treatment* was reasonable and demonstrably justified?

Part 4: Safety and Collateral Damage

The government and media narrative has consistently proclaimed that the Pfizer vaccine is 'safe and effective'. But what does this mean? Just how safe is safe?

The answer to this question can be easily determined with reference to two current Medsafe documents:

- The Risk Management Plan (RMP) is a document that may be requested by Medsafe as part of the application for a new medicine. It details important risks, how these risks can be minimised, and the various uncertainties due to 'missing information'.
- The 'Data Sheet' is a document that the manufacturer of the medicine (in this case Pfizer) must produce that describes for medical professionals and consumers, among other things, the various unknowns, and risks with their product.

So, what do these two official documents tell us about the safety of Pfizer's Comirnaty vaccine?

Risk Management Plan (version 8)

This was updated sometime after 5 February 2023, and contains the following safety information:

1. **Identified risks** are concerns for which there is sufficient proof of a link with the use of the medicine. Currently these are:
   - Myocarditis
   - Pericarditis
   - (Anaphylaxis also used to be on this list until at least Mar 2022)
2. **Potential risks** are concerns for which an association with the use of this medicine is possible based on available data, but this association has not yet been established and needs further evaluation. These are:
   - Vaccine-associated enhanced disease (VAED)
   - Vaccine-associated enhanced respiratory disease (VAERD)
3. **Missing information** refers to information on the safety of the medicinal product that is currently missing and needs to be collected. The following are listed:
   - Use in pregnancy
   - Use while breast feeding
   - Use in immunocompromised patients
   - Use in frail patients with co-morbidities
   - Use in patients with autoimmune or inflammatory disorders
   - Interaction with other vaccines
   - Long term safety

So, despite all the confidence that has been expressed concerning the safety of the vaccine in pregnancy, while breast feeding, in the frail elderly, in those with autoimmune or inflammatory

disorders, and in the long-term – the manufacturer makes no such claim, but plainly states that more information is required before the safety in these situations can be assured.

The Risk Management Plan lists a number of studies that are currently underway to provide additional data. The completion dates for the studies looking at long-term safety range from December 2023 to December 2026.

It is unconscionable that the Government can express confidence in the safety of the vaccine before these critical studies are completed. It is of concern that in the absence of this safety data, the courts would consider it *demonstrably justified* to mandate the vaccine.

New Zealand Data Sheet

This was revised on 5 January 2023.

As if the Risk Management Plan wasn't bad enough, the current New Zealand Data Sheet for the Pfizer vaccine contains even more information on important safety risks. For example:

Myocarditis and pericarditis

"Cases of myocarditis and pericarditis following vaccination have rarely been associated with severe outcomes including death. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis, including atypical presentations. Vaccinees should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination. Non-specific symptoms of myocarditis and pericarditis also include fatigue, nausea and vomiting, abdominal pain, dizziness or syncope, oedema and cough."

Duration of protection

"The duration of protection afforded by COMIRNATY is unknown as it is still being determined by ongoing clinical trials."

Use in the elderly

"The data for use in the frail elderly (>85 years) is limited. The potential benefits of vaccination versus the potential risk and clinical impact of even relatively mild systemic adverse events in the frail elderly should be carefully assessed on a case-by-case basis."

Fertility

"In a combined fertility and developmental toxicity study, female rats were intramuscularly administered COMIRNATY prior to mating and during gestation (4 full human doses of 30 µg each, spanning between pre-mating day 21 and gestation day 20). SARS-CoV-2 neutralising antibodies were present in maternal animals from prior to mating to the end of the study on postnatal day 21 as well as in fetuses and offspring. There were no vaccine related effects on female fertility and pregnancy rate." [Note: this is referring to female rats not women]

Pregnancy

"There is limited experience with use of COMIRNATY in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition or post-natal development. Administration of COMIRNATY in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus."

Lactation

"It is unknown whether tozinameran is excreted in human milk. A combined fertility and developmental toxicity study in rats did not show harmful effects on offspring development before weaning (see Section 4.6 Fertility, pregnancy and lactation, Fertility)."

Genotoxicity/Carcinogenicity

"Neither genotoxicity nor carcinogenicity studies were performed. The components of COMIRNATY (lipids and mRNA) are not expected to have genotoxic potential."

Informed consent is one of the cornerstones of medical ethics. If the information in either one of these documents had been fully explained, it is likely that many New Zealanders would have refused the vaccine if given a choice.

If there are known risks and a procedure is mandated, some people are going to be harmed or suffer as 'collateral damage'. How does the court weigh this up and should there have been a public discussion about how much collateral damage was acceptable?

Did Justice Cooke consider the information in these two government documents – demonstrable risk and lack of conclusive studies on fertility, pregnancy, lactation, genotoxicity and carcinogenicity – when finding that the vaccine mandates were reasonable and justified?