THE NEED FOR TRUE INFORMED CONSENT FOR THE PFIZER COMIRNATY COVID-19 VACCINATION

OPEN LETTER from NZDSOS | FOR URGENT RELEASE - 14 June 2021

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As registered medical & dental practitioners we have a legal, ethical and trusted duty of care towards our patients. We are extremely concerned that the current Ministry of Health (MOH) publicity and 'Informed Consent' documentation on the Covid-19 ‘vaccination’ compromises this responsibility. We see that it misinforms the public, as it fails to declare many of the known risks associated with this ‘vaccine’ and the limits in our knowledge of the 'vaccine' due to its incomplete testing and its new mechanism of action.

Specifically, the MOH 'Informed Consent Documents' fails to inform the public the following:

That the 'Covid-19 vaccine' uses a fundamentally different approach from any other vaccine the public are familiar with, namely the vaccine is a biological agent classified as gene therapy and even calling it a vaccine is misleading, as its method of action is so different from past vaccines.

These differences are highlighted by the many aspects of the Covid-19 vaccine which are unprecedented for a vaccine deployed for use in the general population and include that this vaccine is:

I. First to use mRNA-vaccine technology against an infectious agent,

II. First to use PEG (polyethylene glycol) in an injection,

III. First to have public health officials telling those receiving the vaccination to expect an adverse reaction,

IV. First to be implemented publicly with nothing more than preliminary efficacy data,

V. First vaccine to make no clear claims about reducing infections, transmissibility, or deaths,

VI. First coronavirus vaccine ever attempted in humans,

VII. First injection of genetically modified polynucleotides in the general population.

https://ijvtpr.com/index.php/IJVTPR/article/view/23/49

- That there are inherent risks with using untested new technology.
- That the specific and significant COVID-19 risk of vaccine-elicited enhancement of disease also called Antibody Dependant Enhancement (ADE) should have been and should be prominently and independently disclosed to research subjects currently in vaccine trials,

as well as those being recruited for the trials and future patients after vaccine approval, in order to meet the medical ethics standard of patient comprehension for informed consent. N.B. As confirmed by the manufacturer, the Pfizer Comirnaty agent is still being studied in clinical trials and only has Medsafe provisional consent, the full facts on the product's safety and efficacy are not yet known. Pre-market testing and post-market surveillance are being carried out simultaneously, therefore every inoculated individual is part of said clinical trials due for completion 2 May 2023.

https://clinicaltrials.gov/ct2/show/NCT04368728
https://pubmed.ncbi.nlm.nih.gov/33113270/

- That there is a major difference between relative risk and absolute risk figures. When informing a member of the public of the risks and benefits of Covid-19 vaccination, it is critical that the use of relative risk figures needs to be accompanied with the context of absolute risk figures as without this the public are given a very misleading impression of the facts. Members of the public need to be informed in such a manner that they can understand whether a Covid-19 vaccination provides a net meaningful risk reduction or not, after balancing all risks and benefits. For more information see: COVID-19 vaccine efficacy and effectiveness—the elephant (not) in the room.

  https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(21)00069-0/fulltext

- That USA(VAERS) and European (EudraVigilance) databases on adverse vaccine reactions are showing markedly higher injury and death rates, compared to the familiar seasonal flu vaccine. The public must be provided with accurate factual information on the rates of death and serious side effects from the Covid-19 vaccine, in both absolute and relative terms compared with familiar vaccine rates of death and serious side effects and currently they are not being given this information.

- That their risk from Covid-19 infection itself has dropped significantly from early estimates and that the most recent published average global Infection Fatality Rate (IFR) of COVID-19 of approx. **0.15%** is very close to that of the seasonal influenza of **0.1%**.

  https://doi.org/10.1111/eci.13554
  https://www.bmj.com/content/371/bmj.m3883/rr

- That a mass vaccination of the population, especially with an experimental agent, is not supported by a risk/benefit analysis since the risk of Covid-19 varies significantly by age group according to the most recent CDC estimates. As of 19 March 2021:

  INFECTION FATALITY RATE (IFR) OF COVID-19
  The best estimate is:
  0-17 years: 0.002% so survival rate is 99.998%
  18-49 years: 0.05% so survival rate is 99.95%

50-64 years: 0.6% so survival rate is 99.4%
70+ years: 9% so survival rate is 91% (This is the group at higher risk)
We also now have very effective treatments for COVID-19.

https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html

- That the current mass vaccination programme and MOH informed consent process does not take into account individuals who have already been exposed to SARS-CoV-2 and developed natural immunity. People with evidence of past infection were excluded from the initial trials. Research has proven that contracting the virus can give people cells that "produce antibodies for the rest of people's lives" against the SARS-CoV-2 virus and that the presence of such antibody cells is "*strong evidence for long-lasting immunity*" against COVID-19, if one has been previously infected. Such individuals do not benefit from the Pfizer vaccine while they incur the risks.

  https://www.nature.com/articles/s41586-021-03647-4

- That the Pfizer Comirnaty only provides incomplete and temporary protection so that vaccinee will need booster shots within a year afterward, and then annual vaccinations, to maintain protection against the virus as it evolves. Vaccinated individuals may still become infected and transmit the virus via the upper respiratory airway.

  https://www.wsj.com/articles/annual-covid-19-vaccine-booster-shots-likely-needed-pfizer-ceo-says-11618520527

  https://pubmed.ncbi.nlm.nih.gov/33320052/

- That the manufacturer, Pfizer, does not accept any liability for their product, and the financial burden of adverse effects is transferred to the patient and the taxpayer. *(On 22 Nov 2020 Grant Robertson, Minister of Finance, on behalf of the Crown, gave an indemnity to Pfizer Inc and BioNtech and associated persons in relation to the supply of the COVID-19 vaccine - Statement of Indemnity under section 65ZD of the Public Finance Act).*

- That there are alternative means to reduce the risk of harm from Covid-19. That these approaches could be listed as options for those members of the public who wish to avoid the Covid-19 vaccine or to allow more time for the benefits and risks of the Covid-19 vaccine to be revealed. e.g. optimising individual immunity through lifestyle recommendations including correcting any deficiencies in key nutrients such as zinc, vitamin C and D. The value of using repurposed medication such as oral corticosteroids, budesonide, Ivermectin etc. for the prevention and/or treatment of Covid-19 must be considered.

  https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8088823/

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The current MOH consent form and related COVID-19 information pamphlet titled “What to Expect” does mention the risk of severe allergic reaction to the Pfizer-BioNtech product but fails to explain one cause of such severe adverse reaction is the ingredient polyethylene glycol that the manufacturer added to their product in 2020, in spite of published evidence of severe adverse reactions caused by polyethylene glycol being available 4 years earlier.

https://aacijournal.biomedcentral.com/articles/10.1186/s13223-016-0172-7

Then, the manufacturer, Pfizer-BioNtech took specific steps to exclude people with a history of severe allergic reactions in their pre-EUA clinical trials. We quote: *“Participants with a “history of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)” were not included in the pool of 44,000 trial volunteers.”*

According to the US Food and Drug Administration's evaluation of the Pfizer data, there was a slight increase in events that may be considered allergic reactions in the vaccine group.

https://edition.cnn.com/world/live-news/coronavirus-pandemic-12-09-20-intl/h_41ebb700c038314dbe06b53dc9580392

Once mass vaccination started, predictably, severe allergic reactions (anaphylaxis) began to occur and William Gruber, Pfizer’s senior vice president of vaccine clinical research and development said at a regulatory conference: “*We’ve not had any anaphylactic episodes related to the vaccine*.” as if such severe adverse events were unexpected....

https://www.reuters.com/article/us-health-coronavirus-vaccines-cdc-idUSKBN28L2Q8

Such actions affect on the credibility of the manufacturer, and this needs to be taken into consideration when formulating informed consent information for our patients.

Currently, in the MOH Consent Form and related documents:

https://www.health.govt.nz/system/files/documents/information-release/h202101370_12_march_2020_covid_vaccine_information_to_recipents.pdf

only list the following adverse effects for the Pfizer-BioNtech Comirnaty:

- Pain at the injection site,
- Headache,
- Feeling tired and fatigued
- Muscle aches
- Feeling generally unwell,
- Chills,
- Fever,

- Joint pain,
- Nausea.

Serious allergic reactions can occur but are extremely rare.

If we compare this with the information provided by Pfizer on their webpage: THE FACTS ABOUT THE PFIZER-BIONTECH COVID-19 VACCINE https://www.pfizer.com/news/hot-topics/the_facts_about_pfizer_and_biontech_s_covid_19_vaccine

we find significant discrepancies:

Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:

- Severe allergic reactions,
- **Non-severe allergic reactions such as rash, itching, hives, or swelling of the face,**
- Injection site pain,
- Tiredness,
- Headache,
- Muscle pain,
- Chills,
- Joint pain,
- Fever,
- Injection site swelling,
- Injection site redness,
- Nausea,
- Feeling unwell,
- **Swollen lymph nodes (lymphadenopathy)**

- **Diarrhoea**
- **Vomiting**
- **Arm pain**

These may not be all the possible side effects of the Pfizer-BioNTech COVID-19 Vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech COVID-19 Vaccine is still being studied in clinical trials.

We have **highlighted above** in bold print the additional information provided by the manufacturer. Notwithstanding the credibility issue mentioned above about Pfizer, the MOH is not only omitting adverse effects from their Informed Consent documents but that they are also downplaying the potential severity of such effects and are failing to warn the public about the experimental nature of the product.

Since mass COVID-19 inoculations began, numerous reports of severe adverse effects have been issued and published research has confirmed Pfizer's warning about additional "**serious and unexpected side effects"** of their COVID-19 gene therapy, including vascular, immune and neurological sequelae with sufficient severity to cause death.

It has been well established that once a person is injected with the Pfizer Cominarty agent (synthetic mRNA encapsulated in lipid nanoparticles - LNP), the host cells of the inoculated individuals begin to produce the SARS-CoV-2 Spike proteins. The manufacturer's own animal study shows that the LNP do not remain at the injection site and are found in various organs of test animals. Using the enzyme luciferase as well as radioactive labelling to track the LNP, Pfizer found that: "*Locally administered luciferase RNA-encapsulated LNP circulates in the liver... When the radioactivity-labeled body of ZeRNA-encapsulated LNP was intramuscularly administered, the radioactivity concentration was the highest at the administration site...Other than the site of administration, it was highest in the liver, followed by the spleen, adrenal glands and ovaries*."

https://www.pmda.go.jp/drugs/2021/P20210212001/672212000_30300AMX00231_I100_1.pdf

https://www.naturalnews.com/files/Pfizer-bio-distribution-confidential-document-translated-to-english.pdf

This fact is in direct contradiction to the often repeated assumption that because COVID19 vaccines are injected into the deltoid muscle, they are taken up by muscle cells so that the vaccine remains largely contained near the site of injection.

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Recently published scientific evidence has contradicted other claims such as:

- The spike proteins from the vaccine are anchored to the host cells so do not circulate freely in the blood stream.
- The spike proteins from the vaccine are a fixed target for the immune system to recognise this foreign protein.
- The spike proteins from the vaccine are inactivated so cannot bind to ACE2

Published 20 May 2021, a study titled "Circulating SARS-CoV-2 Vaccine Antigen Detected in the Plasma of mRNA-1273 Vaccine Recipients" proved that the vaccine-generated spike proteins do not necessarily remain attached to the host cells and rather freely circulate in the blood of individuals who have received one or two mRNA gene therapy injections. Free SARS-CoV-2 Spike Protein S1 Particles that allows the spike proteins to bind to ACE2 are also present.

https://pubmed.ncbi.nlm.nih.gov/33838638/

The authors comments are revealing: "*We hypothesize that the cellular immune responses triggered by the T-cell activation, which would occur days after the vaccination, lead to the direct killing of cells presenting spike protein and an additional release of spike into the blood stream. The mechanisms underlying release of free S1 and the subsequent detection of the intact spike protein remain unclear and require further studies*."

https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab465/6279075

Nature does not always conform to human design so there is obviously a lot more to be learned about this experimental gene therapy agent and the way it works in different individuals with their particular combination of genetic polymorphisms, pre-existing health conditions and level of immunity so that pre-emptive claims of safety based on incomplete data and assumptions should be examined in that context.

It has now been proven that the spike proteins are implicated in the pathophysiology of COVID-19 and can, *independently of the virus*, induce inflammation, clot formation, heart, lung damage and other pathological changes as well as induce the production of antibodies.

https://www.biorxiv.org/content/10.1101/2020.12.21.423721v1.abstract

https://www.medrxiv.org/content/10.1101/2021.03.05.21252960v1

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7547916/

https://www.nature.com/articles/s41593-020-00771-8

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We have mentioned above some of the information that needs to be included in an informed consent process that meets our HDC (Health & Disability Commisioner Act) , MCNZ (Medical Council of New Zealand) and NZMA (New Zealand Medical Association) standards. There is very real risk of physical harm arising from the public making misinformed choices based on a not fit for purpose MOH informed consent process.

MOH publicity and related mainstream media reporting in regards to Covid-19 and the Covid-19 vaccine provides the context for their informed consent documentation. Since the information is one sided and does not state the full potential for harm and the significant limitations of the vaccine, the New Zealand public is not truly informed.

We would also like to draw your attention to the *risk of profound and lasting damage to public trust and to the patient-practitioner relationship*, that could be caused by the Ministry of Health and health care professions failing to meet their legal and ethical responsibilities in regard to informed consent for the Covid-19 vaccine.

In the past, the 'Unfortunate Experiment' and the Cartwright Enquiry have given us an indication of the outfall from just one doctor's breach of trust.

Delivering a vaccine based on a new mechanism of action with incomplete testing, unbalanced MOH/government advertising and inadequate informed consent, carries a risk of betrayal of public trust, which is pervasive and damaging.

In summary, the current unbalanced and incomplete MOH Covid-19 vaccine marketing campaign and informed consent process are putting the New Zealand public and the health care professions at risk. The intense one-sided pro-vaccine advertising campaign is operating as a media-driven vaccine-consent-coercion process . Coerced consent is not the same as legally and ethically required informed consent.

We request that you require the MOH to alter their 'Informed Consent Procedure', including MOH/government Covid-19 media and other advertising, to meet the legal and ethical standards required by the HDC Act and as outlined in the MCNZ and NZMA guidelines on Informed Consent.

https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/

https://www.mcnz.org.nz/assets/standards/79e1482703/Statement-on-informed-consent.pdf

https://www.nzma.org.nz/news/revised-code-of-ethics-now-available

Sincerely.

NZ Doctors Speaking Out with Science

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Documents attached:

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MOH Documentation for Informed Consent – Pfizer BioNtech Comirnaty as provided under the Official Information Act 1982 by Matthew Parr – Programme Director, COVID-19 Immunisation. Covid-19 Health System Response. See list below.

#	Date	Title	Decision on release
1	19 February 2021	COVID-19 vaccination consent form	Released in full
2	15 February 2021	COVID-19 vaccine: what to expect	Released in full
3	16 February 2021	After your immunisation	Released in full
4	19 February 2021	Privacy Statement	Released in full
5	N/A	Information provided to vaccinators about obtaining informed consent	Released in full