

AFFIDAVIT OF DR ALISON JANE GOODWIN

I, Alison Jane Goodwin, a medical doctor of Hawkes Bay, New Zealand swear:

1. I am a medical doctor with the qualifications MBChB Otago 1993, FRNZCGP 2015. I have also recently become board certified in Lifestyle Medicine (2020), the purpose of which is to create health by optimising the foundations of health (nutrition, exercise, sleep and stress management). I have practiced medicine since 1993.
2. I have read and understand the High Court Code of Conduct for Expert Witnesses. I have complied with it in all respects when preparing my evidence.
3. As part of my training and practice I am required to assess the health of patients and provide advice on treatments including medicines. Part of my work includes being aware of the potential benefits and side effects of medicines and discussing these, along with other options a person may have so they can make informed decisions about their own care. This is known as "Informed Consent".
4. Informed Consent is fundamental to the practice of medicine, and doctors' obligations under the *Code of Health and Disability Services Consumers' Rights* are fundamental to patients' rights. The Code requires that patients be made aware of and understand the possible risks and benefits of any medical treatment, and any uncertainties, as well as alternative options, so they can make an informed decision as to whether to accept that treatment or not. I attach this Code as **Exhibit "A1"**.
5. Different people will react to the same medicine in different ways depending on their genetics, their current state of health, lifestyle factors (such as smoking, alcohol, nutrition, stress) and interactions with other medications they may be taking. A person's view of health and wellbeing will also be relevant in determining whether a person consents to a particular treatment. It is important to take these *individual* factors into account. This is why medicine is an art as much as a science.

Covid-19 Origins

6. During early 2020 a new disease known as Covid-19 was a frequent headline news item. Covid-19 was first reported in Wuhan, China and was reported to be causing death to a significant number of those it infected. There were reports of severe illness and easy spread of infection between people.
7. In January 2020 Covid-19 was classified by Public Health England as a High Consequence Infectious Disease, alongside diseases such as Ebola Virus, Lassa Fever, Avian Influenza H7N9 and H5N1 and H5N6 and H7N7, Monkeypox, Pneumonic Plague and Severe Acute Respiratory Syndrome (SARS).

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8. On 19 March 2020, the UK government on the advice of the Advisory Committee on Dangerous Pathogens (ACDP) removed Covid-19 from the list of High Consequence Infectious Diseases. The reasons for this state that as more information became known several features changed "*more information is available about mortality rates (low overall), and there is now greater clinical awareness and a specific and sensitive laboratory test, the availability of which continues to increase*". I attach a relevant gov.uk webpage explaining the classification status of Covid-19 as **Exhibit "A"**.

Covid-19 in New Zealand

9. The first case of Covid-19 in New Zealand was reported on 28 February 2020. I attach a copy of a press release is as **Exhibit "B"**.
10. New Zealand developed a strategy to close its borders and "flatten the curve" to manage the spread of Covid-19 in New Zealand. Initially the objective was to avoid overloading hospitals and intensive care facilities and the demand on ventilators. As medical professionals became more expert at managing Covid-19, a variety of effective treatments were identified and best practice was to avoid using ventilators.
11. New Zealand adopted a range of strategies including an intensive public health education campaign, testing suspected cases, contact tracing, quarantine of persons who tested positive, a series of national and regional lockdowns and closing New Zealand's borders to most non-New Zealanders.
12. On 8 May 2020 New Zealand changed its strategy from managing Covid-19 to eliminating Covid-19. I attach a copy of the Ministry of Health Covid-19 Elimination Strategy is as **Exhibit "C"**.
13. In total, as at 1 Apr 2021, there have been 2145 reported 'cases' of Covid in New Zealand and 26 deaths with Covid. <https://nzcoviddashboard.esr.cri.nz/#/> Since May 2020 almost all these cases were people who had travelled from overseas who were detected using PCR testing at MIQ quarantine facilities. This is a death rate of just 1.2% from the limited number of cases. I understand there have been only five deaths recorded with Covid in New Zealand since May 2020. Covid-19 does not meet the definition of an "epidemic" in New Zealand. Worldwide the death rate is well below 1% for the overall population, with much lower rates in the young and higher mortality rates in the elderly. I attach the New Zealand Immunisation Handbook with more epidemiological data as **Exhibit "D"**.
14. The definition of a 'case' needs consideration. Historically when diagnosing a disease, a medical practitioner would listen the history of the patient to elicit the symptoms, then conduct an examination to determine the signs of disease. Sometimes this would be sufficient but if more information were needed, one or more tests may be done. With Covid-19 a positive PCR test appears to be sufficient to diagnose a disease regardless of whether a person has any clinical

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features of disease. This means that people without symptoms are potentially being counted as Covid cases.

15. From mid-2020 the Prime Minister of New Zealand, the Minister of Health and the Minister for Covid-19 Response advised the public on various occasions that New Zealand was supporting an international Covid vaccine development programme.
16. As a medical practitioner I was surprised and disappointed that the sole focus was on developing a vaccine. This is because there is considerable research showing that people can enhance their immunity by optimising lifestyle factors such as nutrition, exercise, sleep, stress management, sun exposure for vitamin D synthesis, fresh air and social connection. There are also a number of medical treatments being used by doctors overseas with good effect (for example, vitamin D, vitamin C, zinc, hydroxychloroquine, ivermectin and steroids).
17. For the vast majority of people Covid 19 will be an unpleasant but not life-threatening illness. For the elderly or frail or those with other underlying medical conditions it can be a more serious and potentially life-threatening illness. If someone's immune system is too frail to protect them against Covid, they are less likely to develop a protective immune response from the vaccine. Vaccines always carry some risk.
18. There are ethical dilemmas for a doctor to consider when deciding whether to recommend an experimental vaccine to a patient. That is why our Medicine Act 1981 provides for "provisional consent" to allow a new medicine that has not completed safety and efficacy testing to be used only for a limited number of patients. The dilemma is more significant when one is advised to recommend that a healthy patient take an experimental medicine to try to prevent a condition that is extremely unlikely to cause them any serious harm.
19. Even if a medicine has full approval, each case must be assessed on its merits, taking into account the patient's general state of health, any particular risk factors for the patient, the patient's personal views and any relevant ethical beliefs. My starting point is the principle of "First Do No Harm" which requires me to be cautious and avoid experimental treatments unless they are justified and the patient understands the risks and gives informed consent.
20. I am very concerned that the government's extensive media campaign has oversold the benefits of this experimental vaccine without making New Zealanders aware that it is still going through clinical trials and nobody can yet be confident about its effectiveness or long-term safety. I am also concerned that patients in some occupations are being threatened with loss of employment unless they agree to accept this experimental vaccine. My interpretation of Informed Consent is that it must be freely given without any compulsion or duress.

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The New Zealand Covid Vaccine programme

21. On 17 December 2020 the Prime Minister and Ministers of Science, Covid-19 Response and Health made a joint announcement that pre-purchase agreements had been secured for two further vaccines and that NZ now had four vaccines with pre-purchase agreements which would provide sufficient doses (15 million courses) to vaccinate the whole population. They also announced that Medsafe processes had been streamlined for timeliness, readiness for the largest ever immunisation campaign was progressing well and systems were on track to deliver the first vaccines to border workers in the 2nd quarter of 2021 with vaccination of the general population in the second half of the year. I attach the Government Press Release dated 17 December 2020 is as **Exhibit "E"**.
22. On 1 February 2021 the New Zealand Medicines and Medical Devices Safety Authority, a division of the Ministry of Health known as "Medsafe", published an agenda for the 2 February meeting of its "Medicines Assessment Advisory Committee". Agenda item 4 is "*Application for consent to distribute a new medicine under s20/23/24 of the Medicines Act 1981*" for Comirnaty (COVID-19 mRNA vaccine) by Pfizer New Zealand Ltd. I attach a copy of the agenda is as **Exhibit "F"**.
23. On 3 February 2020, a "*Provisional Consent to the Distribution of a New Medicine*" notice was published in the Gazette pursuant to s23(1) of the Medicines Act 1981 by Chris James under delegated authority of the Minister of Health, advising of provisional consent for Comirnaty (COVID-19 mRNA vaccine) for nine months to address an urgent clinical need subject to the NZ sponsor fulfilling 58 listed obligations. A copy of this notice is **Exhibit "G"**.
24. A copy of the Medsafe Risk Management Plan is attached as **Exhibit "H"**. A copy of the Australian Public Assessment Report is attached as **Exhibit "HA"**.
25. A document published by Medsafe on 4 February 2021 explains "mRNA vaccines". This is **Exhibit "I"**. "*mRNA vaccines are a new technology being used for preventing COVID-19 infection*" "*mRNA vaccines contain pieces of mRNA that tell the cells in the body how to make a viral protein that will be recognised by the immune system as foreign.*" "*In this case the mRNA contains instructions for the spike (S) protein on the surface of the SARS-CoV-2 virus. The S protein helps the virus enter human cells.*"
26. This type of vaccine which uses mRNA is novel. There is no research to show how long the injected mRNA will continue to promote the manufacture of S protein in a person's body. There are also questions about "truncated and modified mRNA species present in the finished product" and whether these will be translated into "truncated S1S2 proteins/peptides or other proteins/peptides". In addition, Medsafe is awaiting further evaluation of whether there is any similarity between these other potential proteins or peptides and other native human proteins that might cause an autoimmune problem. It is inevitable that different people will react in different ways

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to this vaccine. There is potentially no “off switch” if someone has an adverse reaction. See condition 5 in **Exhibit “G”** above (**Gazette notice**).

27. On 10 February 2021 Medsafe published a summary of recommendations from its meeting of 2 February including the recommendation that the Minister of Health should grant “provisional consent” to distribute Comirnaty (Covid-19 mRNA Vaccine) under s23 of the Medicines Act. A copy of this notice is attached as **Exhibit “J”**.
28. The same day a press release from the Minister for Covid-19 Response, Hon Chris Hipkins, announced that Cabinet had confirmed formal government approval following Medsafe’s recommendation of provisional approval for the use of the Pfizer/BioNTech COVID 19 (Comirnaty) vaccine. He announced a programme to start vaccinating border workers and then the people they live with. I attach a copy of this press release as **Exhibit “K”**.
29. A press release from the Minister of Covid-19 Response dated 18 February 2021 about final preparations for Phase 1 of vaccination rollout is attached as **Exhibit “L”**.
30. The Medsafe website page headed “approval status of Covid vaccines application received by Medsafe” revised 3 March 2021 is attached as **Exhibit “M”**. This refers to the New Zealand data sheet for the Comirnaty (Covid-19 mRNA Vaccine) which is attached as **Exhibit “N”**. Advice from the promoter Pfizer New Zealand to Healthcare professionals for the Comirnaty (Covid-19 mRNA Vaccine) published on the Medsafe website is attached as **Exhibit “O”**.
31. A press release from the Prime Minister and Minister of Covid-19 Response, dated 8 March 2021 advises “The government has guaranteed that every New Zealander will have access to the Pfizer/BioNTech vaccine after securing an additional 8.5 million doses.” “This brings our total Pfizer order to 10 million doses or enough for 5 million people to get the two shots needed to be fully vaccinated against Covid-19”. I attach a copy as **Exhibit “P”**.
32. A publication on the NZ Government Unite Against Covid-19 website is titled “How our Covid-19 vaccine rollout will work”. A copy is attached as **Exhibit “Q”**. This sets a timeline when it is proposed to vaccinate different groups. Group 4 - from July is “everyone”.

Lack Of Informed Consent For New Zealanders

33. In an OIA response attached as **Exhibit “R”**, Mathew Parr, Programme Director Covid Immunisation at New Zealand’s Ministry of Health, responded to a request seeking “copies of information that is required to be given to recipients of Covid-19/SARS/CoV-2 vaccines so that they can make an informed choice before

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deciding whether to have the vaccine or not". His letter (with date redacted) has an Appendix 1 scheduling five documents, which include:

- a. A document headed "Covid-19 Vaccination consent form" is attached as **Exhibit "S"**. This consent form makes no reference to this being a new medicine that has only s23(1) provisional approval or that it is authorised for use only for a limited number of patients.
 - b. A sheet headed "Getting your COVID-19 vaccine: what to expect" states "Medsafe only grants consent for a vaccine to be used in New Zealand once they are satisfied it's safe and effective enough to use..." This public information sheet does not explain that this vaccine has only provisional approval under s23(1) of the Medicines Act. A copy of this is attached as **Exhibit "T"**.
 - c. An advice sheet headed "After your immunisation" is attached as **Exhibit "U"** does not mention that other rarer, not-yet-recognised adverse effects could occur some time after the vaccination event.
 - d. A document titled "Privacy" is attached as **Exhibit "V"**.
 - e. A document headed "Document 5. Information provided to vaccinators about obtaining informed consent" which advises reporting adverse events during and after the post vaccine observation period to The Centre for Adverse Reaction Monitoring ("CARM"). I attach a copy of this document as **Exhibit "W"**.
34. The following information about CARM is available online and I attach here:
- a. **Exhibit "X"** is Medsafe's guide to Adverse Reaction Reporting to CARM.
 - b. **Exhibit "Y"** is the Covid-19 Adverse Event Following Immunisation Form.
 - c. **Exhibit "Z"** is the Covid-19 Vaccine Adverse Event Report (available from nzphvc.otago.ac.nz). This lists a range of different possible adverse events following immunisation and has space for signs and symptoms to be described.
35. It is interesting to compare the information provided to New Zealanders as above with the information prepared for Americans under the USA's Pfizer-BioNTech Covid-19 Vaccine rollout.
36. I attached as **Exhibit "ZA"** a copy of the current "*Fact Sheet for Recipients and Caregivers*" in the USA regarding Emergency Use Authorisation (EUA) of the Pfizer-BioNTech Covid-19 Vaccine for individuals aged 16 years and older. It provides important information about what an Emergency Use Authorisation is, who should not get the Pfizer BioNTech vaccine, (including people who have had a

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severe allergic reaction to any ingredient of the vaccine), a list of the ingredients, and possible risks including severe allergic reactions.

37. It also advises that "serious and unexpected" side effects of the Pfizer BioNTech COVID-19 Vaccine may occur, that it is still being studied in clinical trials, that you have a choice whether or not to receive the vaccine and an explanation that this vaccine has not undergone the same type of review as an FDA-approved or cleared product. There is a recommendation to seek medical advice if you are pregnant or breastfeeding. This is much more detailed information than is being provided to the NZ public about the same vaccine.
38. For example, the New Zealand data sheet does not highlight one of the ingredients more likely to cause an allergic or anaphylactic reaction - polyethylene glycol (PEG). Rather it is listed with its lengthy chemical name under "List of Excipients" where it may not be easily noticed.
39. The US government website <https://clinicaltrials.gov/ct2/show/record/NCT04368728> provides information about the ongoing Clinical Trials for the PfizerBioNTech Covid-19 vaccine. The Sponsor is BioNTech SE, the Collaborator is Pfizer and the Information is provided by BioNTech SE. The official title of this study is "A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS".
40. Under Study Design on the Study Details tab, it states that the study start date was 29 April 2020, the Estimated Primary Completion Date is 3 August 2021 (later changed to 29 October 2021) and the estimated Study Completion date is 31 January 2023 (later changed to 6 April 2023). A copy of this page from the US government clinical trials website on 25 March 2021 is attached as **Exhibit "ZB1"**, and on 7 Apr 2021 is attached as **Exhibit "ZB2"**.
41. Until the full Phase 1/2/3 safety and efficacy study is completed nobody can properly claim this vaccine is safe or effective.

My Main Concerns

42. I am swearing this affidavit because I am extremely concerned about many aspects of this vaccine rollout, particularly the inadequate information provided for prospective recipients to give informed consent.
43. The vaccine is experimental, novel and has not undergone the usual testing required for FDA or New Zealand approval. It only has provisional consent under s23(1) for a limited number of recipients. This is not made clear in the patient information sheets or in the loud media campaign which asserts the vaccine is "safe and effective". An example is the newspaper advertisement attached as **Exhibit "ZC"**.


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44. I am also concerned about government and media pressure implying that people who choose not to receive the vaccine are letting New Zealand down and putting others at risk.
45. The current evidence is that the vaccine may reduce the severity of symptoms (at least for a period of time), and may create asymptomatic carriers, but the Ministry of Health's own documents advise "*However, we don't know yet if it (vaccine) will stop you from catching and passing on the virus*" (annexed above marked "T") and "*Does the vaccine prevent me from transmitting the virus to others? We don't know at this stage.*" The latter from the Ministry of Health document: "Covid-19 vaccine: FAQs Feb 2021" which is attached as **Exhibit "ZD"**.
46. I am also concerned that there is no advice or recommendation to test patients *before* they receive this experimental vaccine to see if they already have antibodies to Covid-19 and so are immune. This is a simple step that could avoid exposing patients (whether healthy or immune compromised) to this experimental injection. Serology tests for other diseases are common in New Zealand.
47. On the contrary, I note that on 22 April 2020 Medsafe prohibited the importation, sale, supply, and use of Covid 19 Point of Care (POC) test kits and materials in New Zealand while work was done on accuracy and reliability. The Medsafe website on 25 March 2021 reported that currently no COVID-19 POC tests kits can be sold or supplied in New Zealand. I attach a copy of this advice from Medsafe as **Exhibit "ZE"**.
48. All medical doctors, including myself are taught medical ethics and are bound by our professional ethics, Medical Council of New Zealand guidelines and the *Code of Health and Disabilities Services Consumer's Rights*. These require us to a) "First Do No Harm", b) ensure that patients give informed consent to any medical procedure and c) ensure patients are aware that they have the right to decline a medical treatment.

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49. I do not believe it is possible for patients to give informed consent to receiving this experimental vaccine if they are told it is "safe and effective" when in fact it only has "provisional consent" for a limited number of patients, the safety testing will not be completed until at least 2023 and the evidence is not clear that the vaccine prevents transmission of the virus to others. I attach the NZ Medical Council Statement on Informed Consent as **Exhibit "ZF"**.

Sworn at Hastings)
BY ALISON JANE GOODWIN)
This 8th day of April 2021)


ALISON JANE GOODWIN

Before me:



Barrister and Solicitor/ Registrar of the High Court of New Zealand

Louise Sally Curran
Solicitor
Hastings