IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY

I TE KŌTI MATUA O AOTEAROA
TE WHANGANUI-A-TARA ROHE

CIV-2022-485-013

IN THE MATTER	of an application under the Judicial Review Procedure Act 2016
BETWEEN	**DCB**
	First to Eighth Applicants
AND	**THE MINISTER OF HEALTH**
	First Respondent
AND	**THE GROUP MANAGER OF THE NEW ZEALAND MEDICAL DEVICES SAFETY AUTHORITY (MEDSAFE)**
	Second Respondent

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AFFIDAVIT OF PHILLIP MICHAEL ALTMAN IN SUPPORT OF APPLICATION FOR JUDICIAL REVIEW

Dated 2 May 2022

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AND **THE COVID-19 RESPONSE MINISTER**

Third Respondent

I, **Phillip Michael Altman**, BPharm (Hons), MSc, PhD, of New South Whales, Australia affirm:

1. I hold the degrees of Bachelor of Pharmacy (Hons), Master of Science and Doctor of Philosophy. My doctorate was concerned with the development of new cardiotonic drugs with lower intrinsic toxicity compared to existing drugs including their chemical synthesis and testing in various animal models.

2. Since 1974, I have been working within the Australian pharmaceutical industry. My work has been in relation to clinical trial design, management and reporting and in relation to obtaining new drug approvals dealing with the Australian Therapeutic Goods Administration (TGA). I have both experience working as a staff member for multinational pharmaceutical companies and later as a senior industry pharmaceutical consultant through my Contract Research Organisation (CRO), Pharmaco Pty Ltd., which has provided both clinical trial and regulatory consultant services to the Australian pharmaceutical industry.

3. I have personally consulted for more than half of the multinational pharmaceutical companies in Australia in various capacities with a focus on drug regulatory affairs.

4. In 1978, I founded the Association of Regulatory and Clinical Scientists (ARCS) which now includes more than 2000 Australian and New Zealand scientists, clinicians and associated health professionals involved in both clinical trial and regulatory affairs in Australia and New Zealand. This Association continues to be the foremost educational forum for both industry and government (drug regulatory) personnel involved in clinical trials and regulatory affairs.

5. My personal experience involves more than 100 clinical trials covering Phase I, II, III and IV trials (ie from first administration to post-approval trials) and a similar number of new drug applications, TGA appeals and applications to modify existing approvals. In collaboration with the TGA and on behalf of pharmaceutical companies, I have also managed two major international drug safety withdrawals (Gravigard – Searle and

Debendox – Merrell Dow Pharmaceuticals) and I have been involved in national adverse drug reporting as part of staff responsibilities working for multinational pharmaceutical companies.

6. During my years as a senior pharmaceutical industry consultant, I worked on several New Zealand drug regulatory files for several clients and visited the New Zealand Deptartment of Health (as it then was) in Wellington and was familiar at the time with their regulatory system and guidelines. The Australian and New Zealand drug regulatory agencies generally work closely together, have similar regulatory standards and share technical evaluations in relation to drug registration and safety.

7. My curriculum vitae is exhibit A to this Affidavit

8. I confirm that I have read, understand and agree to comply with the New Zealand High court Rules 2016 Schedule 4 Code of Conduct for Expert Witnesses. I confirm that the evidence that I give is within my area of expertise.

INTRODUCTION

9. Before commenting specifically upon the Crown's affidavits, it is important to summarise and clarify for the Court certain important and relevant drug regulatory and technical pharmaceutical background information which is generally known and accepted. This background information is presented to assist the Court in assessing and placing into context my opinions. This background information is presented in PART ONE of this affidavit under the following headings:

A. Background to drug regulatory and technical background information which is generally known and accepted - risk-benefit analysis
B. Terminology of vaccine
C. Gene-based mRNA technology
D. Lipo-nanoparticle delivery vehicle
E. Criteria for clinical safety-report
F. Criteria for clinical efficacy
G. Vaccine development

H. The clinical trial processes

I. PCR COVID-19 testing

J. Dying "with" COVID-19 or dying "from" COVID-19

K. COVID-19 relative risk in perspective

10. From paragraph 74. onwards (PART TWO) I comment specifically upon the Crown affidavits and utilise the following headings:

L. Responses to the following Crown affidavits

M. Initial perceptions if the gene-based vaccines

N. COVID-19 in children's

O. The clinical efficacy of the COVID-19 vaccines

P. Pfizer's First Clinical Trial - C4591001 (adolescents and adults)

Q. Pfizer's Paediatric Clinical Trial - C4591007 (including children 5 to < 12 years of age)

R. Safety of the COVID-19 vaccines

S. Vaccination in relation to children

T. Evolving risk of COVID-19

U. Manufacturing and quality control aspects

V. Public health risk of COVID-19 in perspective

W. New Zealand COVID-19 in children 5-11 years of age

X. Mutagenic and genotoxcity

PART ONE

A. Background to drug regulatory and technical background information which is generally known and accepted - risk-benefit analysis

11. All therapeutic agents, including vaccines, present a safety risk. It is the job of the drug regulator to critically assess and balance the risk versus the benefit for each therapeutic. In doing so, the Precautionary Principle is normally employed ie it is not assumed from the outset that a particular drug is safe and effective – evidence must be presented to establish safety and efficacy. The Precautionary Principle has at its core the hippocratic concept of "do no harm". This oath applies to everyone in medicine and health care.

12. It is not possible to determine a reliable estimate of risk-benefit if either the risk or the benefit is ill-defined and/or not quantified by reliable metrics. This analysis becomes even more important if large numbers of individuals, especially otherwise healthy individuals, are to be administered the therapeutic and/or when the use is advocated in vulnerable populations such as in children or pregnancy. In the case of SARS-CoV-2, the viral pathogen responsible for COVID-19; should this pathogen become less pathogenic with time (ie causes less severe disease), the risk-benefit calculation necessarily changes. In addition, if the risks (adverse effects) become better recognised and quantitated with time, the risk-benefit calculation will again change.

B. Terminology of "vaccine"

13. "Vaccines" by classical definition are therapeutics which prevent infection and transmission of a pathogen. Initially, it was widely thought that the new generation mRNA "vaccines" would prevent infection and transmission. However, after more than a year of widespread use, it is widely accepted that these "vaccine" products, to a significant extent, neither prevent infection nor transmission of infection. This is why, despite a high proportion of the population being "fully vaccinated" with two injections and many with booster injections, the number of "cases"

persist at relatively high levels. Moreover, the durability of protection has been generally disappointing with, at first, a "booster" injection being recommended and this has been followed by the notion of multiple booster shots.

14. The general rationale for COVID-19 "vaccine" use has shifted - with a focus upon claims regarding the protection of vulnerable segments of the population such as the aged with co-morbidities.

15. It is my understanding that coincident with the introduction of the Pfizer COVID-19 vaccine (otherwise known as "COMIRNATY COVID-19 Vaccine" or the "Pfizer-BioNTech COVID-19 vaccine") and similar gene-based vaccines, this definition of "vaccine" was modified to accommodate these therapeutics which permitted a better fit to their more relaxed regulatory data requirements, the CDC has changed the definition of vaccine a number of times in the last decade[1]:

a) Pre 2015: Injection of a killed or weakened infectious organism in order to prevent disease;

b) 2015-2021: The act of introducing a vaccine in the body to produce immunity to a specific disease;

c) Sept 2021: The act of introducing a vaccine in the body to produce protection from a specific disease; A preparation that is used to stimulate the body's immune response against diseases.[2]

16. Use and acceptance of the term "vaccine" for the Pfizer COVID-19 "vaccines" (including the lower strength paediatric formulation of 10ug/0.2mL active ingredient tozinameran) has major implications:

a) It permits the manufacturer in many countries to claim indemnity from legal prosecution in the event of harm caused by the vaccine under legislation.

b) It excuses the vaccine manufacturer from conducting certain lengthy and expensive safety testing normally required for a new product according to World Health Organisation guidelines for vaccine development.

[1] https://deathship.wordpress.com/2021/09/25/cdc-changes-the-definition-of-vaccines/
[2] https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm

c) It conveys an overall sense of safety and acceptance by the community as most of the population is aware of the beneficial effects of vaccines in general and readily accept their wide usage.

d) Also, the inclusion of a "vaccine" on children's approved vaccination schedules may automatically impart additional manufacturer liability protection in many jurisdictions.

17. The Pfizer COVID-19 vaccine (sometimes referred to as Pfizer-BioNTech COVID-19 vaccine or COMIRNATY vaccine) does not conform with the traditional definition of "vaccine" and has been continuously misrepresented by its proponents, pharmaceutical companies, media and governments. Pfizer-BioNTech's "vaccine" contains messenger ribonucleic acid (mRNA) genetic material and is the first of its kind, utilizing a new lipo-nanoparticle delivery system and a type of gene therapy technology. Unlike vaccines that have come before it, this biologic does not actually contain any part of the SARS-CoV-2 virus or a weakened version of the SARS-CoV-2 virus used to trigger an immune response, but rather it delivers synthetic mRNA genetic material contained in the lipo-nanoparticle protective coating which is intended to penetrate the body's cells. Once inside the cell, the mRNA component utilizes the host cell's own biochemical machinery to produce spike protein which resembles the spike protein on the surface of the virus. It is the spike protein which is meant to trigger the body's natural defensive immune system to produce antibodies which prepare the body for any future infection by the SARS-CoV-2 virus.

18. This is a different mechanism than that of traditional vaccines, such as inactivated, attenuated, subunit, or protein-based vaccines that do not employ a genetic mechanism to produce a foreign protein. While the spike protein is the component which triggers the immune response, this spike protein also possesses inherent cardiovascular and neurological toxicity in its own right.[3]

[3] Seneff, S and Nigh, G. (10/05/2021) *Worse Than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19.* International Journal of Vaccine Theory, Practice and Research. https://www.ijvtpr.com/index.php/IJVTPR/article/view/23

19. The Pfizer COVID-19 "vaccine" therapeutic falls under the US Food and Drug Administration (**FDA**) Office of Cellular, Tissue, and Gene Therapies' definition of "gene therapy products" in that it involves "introducing a new or modified gene into the body to help treat a disease"[4] although the FDA did not evaluate this therapy in relation to the established gene therapy guidelines. Gene therapies have never been widely used in a general population and using them in this manner should be considered experimental due to potentially serious safety concerns which may involve long-term genetic implications.

C. Gene-based mRNA technology

20. Prior to the introduction of COVID-19 "vaccines", all vaccines employed whole dead pathogenic organisms, attenuated (disabled) live organisms or fragments of infective bacteria or viruses or their protein products, referred to as subunit vaccines, as the means to stimulate the body's immune system and prepare it for a real pathogenic attack by a pathogen.

21. The mRNA based "vaccines" (such as the Pfizer COVID-19 paediatric "vaccine") uses a gene-based biotechnology never successfully deployed for a fully approved therapeutic agent for any use.

22. Gene-based "vaccines" such as the Pfizer COVID-19 "vaccine" have either been approved under emergency use powers in some jurisdictions (such as the US) or under relatively new provisional release regulatory pathways without the full complement of safety and efficacy clinical trials normally required for a new drug prior to approval. The provisional approval pathways employed by both Australia and New Zealand acknowledge that the safety and efficacy data packages are incomplete and the regulatory agencies are expected to specify the scope of outstanding data which must be submitted within a specific timeframe (currently May 2023[5] (at this stage), with data being made available a further 24 months thereafter (May 2025 at this stage[6]). These provisional

[4] What is Gene Therapy? (25/7/2018) US-FDA https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy
[5] https://www.pfizer.com/science/coronavirus/vaccine/about-our-landmark-trial
[6] Being 24 months from the "primary study completion date" https://www.pfizer.com/science/clinical-trials/trial-data-and-results/data-requests

"approvals" are subject to the satisfactory assessment of the outstanding safety and efficacy data.

23. The use of mRNA technology to develop new drugs has been the subject of very early clinical trials tested in small numbers of individuals mainly in relation to rare genetic diseases and the treatment of life-threatening cancers. The technology is widely referred to as "gene therapy" by the manufacturers and carries with it special efficacy and safety issues which are recognised by drug regulatory agencies. These safety issues include the possibility of reverse transcription (ie the mRNA being copied into the body's DNA permanently and being passed on to future generations) and hindering of the normal DNA repair processes which are essential in protecting the development of cancers.

24. Most new drugs reviewed and approved by drug regulatory agencies fall into an existing class of drug in terms of their mode of action. In this respect, many of the safety and efficacy attributes of a new drug are predictable to a certain extent due to their established pharmacological class. Given widespread usage, the regulatory agencies generally know what to look for in terms of potential problems with safety and efficacy dependent on the class. But in the case of a completely new class of drug, such as the Pfizer gene-based "vaccine", special care needs to be exercised in assessing the risk-benefit because many serious safety issues cannot be predicted, especially those serious adverse events which may occur infrequently, and may not be detected in clinical trials which use relatively small numbers of individuals.

25. Gene therapy is an experimental treatment that involves introducing genetic material into a person's cells to fight or prevent disease. Researchers are studying the potential of gene therapy for a number of diseases. A gene (sequence of single stranded nucleotide RNA or double stranded DNA, deoxyribonucleic acid, bases which code to produce a protein) is delivered to a cell using a carrier known as a "vector". Vectors are used because RNA or DNA on its own is not stable and quickly broken down in the body. The most common types of vectors used in gene therapy are viruses. The Janssen/Johnson & Johnson COVID-19 vaccine and the AstraZeneca COVID-19 vaccine use an attenuated (or weakened) vaccinia virus to deliver their genetic

material to cells. The Pfizer and Moderna COVID-19 vaccines on the other hand deliver their genetic payload using lipo-nanoparticles (LNP – see below) rather than a viral vector which acts to both protect the genetic material from degradation and allows the genetic material (RNA) to penetrate the body's cells.

26. All cells in the body contain genes making them potential targets for gene therapy. These cells can be divided into two major categories: somatic (most cells of the body) or germline cells (eggs or sperm). In theory, it is possible to transform (edit) either somatic cells or germ cells. Gene therapy which affects germ line cells results in permanent changes that can be passed down to subsequent generations raising serious ethical considerations. Somatic cells are nonreproductive. Somatic cell therapy is viewed as a more conservative, safer approach because it affects only the targeted cells in the patient and is not passed on to future generations.

27. The term "gene therapy" is appropriate for the Pfizer COVID-19 therapeutic product for the reasons stated above. It is much more a gene therapy than it is a vaccine in the conventional sense.

D. **Lipo-nanoparticle delivery vehicle**

28. Until recently, gene therapy was hampered by the inability to deliver foreign or synthetic mRNA effectively and broadly to cells of the body without it being destroyed by the body's natural protective degradative systems (eg RNA depolymerases). The development of LNPs has allowed mRNA to be encapsulated within a layer of cholesterol and phospholipids and protected from immediate degradation. Unlike conventional vaccines which largely remain at the site of injection, the LNPs containing mRNA in the gene-based vaccines are known to widely distribute to all organs and tissues and preferentially accumulate in certain organs (such as the ovaries) and can penetrate the critical blood-brain barrier which normally is a protective barrier for the brain and spinal cord. Importantly, the spike protein produced by the mRNA vaccines, which is considered to be pathogenic (cause disease), has access to all the tissues and organs of the body. Such wide biodistribution appears to have been studied and reported upon but perhaps not fully understood or

appreciated at the time of the initial regulatory approvals and this realisation has subsequently raised a number of serious ongoing safety concerns. I deal with this further in Part Two below.

E. Criteria for clinical safety

29. Drug regulatory agencies are tasked to assess the safety of new and modified therapeutic agents based on limited clinical trial data spanning maybe 10-20 clinical trials and several thousand volunteers and patients. While this clinical trial data provides an preliminary assessment of safety, infrequent adverse effects which occur in association with the administration of a new drug may not be recognised as actually causing the adverse effect. For example, if an effect has a true incidence of 1 in 2000, such an adverse effect may not be observed in a clinical trial of 2000 – 3000 individuals simply due to randomness in any population. That is, if a trial of 2000 individuals is repeated using different randomly selected sets of individuals, such an adverse event might occur zero times in one trial, once in another or maybe twice in yet another and a causal link may not be obvious.

30. For this reason, it is recognised by drug regulators that it is important to monitor the safety and efficacy of drugs following their release for public use where literally millions of individuals may be exposed to the new drug (or vaccine). There are numerous adverse drug report (**ADR**) systems in various countries and in various organisations/institutions. In the case of vaccines, specialised ADR systems have been established. One of the most extensive vaccine ADR systems is the US Vaccine Adverse Event Reporting System (**VAERS**) which has been in operation for several decades. New Zealand and Australia each have their own general ADR systems being Centre for Adverse Reactions Monitoring (**CARM**) and Database of Adverse Event Notifications (**DAENS**), respectively.

31. The tracking of adverse events is important for all drugs. However, specifically in relation to vaccines there have been a number of vaccine products have been shown to be unsafe when used in the wider population. Namely:

- Yellow fever vaccine contaminated with Hepatitis B - 1942
- Smallpox vaccine toxicity - 1947
- Polio vaccine toxicity (Cutter Incident) – 1950s
- Polio vaccines with contaminated simian virus – 1953 to 1963
- Dengue fever vaccine - 2017
- Measles vaccine – 1960s
- Respiratory syncytial virus (RSV) – 1960s
- Swine flu vaccine and Guillain-Barre Syndrome – 1976
- Rotavirus vaccine – 1998
- Gardasil, papillomavirus vaccine – 2013
- Influenza vaccine for infants

32. In addition, numerous national vaccine injury compensation schemes have been established in recognition of the potential for vaccines to produce serious adverse effects. Australia has just released a compensations scheme for COVID-19 vaccine adverse events.[7]

33. While ADR systems are capable of qualitative detection of adverse events, they are universally recognised as being poor quantitative adverse event indicators. By their very nature, ADR systems under report the incidence of adverse events. It is a matter of debate as to the degree of under reporting but estimates range from about 5 times to 30 times or more ie the true incidence of an adverse event reported in these systems need to be multiplied by somewhere between 5 and 30 times to obtain a more realistic estimate of the true incidence of a particular adverse event. This is important when considering any estimate of risk-benefit for a therapeutic agent.

34. ADR systems, whether they be part of a multinational pharmaceutical company or government-based, work on the same principles. Adverse and/or unexpected reactions are reported in relation to the administration

[7] https://www.health.gov.au/initiatives-and-programs/covid-19-vaccine-claims-scheme

of a therapeutic agent. Each report is individually assessed to determine the degree of confidence that the administered therapeutic caused the adverse effect. In most, but not all cases, it is extremely difficult to be 100% sure that the therapeutic in question caused the adverse effect. So, a progressive classification of degree of confidence has been adopted to assist in identifying emerging patterns of adverse reaction reports. This assessment classification varies from system to system but, for example, the WHO Vaccine Causality Assessment Form[8] lists the following possible classifications: unlikely, unrelated, unclassifiable, possible, probable and very likely-certain.

35. In investigating each adverse event (especially serious adverse events involving the need for medical care, hospitalisation, sustained disability or death) additional investigations and/or pathology may be required as well as post-mortem information in the event of death.

36. To assist the classification of each ADR, generally accepted rules are applied. One of the most commonly used sets of rules is called the Bradford Hill Criteria[9]. These criteria involve the following:

Strength:	Effect magnitude
Consistency:	reproducibility
Specificity:	causation is likely if there is a very specific population at a specific site and disease with no other explanation
Temporality:	time relationship to the adverse event – a highly correlated indicator
Biological gradient:	dose-response relationship
Plausibility:	existence of a possible mechanism between cause and effect
Coherence:	coherence between epidemiological and laboratory findings
Experiment:	occasionally it may be possible to revert to experimental evidence
Analogy:	use of analogies or similarities between the observed association and other associations
Reversibility:	if the cause is removed, then the effect should disappear (unless permanent damage)

[8] https://apps.who.int/iris/bitstream/handle/10665/259959/9789241513654-eng.pdf
[9] https://en.wikipedia.org/wiki/Bradford_Hill_criteria

37. The degree of under reporting is dependent on various factors and circumstances. In the case of the COVID-19 vaccines, there is a reluctance, to report "serious adverse events" post-vaccination (defined as those requiring medical attention, hospitalisation, permanent injury or death) for fear of being accused of being opposed to the government's pro-vaccine policies and/or attracting potential health regulator investigations.

38. ADR systems have been essential in the ongoing safety assessment of therapeutic agents. Some drugs have been withdrawn with as few as around 100 reported incidents of death assessed as being caused by the drug (eg Roche and Posicor) while other drugs have only been withdrawn after many years of use and suspected of causing the death of thousands of individuals (eg the anti-inflammatory agents Vioxx made by Merck and Bextra made by Pfizer).

F. Criteria for clinical efficacy

39. It is possible to design a clinical trial which is more likely than otherwise to produce a favourable efficacy measure or to minimise safety issues. This is in the hands of the drug manufacturer. Accordingly, there must be careful, critical scrutiny of the methodology adopted in clinical trials by drug regulators to ensure a reasonable estimate of the efficacy and safety of the trial drug has been achieved.

40. There are many different types of clinical trial designs and it takes skill to properly design a clinical trial which answers important questions of safety and efficacy in the most useful and unbiased manner. However, within the pharmaceutical industry there are often enormous commercial pressures to produce the most favourable efficacy results possible while minimising safety issues.

41. This can result in manipulations in the design of the clinical trial, which can largely go unnoticed. For example, the most important consideration in clinical trial design is the setting of the "Primary Endpoint". This is the observation or measurement which is of utmost importance determining the efficacy of a drug. Success or failure of clinical trials depend heavily upon the selection of the Primary Endpoint. There can be several Secondary

Endpoints of lesser significance, but if the Primary Endpoint fails to meet its defined goal, then the trial cannot be considered to have proven its main objective (ie the trial would be considered a failure).

42. Some ways of manipulating the design of a trial to produce a desired result involves the selection of particular patient types, what dose to administer, selecting patients of a certain risk profile, the duration of follow up to observe adverse effects, the selection of the comparative treatments and controls and, most importantly, selecting how success is measured (Primary Endpoint).

43. In the case of Pfizer's first clinical trial of its mRNA gene-based COVID-19 vaccine (C4591001) which involved mainly adults and some adolescents (**Pfizer's First Clinical Trial**), the Primary Endpoint was <u>not</u> set at preventing severe disease, hospitalisation or death due to COVID-19 which would appear to be the most relevant clinical Primary Endpoint in this case. In these Pfizer COVID-19 vaccine trials, the Primary Endpoint related to surrogate measures of the level of antibody immune response and these immune responses were assumed to translate into some degree of beneficial clinical effects. This is the basis of the original 95% efficacy claim for the Pfizer vaccine. The claimed 95% efficacy did not relate to the prevention of severe disease, hospitalisation or death due to COVID-19 but rather related entirely to a very small subset of individuals who had both a positive COVID-19 test and even mild symptoms of COVID-19 in the trial.

44. It is reasonable to assume that if prevention of severe disease, hospitalisation or death could have practically been set as a Primary Endpoint and measured, it would have. But in this case, the incidence of such clinically meaningful observations was far too small to measure. The popularly accepted claim of unqualified "clinical efficacy" conveyed to the public based upon surrogate laboratory indicators is an example of how clinical trial design detail can be obscured resulting in the misinterpretation of the results and present otherwise unimpressive trial clinical results in a more favourable light.

45. Pharmaceutical companies, being commercial in nature, understandably present their drug registration data in the best possible light. It is the drug

regulator's role to critically evaluate the quality, safety and efficacy data in an unbiased manner and consider the risks and benefits of each case. In doing so it is acknowledged that ongoing reassessment of the risks and benefits is necessary based on the experience in using the drug in the wider population if that occurs. In other words, the drug companies will advance their product in the best light and regulators, aware of this, must be vigilant in critically reviewing the supporting data and analysing the clinical trial design, methodology and efficacy.

G. Vaccine development

46. Conventional vaccines usually take about 7 years to develop and test. In a 2018 publication sponsored by the Bill and Melinda Gates Foundation, vaccines were divided into three categories: simple, complex and unprecedented.[10] The unprecedented category represents those vaccines directed towards a disease that has never before been successfully treated and include vaccines against HIV and malaria. According to authors Seneff and Nigh[11] unprecedented vaccines are expected to take more than 12 years to develop due to the technical difficulties and they are expected to have a very low chance (about 5%) of proving safety and efficacy in even early Phase II clinical trials involving small numbers of individuals and a very much lower chance (about 2%) of moving to larger Phase III clinical trials and demonstrating safety and efficacy before being considered for marketing.

47. The mRNA COVID-19 vaccines are in the unprecedented category.

48. The gene-based COVID-19 vaccines, including the Pfizer COVID-19 vaccine, utilised mRNA technology and were largely developed within a year of the start of the pandemic in 2020. In doing so, there was insufficient time to produce all the usual safety and efficacy data normally required in light of the perceived urgent need for an effective vaccine. This was a

[10] Young, R., Bekele, T., Gunn, A., Chapman, N., Chowdhary, V., Corrigan, K., . Yamey, G. (2018). *Developing New Health Technologies for Neglected Diseases: A Pipeline Portfolio Review and Cost Model.* Gates Open Res 2:23. https://doi.org/10.12688/gatesopenres.12817.2.

[11] Seneff, S and Nigh, G; (10/05/2021) *Worse Than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19.* International Journal of Vaccine Theory, practice and Research: 2(1) https://ijvtpr.com/index.php/IJVTPR/article/view/23

considered and calculated risk in the wake of dire epidemiological pandemic modelling predictions of death and the need for hospitalisation (which did not eventuate). Since the introduction of the Pfizer COVID-19 gene-based vaccine and other gene-based vaccines, much has been learned in terms of safety and efficacy of these therapeutics. The manufacturers of these gene-based vaccines are obligated to provide the New Zealand (and other drug regulatory agencies) specific ongoing data in relation to both safety and efficacy for a defined period of time as a condition of the Provisional Consent to use the drug in the population at large.

49. Short-term data is accumulating in the form of adverse drug reaction reporting but there is no long-term safety data available currently for these products. This presents a significant potential problem of unknown dimensions in assessing the safety risk versus any perceived benefit.

50. Certain safety tests are commonly used to predict long-term safety for new drugs – especially drugs of an entirely new therapeutic class. These tests include mutagenicity and genotoxicity testing to estimate the potential for the later development of cancers and genetic dysfunction. However, these tests were not conducted in the development of the gene-based vaccines. A World Health Organisation policy decision in 2005 exempted traditional (pre-COVID) vaccines from the need to conduct such in-vitro pre-clinical safety studies. Because the definition of a "vaccine" was changed in 2021 (see paragraph 15. above) to capture the gene-based mRNA technology, Pfizer took advantage of this WHO policy decision in 2005 to assert that it was not required to conduct such in-vitro safety studies for its COVID-19 "vaccine". No pharmaceutical regulator in the United States, United Kingdom, Canada, Australia or New Zealand that has approved the Pfizer "vaccine" has challenged Pfizer's position that it did not need to conduct these important pre-clinical evaluations which relate to long-term safety involving the potential to cause cancer and rule out possible adverse genetic effects would could possibly affect future generations.

H. The clinical trial process

51. Pharmaceutical companies conduct their own basic drug development research and clinical trials but they also subcontract research and development into new drugs to CROs. They also work hand in hand with other companies in order to speed the process of clinical trials, which can normally take 5-8 years or more.

52. Clinical trials are divided into phases:

> **Phase I** involves the administration of gradually increasing doses of a drug to test its safety in small numbers of healthy volunteers and determine how the drug is absorbed, metabolised, distributed and eliminated from the body. Small doses of an investigational drug are administered to individuals and provided there are no obvious safety concerns the dose may be gradually raised to test the dose in other volunteers while continuing to monitor safety parameters.
>
> Phase II clinical trials (exploratory trials) involves relatively small numbers of subjects to test the safety and efficacy of a new drug in patients for the intended clinical use. Often Phase II clinical trials are divided into Phase IIa and IIb with the later trials focusing more on the disease to be treated.
>
> **Phase III** clinical trials are much larger clinical trials, again in patients. Normally several thousands of patients in many clinical trials over many years are required to demonstrate safety and efficacy to a level which can be assessed by drug regulatory agencies. The vaccines for COVID-19 are in this phase of trials.

53. The clinical trial process is a stepwise and iterative process by necessity as time is needed to adequately consider at each step all the pharmacological effects and safety information acquired for the new agent and to use this information to design future clinical trials to better assess both safety and efficacy.

54. Often pharmaceutical companies contract out the clinical trial work to CROs. These CROs find and screen suitably qualified investigators and subjects or patients to enrol in trials, train doctors and other health professionals to conduct the trials according to approved protocols, provide logistical and data management support for the trials, monitor and record the collection of clinical efficacy and safety data and report to the sponsoring drug company. All these processes are conducted under strict ethical and procedural guidelines known as Good Clinical Practice Guidelines. Only highly trained CRO health professionals are usually involved in generating reliable and complete data emanating from the trial sites. In addition, CROs often compile and manage the clinical trial approvals necessary to conduct the trials and may also compile the drug regulatory files for ultimate government approvals. My own CRO in Australia worked for more than half the major pharmaceutical companies in these roles.

55. There are a number of safeguards put in place to ensure the integrity of the data collected in the clinical trials. For example, there are specific procedures to identify inconsistencies in data collection or data entry into database systems and procedures to verify the authenticity of data and accuracy of the data. For trials of critical importance, such as those involving a new drug representing a new class of therapeutic (such as the gene-based vaccines) either the company itself can superimpose an audit function on its contracted CRO or major regulatory agencies such as the FDA can audit clinical trial sites, sometimes appearing at trial sites without forewarning. Regulatory oversight of clinical trials is an important quality assurance mechanism and to prevent any potentially fraudulent or otherwise unacceptable activity.

56. The integrity of clinical trial data is of utmost importance especially when dealing with a single pivotal clinical trial for a completely new class of therapeutic agent being conducted under highly expedited circumstances. It is fundamental to safety considerations that absolute rigour is applied when considering the clinical trial. In Pfizer's First Clinical Trial used to obtain emergency or provisional approvals for the adult and adolescent Pfizer vaccine, the FDA was responsible for monitoring and auditing the progress of the trial, failed to adequately monitor the integrity of the clinical data

despite being officially informed of possible concerns raised by a senior manager of one of the CROs.[12]

57. Once a drug is finally approved for use by a drug regulator, often **Phase IV** post-marketing surveillance studies (pharmacovigilance studies) are conducted in order to monitor the safety of drugs when used on a larger scale and detect adverse effects which may not have been detected in the limited number of patients used in Phase III clinical trials. Thus, safety and other issues which may not have been apparent or evident from the clinical trial data are continually monitored as the new drug is used and this new information is used to update official prescribing information for doctors.

I. PCR COVID-19 testing

58. Public health and vaccination policies have been driven by the number of positive COVID-19 tests.

59. The focus has been largely centred on "case" numbers; that is the number of individuals testing positive for COVID-19 whether they are symptomatic (display disease symptoms) or asymptomatic (devoid of symptoms). Given the broad acceptance that SARS-CoV-2 has mutated into less virulent strains (variants which are less likely to produce serious consequences) case numbers, according to many, now have less significance to the point of irrelevance. To assess the risk to public health posed by SARS-CoV-2 the most relevant statistic is considered by many to be the incidence of serious disease as measured by hospitalisation and intensive care rates. These statistics should be considered of primary importance in the fundamental calculation of risk-benefit for any sector of the population (eg use in children).

60. For SARS-CoV-2, polymerase chain reaction (**PCR**) testing was used as the primary analytical tool to identify SARS-CoV-2 "cases".

61. The PCR test was invented by Dr. Kary Mullis in 1983 and he and a co-worker were awarded the Nobel Prize in Chemistry in 1993 for this work highlighting the importance of this breakthrough technology. The PCR test is a method to detect incredibly small traces of DNA genetic material, even

[12] https://www.bmj.com/content/375/bmj.n2635

a single molecule, and amplify this signal billions of times to produce a "positive test". Multiple applications of this technology have arisen since its invention but in February 2020, PCR testing was introduced under Emergency Use Authorisation for the detection of SARS-CoV-2[13] and the population became generally aware of PCR testing as a tool to detect SARS-CoV-2 infection via widespread media reporting.

62. A "positive" PCR test was interpreted as an infection "case", despite the fact that many "positive test" individuals did not display any symptoms of COVID-19 illness and did not progress to serious COVID-19 illness. This eventually brought into question the value and role of PCR testing in guiding health policy.

63. The PCR test method employs a variable and arbitrary number of temperature cycling steps. The PCR test sensitivity can be adjusted upwards by increasing the number of cycling steps. When adjusted by increasing the cycling steps to around 40 or more, as used widely by government health authorities, this test becomes exquisitely sensitive. Using cycling steps above 30 or so is considered by many experts to be scientifically unreliable and unjustified but some laboratories use PCR testing cycling of 40-45 cycles. It is my understanding that New Zealand typically used 40 cycles[14] to determine if a test was positive. The end result is that for many people who tested positive, they probably had minimal viral load and were not in danger of being symptomatic or dangerously ill and were not likely to transmit the infection.

64. The PCR test is not designed as a diagnostic test for disease. The official product information for PCR test kits by various manufacturers often bear this advice. A positive PCR test cannot distinguish between a fragment of a virus or an intact virus capable of transmission. The routine PCR test as employed to determine case numbers does not indicate the viral load of the person testing positive; ie the amount of virus present. The viral load is an important parameter because it is generally accepted that relatively higher viral loads are a prerequisite for the expression of symptomatic disease and infection transmission. A PCR test can also detect the

[13] https://www.cdc.gov/csels/dls/locs/2021/07-21-2021-lab-alert-Changes_CDC_RT-PCR_SARS-CoV-2_Testing_1.html
[14] https://www.health.govt.nz/system/files/documents/information-release/h202008534_11_jan_2021_covid_pcr_testing_cycles_0.pdf

presence of other coronaviruses so a positive result may indicate that the tested person was recuperating from a common cold in the past. Lastly, PCR tests are commonly known to produce false positive results. Despite all these drawbacks and limitations, health authorities worldwide depended primarily upon PCR testing to guide public health policies such as lockdowns and mandatory vaccinations.

J. Dying "with" COVID-19 or dying "from" COVID-19

65. The pivotal risk-benefit calculation which forms the fundamental decision on the use of any therapeutic (in this case, the decision to use a gene-based "vaccine" in children 5-11) has been further complicated by a misunderstanding or a lack of discrimination between those individuals reported as dying "with" COVID-19 as opposed to those dying "from" COVID-19.

66. For many jurisdictions, a person who died and coincidentally had a positive PCR test (which does not indicate the severity of infection), was recorded as a "COVID-19 death". This applied to cases of suicide, car accident victims and aged patients with pre-existing multiple serious life-threatening co-morbidities often at or near the end of their natural life expectancy.

67. Given that COVID-19 is rarely fatal in its own right (see below), it is important to discriminate between individuals dying "with" COVID-19 from those dying "from" COVID-19.

68. Knowing that a positive PCR test may not even indicate if a single live virus particle is present, any death with a positive PCR test should not be assumed to be a "COVID-19 death".

69. There is the potential for purposeful failure to discriminate between those dying "with" as opposed to "from" COVID-19 in relation to self-serving arguments. Without proper investigation, the reported COVID "death" statistics may be easily distorted and do not reflect deaths where COVID-19 has been determined to be the *primary* cause.

K. COVID-19 relative risk in perspective

70. In any risk-benefit assessment of a public health policy, it is important to maintain a sense of overall perspective. Those who are responsible for setting health policies may adopt a narrow view of the "health" goals (for example near total vaccination of a population) while ignoring the wider impacts of the social, health and economic impacts including the national economic cost, effect on mental health, effect of lack of diagnosis and management of serious disease (eg cardiac and cancer) and the negative impact on the delivery of educational services.

71. In the case of the COVID-19, perspective may be obtained by a comparison with the health impact of influenza. Both are viral respiratory infections, both are transmitted easily, both largely affect the older segment of the population, both have a known mortality rate and both are managed with vaccinations.

72. Reasonably reliable influenza health statistics are maintained by governments. Consideration of such statistics provides perspective in developing policies to manage COVID-19.

73. For most of the generally healthy population, survivability after contracting COVID-19 is recognised at about 99.97% and virtually nil for children. Indeed, the number of COVID-19 deaths approximate those seen annually with Influenza which mainly affects the old and frail nearing the end of normal life, particularly those with pre-existing co-morbidities when infected.

PART TWO

L. Part 2- Responses to the following Crown affidavits

74. I have been provided with the following affidavits upon which to respond:

a) Ashley Robin Bloomfield – 25 January 2022
b) George Ian Town – 25 January 2022
c) Christopher Mark James – 21 January 2022

75. I understand that the Crown evidence is that it received the following documents from Pfizer in support of its application for the approval of the vaccine for 5-11 year olds:

a) Pfizer's application 4 November 2021 – James Exhibit A page 21
b) Pfizer's resubmitted application 12 November 2021 – James Exhibit A page 21
c) Communications with Pfizer regarding the vaccine used in the trial being different to the one it sought Provisional Consent for – not provided

76. From the Crown evidence, it is not clear to me whether further or other documents formed part of Pfizer's application for Provisional Consent for the Paediatric Vaccine.

77. In my 40-year career, I have prepared and completed many new drug applications. In granting Provisional Consent approval for the paediatric vaccine, Medsafe has failed to adequately consider the following important points in the Pfizer application in four key respects;

a) New Zealand's Medsafe has failed to reliably identify and quantitate with any degree of precision the risk posed by COVID-19 to children in the age group 5-11. It is agreed that children in this age group, if infected, generally show no symptoms or mild symptoms and are not are not at risk of suffering serious consequences of COVID-19, which is accepted on numerous occasions in the Crown evidence.[15] All

[15] Affidavit of Dr. Town at 17; GT-1 *Technical Report – Interim public health considerations for COVID-19 vaccination fo children aged 5-11 years:* first bullet point.

available evidence to date suggests that children in this age group are at virtually no statistical risk, or nil risk, of life-threatening consequences of COVID-19. The Crown's claimed therapeutic need to vaccinate this age group rests upon perceptions which have no scientific basis (eg COVID-19 positive children may perpetuate the pandemic via transmission of the virus) and Pfizer's clinical trial data in this age group has failed to provide any evidence that vaccination does anything more than possibly prevent mild symptoms of COVID-19 in a small group of 19 children. Claims that vaccination would assist in the "wellbeing" of children are both hypothetical and vague and not supported by any direct and meaningful evidence.

b) There is considerable world-wide evidence to support the view that COVID-19 "vaccines" are associated with an unprecedented incidence of serious, life-threatening cardiovascular adverse events (especially within 48 hours of vaccine administration) including myocarditis, stroke and death which may potentially affect children aged 5-11. This was known and well documented at the time Medsafe considered Pfizer's marketing application.

c) The technology employed in Pfizer's COVID-19 "vaccine" has never before been used in a fully approved therapeutic agent and, by definition, is properly defined by the US FDA as a form of "gene-therapy". Both the scope and depth of safety data normally required for a new therapeutic of this class has not been provided to Medsafe for evaluation. Medsafe has acknowledged this in only providing Provisional Consent to distribute the product pending the supply of outstanding quality control and clinical safety data.

d) There is absolutely no long-term safety data available to support any argument to expose children aged 5-11 to a serious therapeutic of ill-defined benefit and known serious adverse effects which may have

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page 7 first paragraphs under each heading, page 8 first, second and last paragraphs under heading, page 15 third paragraph under sub-heading page 16 first bullet point under conclusions; GT-3 *Discussion to use the Pfizer mRNA COVID-19 vaccine for children aged 5-11 years: COVID-19 Vaccine Technical Advisory Group recommendations*, page 4 para b; Affidavit of Mr. James para 60;
Affidavit of Dr. Bloomfield para 13, para 24; ARB-1 *Child Wellbeing Impact Assessment COVID-19 immunisation for children 5 to 11 years*, page 11, 6th bullet point;
And expanded upon further in Part Two of this Affidavit.

enormous consequences to the New Zealand population. It usually takes 7-10 years to develop and test the safety of a new vaccine. There is a potential for gene toxicity induced by the genetic material contained in the vaccine which has not been the subject of critical mutagenicity or genotoxicity studies by Pfizer and other manufacturers. The risk-benefit proposition for using this gene-based vaccine in children fails at many levels.

78. In conclusion, even in the purported emergency conditions that I consider were not in existence as at December 2021 when Medsafe approved the paediatric vaccine, I contend that the approval of the paediatric Pfizer COVID-19 vaccine does not meet an acceptable risk-benefit standard for use in children aged 5-11.

M. Initial perceptions of the gene-based vaccines

79. The introduction of the gene-based vaccines to combat the COVID-19 worldwide pandemic was met with great expectations. These "vaccines" were developed in record time (about a year as opposed to 7 or more years) and many of the lengthy steps usually required to establish safety and efficacy were omitted or abbreviated in the interests of bringing these promising therapeutics to widespread use in the shortest possible time.

80. On balance, the perceived risks posed by the pandemic were considered as being greater than the unknown safety risks posed by this new generation of mRNA vaccines which used hitherto relatively unproven gene-based technology. This was despite the fact that no drug using this mRNA technology had ever previously been approved for marketing for any use. This was a calculated risk on the part of the drug regulatory agencies. In recognition of this safety risk posed by these new gene-based vaccines, regulatory agencies around the world moved to approve, in a provisional manner subject to ongoing safety and data conditional requirements, the release of these products, initially to the adult population, for general use.

81. For most new drugs, especially those representing a new class of drug, the initial use is generally focused on the adult population. Use of such drugs in the more vulnerable groups such as children or infants is usually delayed until there is sufficient experience regarding the safety and efficacy of the new drug when used in many more individuals in general marketing as compared to the relatively limited clinical trial number of patients or volunteers. The same situation applies with regard to the Pfizer COVID-19 "vaccine".

82. Initially, despite limited clinical and epidemiological data, there were a number of community and health professional perceptions which were widely held in relation to these new vaccines including:

- the vaccines prevent infection by the SARS-CoV-2 virus and subsequent COVID-19 developing (COVID-19 being the disease caused by the virus)
- the vaccines prevent transmission of the SARS-CoV-2 virus from infected to non-infected individuals
- if infected, the vaccines prevent serious symptoms and death of COVID-19
- the vaccines are 95% effective
- the vaccines were safe and effective

83. Following more than a year of global use much more is now known concerning the safety and efficacy of these new gene-based vaccines including the Pfizer COVID-19 vaccine.

84. While it continued to be assumed that COVID-19 vaccines are of value in preventing serious disease and death in the older age group with co-morbidities, these vaccines no longer are considered very effective in preventing infection or transmission of infection as witnessed by the high incidence of COVID-19 in the community despite the vaccination rates approximating 90%. In addition, the unprecedented high incidence of serious adverse effects reported under the various adverse drug reporting systems worldwide has challenged the claim that these vaccines are safe with little qualification. The issue confronting a proper

risk-benefit analysis for the use of these gene-based vaccines, is the acknowledgement that most of the population has a chance of surviving COVID-19 of approximately 99.97%, meaning a 0.03% chance of death, and virtually nil for children; yet once receiving a gene-based "vaccine", the recipient takes on a risk of possibly experiencing a serious adverse effect (or effects), possibly including death.

85. Affidavit of Dr. Town at page 21, point 74 Dr Town states:

"Although vaccination with the Parent Product and Paediatric Vaccine does not completely prevent transmission, the evidence is that it does reduce transmission."

86. As a principle in virology, it is generally accepted that infected individuals who have underlying high viral loads are symptomatic and capable of transmitting virus. Generally, children are either asymptomatic or experience very mild symptoms of COVID-19. In my opinion, there are no reliable studies to support the view that vaccinating children 5-11 years of age results in a meaningful public health benefit related to the reduction of virus transmission.

N. COVID-19 in children

87. With respect to vaccine efficacy, it is now recognised that the vast majority of children with COVID-19 experience either no symptoms or mild symptoms. This was known especially in the middle to later part of 2021.

88. Bloomfield affidavit - page 2, paragraph 8, Dr. Bloomfield states:

"While it is correct that children with underlying conditions are at greater risk of severe COVID-19, children who are healthy can and have also suffered from severe COVID-19".

89. I could not locate any reliable and specific evidence provided to support this statement anywhere in the Crown's evidence I reviewed.

90. With reference to the affidavit of George Town: Exhibit GT-1: Technical Report – Interim public health considerations for COVID-19 vaccination of children aged 5-11 years. European Centre for Disease Prevention and Control, 1 December 2021, page 7.

"The clinical manifestations of COVID-19 in children aged 5-11 years are well documented. Most children with COVID-19 have mild symptoms or asymptomatic disease and a very low risk of death."

and

"Severe COVID-19 remains rare among children…" (page 1).

91. What is unclear is the precise number of children who suffer severe disease or die primarily due to COVID-19 and not with COVID-19 because of co-morbidities. No specific evidence was provided in support of this statement in any of the Crown affidavits I reviewed. This lack of discrimination continues to exaggerate the risk of COVID-19 to children and obscure a true risk-benefit assessment.

92. I have searched without success for evidence and statistics for the incidence of severe COVID-19 and death due principally to COVID-19 in children aged 5-11 in New Zealand and Australia.

93. Some information appears in the Australian TGA AusPAR (Public Assessment Report) Pfizer mRNA Vaccine COMIRNATY dated December 2021[16] which may have been available for the New Zealand decision to approve the Pfizer COVID-19 vaccine for children 5-11 years of age. On page 11 of this Australian report, Table 1 includes COVID-19 cases in Australia by age group and highest level of illness severity – 1 January 2021 to 10 October 2021 the numbers of children in age group 0-4 and 5-11 are presented:

[16] https://www.tga.gov.au/sites/default/files/auspar-tozinameran-mrna-covid-19-vaccine-211207.pdf

Table 1: COVID-19 cases in Australia by age group and highest level of illness severity (1 January 2021 to 10 October 2021)

Age group	Count					% of cases		
	Not severe[a]	Hospitalised only (not ICU or died)	ICU (not died)	Died	Total cases	Hospitalised only (not ICU or died)	ICU (not died)	Died
0 - 4	6,848	186	5	0	7,039	2.6%	0.1%	0.0%
5 - 11	10,164	279	4	0	10,447	2.7%	0.0%	0.0%
12 - 15	6,220	233	5	1	6,461	3.6%	0.1%	0.0%
16 - 17	3,494	132	4	0	3,630	3.7%	0.1%	0.0%
18 - 29	24,837	1,922	130	7	26,896	7.1%	0.5%	0.0%
30 - 39	16,588	2,059	222	10	18,750	10.8%	1.2%	0.1%
40 - 49	11,006	1,790	234	25	13,055	13.7%	1.8%	0.2%
50 - 59	7,760	1,561	268	74	9,663	16.0%	2.8%	0.8%
60 - 69	3,767	1,152	299	114	5,332	22.2%	5.6%	2.1%
70 - 79	1,402	600	141	180	2,323	31.5%	6.1%	7.7%
80 - 89	493	528	76	207	1,254	42.5%	6.1%	16.5%
90+	125	137	0	21	283	47.4%	0.0%	7.4%
Age unknown	1	0	0	0	1	0.0%	0.0%	0.0%
Total	**92,551**	**10,960**	**1,483**	**689**	**105,683**	**10.4%**	**1.4%**	**0.7%**

Table 1: Australian TGA AusPAR (Public Assessment Report) Pfizer mRNA Vaccine COMIRNATY dated December 2021, Table 1, page 11

94. This Table shows that no children died and 4 aged 5-11 were admitted to Intensive Care Units (ICU) but, as indicated previously in this affidavit, it is important to distinguish between those children admitted to ICU "due" to COVID-19 or "with" COVID-19. It is possible that these children were admitted for serious co-morbidities (as often is the case) but coincidentally tested positive for COVID-19. Until this reasonable possibility is ruled out, this information should not be relied upon as evidence that children suffer, to any meaningful extent, serious disease caused by COVID-19.

95. In reality, the risk of COVID-19 death in a 5-11 year-old is virtually or statistically nil. Investigations of extremely rare cases have been poorly characterised and it is unclear to what extent any reported death is directly attributable to COVID-19 as opposed to pre-existing medical conditions. A Johns Hopkins study published in July 2021 monitoring 48,000 children diagnosed with COVID-19 found a mortality rate of zero among children without a pre-existing medical condition.[17]

[17] Marty Makari, (19/07/21) *The Flimsy Evidence Behind the CDC's Push to Vaccinate Children*, Wall St. J, https://www.wsj.com/articles/cdc-covid-19-coronavirus-vaccine-side-effects-hospitalization-kids-11626706868

96. If COVID-19 rarely produces serious disease in children, this should have significant impact upon the risk-benefit analysis of using the gene-based "vaccines" with known serious short-term adverse effects and potentially serious unknown longer term adverse effects in this age group.

97. There is argument put in several places contained in the Crown evidence that COVID-19 can lead to long COVID, myocarditis, pericarditis and serious inflammatory issues. I can see no convincing evidence, based on known case numbers, that children aged 5-11 are at significant threat to these serious pathologies.

O. True clinical efficacy of the COVID-19 vaccines

98. Bloomfiield Affidavit at page 10 paragraph 33 Dr. Bloomfield states:

"Vaccinating 5 to 11-year-olds first and foremost provides those children with a high level of protection from COVID-19."

99. I disagree with this statement.

100. If Dr. Bloomfield is referring to the evidence contained in the two controlled clinical trials submitted in support of Pfizer's application to obtain Provisional Consent from the Minister of Health to market these products, then, in my view those trials are both weak and indirect in nature and are undeserving of such an unqualified statement.

101. The clinical efficacy of the Pfizer COVID-19 COMIRNATY Vaccine was based on two international randomised and controlled clinical trials which have been submitted for evaluation by drug regulatory agencies.

102. Pfizer's First Clinical Trial (C4591001) used a dose of 30ug/0.3mL administered mainly to adults generally 18 years and older but in the later stages to some adolescents as young as 12 years of age. The second (later) trial C4591007 used a smaller dose of 10ug/0.3mL and included children aged 5 to <12 years of age (**Paediatric Clinical Trial**).

103. Of critical importance is the fact that with the Paediatric Clinical Trial, the only controlled clinical trial data available to support the use of the "vaccine" for children ages 5-11, used a different formulation to the product which Pfizer applied for and received Provisional Consent in New Zealand. It can unequivocally be stated in drug regulatory terms that no safety or efficacy data exists for the formulation currently being injected into children 5 to 11 years of age in New Zealand.

104. Drug regulators understand fully the potential impacts of changing the formulation of conventional therapeutic dosage forms and normally require evidence of equivalent safety and efficacy. In this case, with a biological agent which is based on mRNA gene-based technology never before approved for any therapeutic, using a completely new LNP delivery system and a highly complex manufacturing process impacting the integrity of the mRNA genetic component, means relatively small changes in formulation or method of manufacture may result in significant safety issues. It is difficult to overestimate the potential impact of such changes. It is conceivable that the "vaccine" product proposed for marketing may be manufactured via a different method and from the information presented to me, I am unable to satisfy myself that this has not occurred.

105. The Provisional Consent provided by the New Zealand health authorities is based, to a large extent, upon MedSafe's evaluation report (Appendix One, pages 124 – 187) presented in Dr Bloomfield's affidavit and the changes in formulation were well noted. However, the level of critical scrutiny regarding this important change, in my opinion, was inadequate.

106. The repeated claims of "protection" in children aged 5 to <12 years of age afforded by the Pfizer vaccine (which is fundamental to the notion of "efficacy" of the vaccines) is presumably based upon the Paediatric Clinical Trial. However, the submitted clinical trial deserves closer scrutiny because in any consideration of the risk-benefit analysis for a drug it is important to clearly define the clinical benefit in unambiguous terms. It is my opinion that the Crown affidavits have failed in this regard for the reasons I set out and detail below.

107. Given that both Pfizer's First Clinical Trial and Paediatric Clinical Trial are closely related in that they employed a similar trial design approach and methodology of analysis of "efficacy" results, I will first examine the Pfizer's First Clinical Trial.

P. Pfizer's First Clinical Trial - C4591001 (adolescents and adults)

108. This pivotal clinical trial using 30ug/0.3mL vaccine was used by Pfizer to obtain approval in many countries including New Zealand. It was widely stated and generally accepted at the time that the clinical efficacy of the vaccine was determined in a large clinical trial of about 44,000 subjects and the efficacy was 95%.

109. Without an understanding of the design, conduct and reporting of clinical trials, the ordinary person might interpret this statement in a number of different ways. For example, this "95%" efficacy might be interpreted to mean that vaccination provides a 95% chance of being protected from being infected following exposure from a person infected with SARS-CoV-2; or it might be interpreted to mean that vaccination reduces the risk of the average healthy person falling seriously ill and needing hospitalisation following SARS-CoV-2 infection; or it might be interpreted as showing the risk of death due to severe COVID-19 illness is reduced by 95%.

110. Indeed, none of these interpretations are correct.

111. The claimed 95% efficacy was based upon only 170 subjects who contracted COVID-19 during the trial which had a median follow up of 2 months post- second dose. The claimed clinical efficacy was not based upon 44,000 subjects. Of the 44,000 subjects enrolled and divided roughly equally between receiving active prophylactic vaccination or placebo, only 170 subjects tested positive for COVID-19 AND developed even mild COVID-19 symptoms which was the criterion set for "clinical efficacy"; with 8 testing positive in the vaccinated group AND displaying a COVID-19 symptom as mild as a sore throat, fever or cough while 162 tested positive in the placebo group AND displayed a COVID-19 symptom as mild as a sore throat, fever or cough. This is where the 95% efficacy claim originated.

112. Unfortunately, this same approach was applied to the Paediatric Clinical Trial which was the basis for the Provisional Consent approval in New Zealand for ages 5 to <12 years of age.

Q. Pfizer's Paediatric Clinical Trial - C4591007 (including children 5 to < 12 years of age)

113. The pivotal evidence of "protection" afforded by the Pfizer COVID-19 vaccine is provided by this clinical trial of about 3000 enrolled individuals and described by the MedSafe evaluator on pages 32-33 of the evaluation report which states:

"9.1.9.5 Confirmed COVID-19 per Protocol Criteria (First Definition)
The observed VE from at least 7 days after Dose 2 for tozinameran 10 µg administered to children 5 to <12 years of age without prior evidence of SARS-CoV-2 infection before or during the vaccination regimen, per protocol case criteria was 90.7% (2-sided 95% CI: 67.7%, 98.3%) based on 3 cases in the tozinameran group and 16 cases in the placebo group after adjusted for surveillance time (noting the 2:1 randomization of vaccine: placebo).

No cases of COVID-19 were observed in either the vaccine group or the placebo group in participants with evidence of prior SARS-CoV-2 infection. Hence, in this case, the observed VE from at least 7 days after Dose 2 in evaluable participants in this age group with or without prior evidence of SARS-CoV-2 infection before or during the vaccination regimen was essentially the same: 90.7% (2-sided 95% CI: 67.4%, 98.3%) based on the same number of observed cases (3 cases in the tozinameran group and 16 cases in the placebo group). The earliest reported and confirmed COVID-19 case in this analysis was in July 2021, with most cases occurring in August and September 2021."

114. That is, the crux of the important measurement of protection from symptom development in this trial was only based on 19 cases and no details or the severity of symptoms were reported. This leaves open the possibility that the vaccine in this trial may have offered protection from only mild symptoms similar to that of a common cold (refer to those listed

in the evaluator's report on page 29 of the MedSafe report) in a small number of children too small to be of any significance.

115. Surprisingly, the MedSafe evaluation offered little critical comment regarding this remarkably weak, and important, efficacy signal in this trial of children aged 5-11. This is because the single Pfizer Paediatric Clinical Trial submitted in support of the registration of this gene-based vaccine product set an antibody immune response as the Primary Endpoint (goal of treatment) and from there, inferred clinical "efficacy". That is, the measured immune response was a surrogate for a clinical response. It was not possible to show conventional and meaningful clinical efficacy because children are so rarely seriously affected by COVID-19. This is important when considering any risk-benefit analysis and should have been obvious to the Medsafe evaluator and the Ministry of Health.

116. The MedSafe evaluator commented in relation to the Paediatric Clinical Trial of vaccine efficacy regarding 5 to <12 year old children (at MedSafe's Evaluation Report page 27) and states:

"The effectiveness of the Pfizer BioNTech paediatric Covid-19 vaccine is being inferred by comparing the neutralising antibody responses……."

117. Importantly, the MedSafe evaluator noted that no severe COVID-19 cases (per protocol definition or per CDC definition) were reported for children aged 5 to 11 in either the treatment or placebo group in trial C4591007. Furthermore, "No cases of MIS-C (ie multi-system inflammatory syndrome in children, per CDC definition) were reported as of the data cut-off date" (see MedSafe evaluator report page 36, 9.1.9.9).

118. Once again, the critically important and pivotal Paediatric Clinical Trial results do not provide evidence of protection from moderate or severe COVID-19 symptoms. The impact of this upon the risk-benefit analysis is obvious in that the goal of vaccination (the benefit) should relate to protection from a disease state and not to any laboratory measurement which may or may not translate to protection from a disease state.

119. Affidavit of James at page 16, paragraph 60.2, Mr James states:

"The clinical data in relation to children aged 5 — 11 years old demonstrated that the vaccine had high levels of efficacy in preventing symptomatic COVID-19 infection in that age group."

120. Furthermore, the affidavit of James, exhibit A, MAAC Minutes page 277 states:

"The Committee [MAAC] discussed the overall benefit-risk of Comirnaty 30ug and Comirnaty 10ug." "They discussed the strong efficacy signal of Comirnaty 10ug in children aged 5 to 11 years old and evidence suggesting a good safety profile, comparable to that observed in adults and adolescents to date".

121. The "strong efficacy signal" referred to is a laboratory measured surrogate immune response which is claimed to infer "clinical efficacy" but such inference is unreliable in my opinion because it has not been shown that there is any correlation between the surrogate immune response in children and a protective effect shown clinically in terms of the incidence of serious disease.

122. I contend that these interpretations are not supported by the pivotal (and only) clinical trial data submitted in support of the New Zealand Provisional Consent to conditionally approve and market the Pfizer COVID-19 vaccine for children aged 5 to 11 years of age. In my opinion, the above statements regarding "efficacy" cannot be relied upon and should have been subject to more critical analysis by MAAC/Medsafe.

R. **Safety of the COVID-19 vaccines**

123. Affidavit of Town at page 11, paragraph 38 Dr Town states:

"Although the Paediatric Vaccine and Parent Product are new, the technology behind these vaccines is not new. Researchers have been working with mRNA vaccines for decades and studying mRNA vaccines to provide protection against influenza, rabies and Zika virus.27One of the benefits of mRNA vaccines is that they can be readily developed and

produced in larger quantities faster than other methods for making vaccines."

124. This statement potentially may incorrectly lead one to assume a certain degree of comfort in relation to safety when administering these gene-based vaccines to children.

125. These mRNA gene-based products have only been researched in clinical trials mainly in relation to rare and serious diseases where the potential benefit is hoped to outweigh the risk of debilitating disease or reduced life expectancy. In such situations involving seriously ill individuals, there is considerably more tolerance in accepting severe adverse effects. However, if a gene-based therapeutic is proposed for use in healthy young individuals at little risk of a disease, there should be much less tolerance to the possible occurrence of serious adverse events (such as myocarditis).

126. Coincident with the introduction of the gene-based COVID-19 vaccines there has been an unprecedented increase in acute or short-term vaccine adverse drug reports around the world which are far above the average annual number reported prior to the introduction of COVID-19 vaccines.

127. Prior to COVID-19 vaccinations, over the last 10 years there has been an average of about 155 deaths per year reported in relation to all conventional vaccines to the US VAERS. This includes all standard childhood vaccines on vaccine schedules, annual flu vaccines, travel vaccines, hepatitis, human papilloma virus vaccines, tetanus vaccines, meningococcal vaccines and herpes vaccines.

128. The unprecedented rise of "vaccine" related adverse effects coincident with the introduction of the gene-based COVID-19 vaccines is shown below.

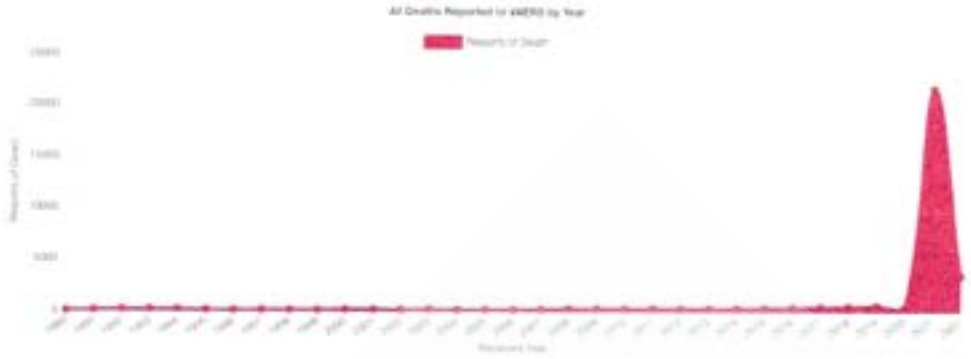

Table 2: All reported potential vaccine deaths to VAERS since 1990

129. Dr. Jessica Rose, specialist data analyst, has focused her attention on the US VAERS data and published on the general ADR data as well as specifically in relation to myocarditis.[18] It has been suggested that the increase in deaths temporarily associated with the introduction of the gene-based "vaccines" is not due to these new "vaccines" but rather due to increased numbers of injections overall. However, this explanation does not appear valid as the COVID-19 vaccines represent a small proportion of all vaccines given in the US since 1990.

130. Recently, in the US VAERS (which is primarily American derived data), COVID-19 vaccine administrations account for 983,756 adverse event reports as of 17 December 2021 including 20,622 deaths. Every adverse drug reaction report needs to be individually assessed to rate the probability of causing any particular adverse reaction – not all reports are assessed as "causal". On the other hand, the underreporting factor can range from 5 to perhaps as high as 30 times or more according to many observers.

131. It is my opinion that the significant increase in adverse effects due to the gene-based COVID-19 "vaccines" cannot be accounted for by the additional number of COVID-19 "vaccines" administered.

132. The confounding assessment factors of underreporting of adverse effects on one hand and the possible lack of evidence of causation (according to

[18]Rose, J. 2021. *A report on US Vaccine Adverse Events Reporting system (VAERS) of the COVID-19 Messenger Ribonucleic Acid (mRNA) Biologicals. Science, Public Health Policy, and the Law.* Volume 2:59-80, May 2021. Clinical and Translational Research. https://www.datascienceassn.org/sites/default/files/VAERS%20Report%20on%20Covid19%20Vaccine%20mRNA%20Biologicals%20-%20May%2C%202021.pdf

the Bradford Hill Criteria etc) on the other hand in relation to deaths caused by vaccines can be resolved to a large degree by an examination of the statistics of death temporarily associated with vaccine administration.

133. Dr. Jessica Rose has analysed the percentage of individuals experiencing adverse effects within 24- and 48-hour periods in relation to COVID-19 vaccine administration.[19]

134. Of particular interest is the Rose analysis of VAERS % reported deaths, emergency room visits and hospitalisations following vaccination with the gene-based vaccines versus the number of days following injection. This analysis is graphically presented below and shows a spike in the % deaths, ER visits and hospitalisations within 48 hours of vaccination compared to the long-term background rate. This temporal relationship provides strong evidence that the gene-based vaccines directly cause serious adverse effects including death.

Figure 8.1 Time series plot — Percentage of reported deaths by time elapsed between the injection date and the reported adverse event

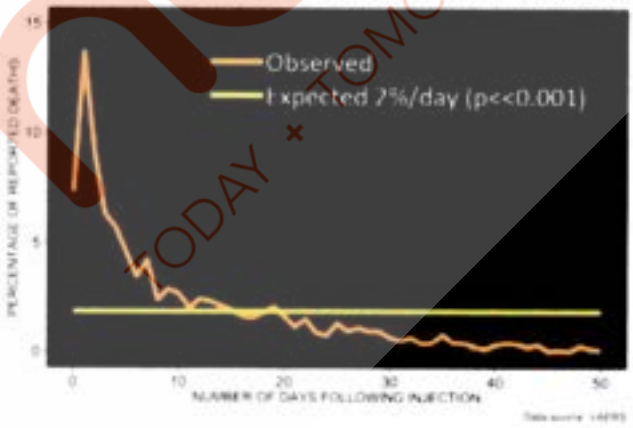

Table 3: Percentage of reported deaths post vaccination by time – US VAERS analysis Dr. Jessica Rose

[19]Rose, J. 2021. A report on US Vaccine Adverse Events Reporting system (VAERS) of the COVID-19 Messenger Ribonucleic Acid (mRNA) Biologicals. Science, Public Health Policy, and the Law. Volume 2:59-80, May 2021. Clinical and Translational Research. https://www.datascienceassn.org/sites/default/files/VAERS%20Report%20on%20Covid19%20Vaccine%20mRNA%20Biologicals%20-%20May%2C%202021.pdf

Figure 8.3 Time series plot — Percentage of reported emergency doctor visits by time elapsed between injection and adverse event

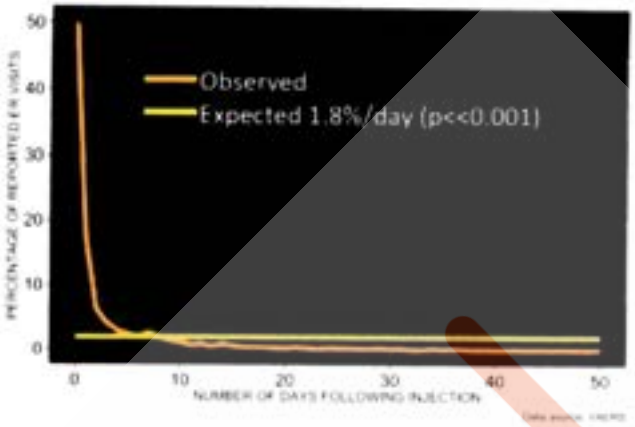

Table 4: Percentage of reported emergency doctor visits post vaccination by time – US VAERS analysis Dr. Jessica Rose

Figure 8.2 Time series plot — Percentage of reported hospitalizations by time elapsed between injection date and adverse event

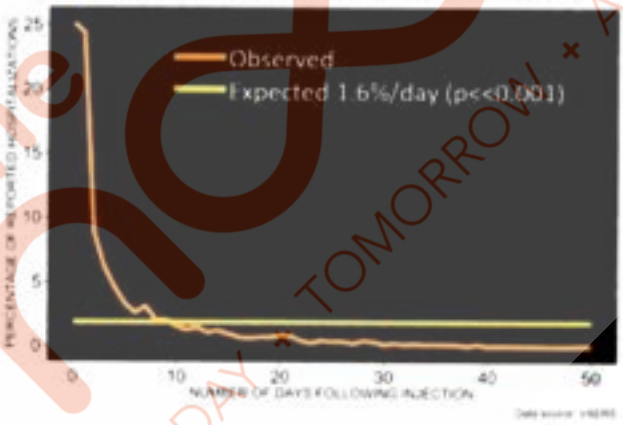

Table 5: Percentage of reported hospitalisations post vaccination by time – US VAERS analysis Dr. Jessica Rose

135. The abovementioned analysis is a short-term analysis. No long-term safety data is available for the COVID-19 gene-based vaccines. The long-term safety of the gene-based vaccines is completely unknown and there are potentially serious concerns which will only be resolved many years into the future. These concerns are based on the identification of pathogenic attributes of the spike protein and include profound disturbances in regulatory control of protein synthesis and natural cancer surveillance protective mechanisms, a potentially causal link to

neurodegenerative disease, immune thrombocytopenia, Bell's palsy, liver disease, impaired adaptive immunity, impaired DNA damage response and tumorigenesis.[20]

136. Of all the serious more short-term adverse events receiving attention in relation to the gene-based COVID-19 vaccines, myocarditis has probably received the most attention due to the seriousness of the condition, potential to be fatal and its potential to affect longevity especially in the younger age groups with a predominance among males.

137. In analysing the possible incidence of myocarditis associated with the gene-based vaccines, it is useful to compare the historical rates of myocarditis in children and youth prior to the introduction of these vaccines with the rate associated with the vaccine rollouts (Pfizer, Moderna and Janssen) during 2021.[21]

138. It appears that there is a risk of myocarditis from both COVID-19 infection (especially in the elderly population) and from gene-based COVID-19 vaccines – both considered to be related to the toxic spike protein. The US Center for Disease Control (CDC) has attempted to discriminate between the two causal factors in order to arrive at a risk of myocarditis caused by the vaccines. If there is a risk of young people contracting myocarditis from SARS-CoV-2 then this is negligible as no health authority anywhere has provided or produced any report or meaningful evidence that SARS-CoV-2 significantly elevates the risk of myocarditis in children 5-11 years of age.

139. However, there remains a distinct risk of myocarditis caused by the Pfizer COVID-19 vaccine, especially in children. This is most recently outlined

[20]Seneff, S et al. Innate Immune Suppression by SARS-CoV-2 mRNA Vaccinations: The role of G-quadruplexes, exosomes and microRNAs. January 21, 2022. https://www.sciencedirect.com/science/article/pii/S027869152200206X Seneff, S and Nigh, G; International Journal of Vaccine Theory, practice and Research: 2(1), May 10, 2021 - https://ijvtpr.com/index.php/IJVTPR/article/view/23

[21]Rose, J and McCullough P, *A Report on Myocarditis Adverse Events in the U.S. Vaccine Adverse Events Reporting system (VAERS) in Association with COVID-19 injectable Biological Products*. 2021 Sep 30. https://ia601003.us.archive.org/4/items/covid-injury/Jessica%20Rose%20PhD%20-%20A%20Report%20On%20Myocarditis%20Adverse%20Events%20In%20The%20U.S.%20.pdf

in an Australian Government report on Guidance on Myocarditis and Pericarditis after mRNA COVID-19 Vaccines dated 29 April 2022[22]:

Table 1: Rates of myocarditis per million doses by age cohort and sex following dose two of Comirnaty (Pfizer) and Spikevax (Moderna) adapted from the rates reported by the Therapeutic Goods Administration (TGA) in Australia[13]

	Pfizer		Moderna	
	Dose 2		Dose 2	
Age Cohort	**Males**	**Females**	**Males**	**Females**
5-11*	Not available	Not available	Not available	Not available
12-17	107	24	159	26
18-29	67	20	142	12
30-39	19	6	52	0
40-49	12	9	0	0
50-59	1	4	0	26
60-69	0	0	0	0
≥70	0	4	0	0
All ages	**37**	**12**	**75**	**11**

*Up to 27 February 2022 approximately 1.2 million doses had been administered to children aged 5-11 years, and no cases of myocarditis had been reported, noting that majority of these would have been first doses.

Up-to-date data on cases and rates of myocarditis and pericarditis reported to the Australian Therapeutic Goods Administration is available at https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report

Table 6: Rates of myocarditis per million doses by age cohort and sex – Australian Government data as at 219 April 2022

140. Other studies have shown that myocarditis is under reported and this needs to be considered when assessing the risk-benefit of the use of the Pfizer COVID-19 vaccine to children.[23]

141. The risk of myocarditis, pericarditis and cardiac arrhythmias associated with several gene-based COVID-19 vaccines (including the Pfizer vaccine) or SARS-CoV-2 infection itself was studied in a large case series study of people aged 16 or older in England between 1 December 2020 and 24 August 2021.[24]

[22] https://www.health.gov.au/sites/default/files/documents/2022/04/covid-19-vaccination-guidance-on-myocarditis-and-pericarditis-after-mrna-covid-19-vaccines.docx

[23] Katie A Shariff MD, David M Dancoes, Jodi L Longueil PharmD, Eric S Johnson PhD, Paul F Lewis MD, MPH. (December 27, 2021) *Risk of Myopericarditis following COVID-19 mRNA vaccination in a Large Integrated Health System: A Comparison of Completeness and Timeliness of Two Methods* https://doi.org/10.1101/2021.12.21.21268209

[24] Patone, M et al, Nature Medicine, https://doi.org/10.1038/S41591-021-01630-0

142. In this large study the temporal relationship between the gene-based vaccines and myocarditis was seen in the subgroup analysis by age showing an increased risk of myocarditis associated with the two mRNA vaccines in those younger than 40 years of age. Subgroup analysis was only performed for myocarditis. While those under 16 years of age were not studied it is widely recognised and accepted that younger males are most at risk of myocarditis. In addition, the authors state:

"Our findings are relevant to the public, clinicians and policy makers. First, there was an increase in the risk of myocarditis within a week of receiving the first dose of both adenovirus and mRNA vaccines, and a higher increased risk after the second dose of both mRNA vaccines. "
"Myocarditis is underdiagnosed in practice, with clinical bias being directed towards myocardial ischemia or infarction."

143. Aside from being under-diagnosed in practice, it is generally known that many doctors avoid reporting myocarditis and other serious possible adverse events in relation to the gene-based vaccines for fear of being seen as critical of the national health COVID-19 vaccination policies and possible health regulator intimidation and retribution. This, combined with the inherent underreporting of adverse events in general, suggest the true incidence of adverse effects such as myocarditis may be much higher than officially reported. This needs to be considered in the calculation of the risk-benefit analysis.

144. Another factor which needs to be considered is the delay in assessing and reporting adverse drug events due to the unprecedented number of such events being reported. Pfizer itself has acknowledged this issue in its *Cumulative analysis of post-authorization adverse event report 5.3.6 of pf-07302048 (bnt162b2)* dated 30 April 2021 (**Pfizer's Adverse Events Report**) (released in or about November 2021 pursuant to court ordered disclosure expedited under the Freedom of Information Act):[25]

[25] FDA released document: 5.3.6 Cumulative analysis of post-authorization adverse event reports of pf-07302048 (bnt162b2) received through 28-feb-2021 – page 6 https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf

"Pfizer has also taken multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately 600 additional full- time employees (FTEs). More are joining each month with an expected total of more than 1,800 additional resources by the end of June 2021."

145. During phase III clinical trials for the mRNA COVID-19 vaccine products, safety was assessed based on a maximum observation period of 6 months. This is not adequate to assess long-term safety outcomes. A typical timeline of up to 10 years would be considered appropriate for long-term follow up. There are many examples of biological product recalls (let alone gene-based products) such as the rotavirus vaccines in 2010, the H1N1 influenza vaccine in 2009 and a meningococcal vaccine in 2005-2008.

146. I would anticipate that Medsafe would have received Pfizer's Adverse Events Report if not at the time it considered Pfizer's application to approve the parental vaccine, then pursuant to the conditions of the Provisional Consent approval and certainly before considering Pfizer's application for the paediatric vaccine.

S. Vaccination in relation to children

147. Bloomfield Affidavit at page 7, paragraph 21.1 Dr. Bloomfield states:

"Immunisation of the wider population is important to protect children and promote their wellbeing."

148. I disagree with this statement for two reasons – the first relates to a consideration of potentially serious adverse effects produced by the Pfizer COVID-19 vaccine and the second relates to the false concept that vaccination prevents transmission of the virus.

149. First, after introduction of the gene-based COVID-19 vaccines in the US, VAERS quickly had more adverse events attributed to COVID-19 vaccines than any vaccine in history. Between November 3 and

December 19, 2021, VAERS received an overwhelming 4,249 adverse reaction reports for children aged five through eleven years who received the Pfizer COVID-19 COMIRNATY vaccine. [26]

150. Secondly, it has been shown that fully vaccinated infected individuals have peak viral loads similar to unvaccinated cases and can efficiently transmit infection.[27]

151. On 6 August 2021, Dr. Rochelle Walensky, Director of the CDC said publicly that fully vaccinated people who get a COVID-19 breakthrough infection can spread the virus to others even if they are not symptomatic. A breakthrough infection is also termed a vaccine failure.[28]

152. In my opinion, the notion that unvaccinated individuals significantly contribute to sustaining the COVID pandemic is recognised as being without foundation and the argument that children should be vaccinated to protect others, and take the risk of serious adverse effects, is not a sustainable argument in the consideration of risk-benefit.

153. I note in particular (Medsafe Evaluation Report page 182, Request for Information 12.2 RFI 2) and Pfizer's response:

"The sponsor is requested to provide data, if available, that provides evidence of reduced infectivity amongst the vaccine recipient cohort 5-12 years of age and would support the approval of the extension of indication in this age group to reduce community transmission."
Page 182 12.2.1 Sponsor response:

"No transmission data is available in the 5 to <12-year-old age group from C4591007. An analysis is being performed in participants 16 years

[26] US CDC Report - COVID-19 Vaccine Safety in Children Aged 5-11 Years – United States, November 3- December 19, 2021
https://www.cdc.gov/mmwr/volumes/70/wr/mm705152a1.htm#T1_down
[27] Kampf, G. COVID-19 : Stigmatising the unvaccinated is not justified. The Lancet, vol 398, Nov. 20 2021; Kampf, G. The epidemiological relevane of the COVID-19-vaccinated population is increasing. The Lancet Regional Health – Europe 11 (2021) 100272; Singanayagam et al. Sars-CoV-2 delta (B.1.1672) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study. www.thelancet.com/infection Published online October 28, 2021
https://doi.org/10.1016/S1473-3099(21)00648-4
[28] https://www.realclearpolitics.com/video/2021/08/06/cdc_director_vaccines_no_longer_prevent_you_from_spreading_covid.html?jwsource=twi

an older in the C4591001 study, and this data will be available early 2022."

154. This Medsafe evaluator question and Pfizer's response argues against any claimed benefit of the Pfizer COVID-19 vaccine in terms of mitigating transmission of virus in children 5-11 years of age.

T. Evolving risk of COVID-19 for children

155. A review of the need to vaccinate children 5-11 should depend on the evolving risk posed by SARS-CoV-2 infection and the risk posed by a better understanding of the incidence of severe adverse drug effects associated with the gene-based COVID-19 vaccines.

156. Early on in this pandemic, it was recognised that SARS-CoV-2 seldom presents a serious risk to children – most infections in young children are asymptomatic or mildly symptomatic. In more recent times, it is universally acknowledged that the virulence of the more recent variants of SARS-CoV-2 (eg. Omicron) is waning. Under these circumstances, given that the potential benefit of the vaccines is recognised as reducing while the potential risk of serious adverse effects remains unchanged, it is logical that the risk-benefit calculation has changed and the argument for vaccinating children is less sustainable than ever.

157. I can certainly say that by 17 December 2021, when Medsafe approved the vaccine for 5-11 year old children, Delta and Omicron were considered to be milder versions of the original virus.

U. Manufacturing and quality control aspects

158. I further note several serious deficiencies in relation to the manufacturing and quality control data in support of the Pfizer paediatric COVID-19 vaccine approval (see Medsafe Evaluation Report), namely: the unusually wide specification limit for the active ingredient (limit ≥58% with no upper limit), the lack of full scale batch stability and the lack of information confirming the specific manufacturing method and any changes in the manufacturing method which may have occurred to

resolve any potential mRNA integrity issues. These issues potentially relate to both safety and efficacy of the product and should have been a major concern to any drug regulator in need of resolution prior to approval.

V. Public health risk of COVID-19 in perspective

159. The threat posed by COVID-19 varies across various age groups with older individuals with multiple co-morbidities being most affected. For probably more than 99% of healthy people, especially young people, it is generally accepted that the symptoms of COVID-19 are either not noticeable or fairly mild and similar to a common cold. Indeed, it is widely acknowledged that healthy people in general have a chance of surviving death from COVID-19 as high as 99.97%. Children are even less likely to be seriously affected producing virtually a nil statistical risk of serious disease or mortality.

160. Based on New Zealand Ministry of Health data, the incidence of deaths caused by influenza and pneumonia from 1948 to 2018 ranged from about 400 to about 1400 per year.[29] The total pandemic number of "COVID-19 related deaths" of all ages ("including people whose cause of death was not COVID-19 but they had COVID-19 when they died" and "people whose cause of death is still under investigation") in New Zealand[30] up to the end of 2021 could probably be estimated to be well under 500.

161. According to the Australian Bureau of Statistics in 2020, COVID-19 was only the 38th leading cause of death (898 deaths) and the median age of death was 86 years.[31] This data includes those individuals dying "with" COVID-19 and cannot be interpreted as individuals dying as a direct result of COVID-19. Prior to the pandemic in 2019, there were 1800 deaths due to influenza and pneumonia.[32]

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[29] https://figure.nz/
[30] NZ official government data: https://covid19.govt.nz/
[31] Australian Bureau of Statistics in 2020 - https://www.abs.gov.au/statistics/health/causes-death/causes-death-australia/latest-release
[32] "Causes of Death, Australia" – https://www.abs.gov.au/

162. Children are at the lowest risk of severe COVID-19 compared to any other age segment of the population. In assessing the risk-benefit of vaccinating children, it should also be remembered that the assumed risk based on PCR testing was highly exaggerated because this test was not diagnostic for COVID-19 and the test was of such exquisite sensitivity that even fragments of old or dead virus might produce a positive test and the test result did not indicate a measure of viral load (amount of virus present).

163. Quietly without media attention, the US Centers for Disease Control and Prevention (CDC) has withdrawn the PCR process as a valid test for detecting and identifying SARS-CoV-2. In a lab alert of 21 July 2021 the CDC Division of Laboratory Systems issued a laboratory alert:

"After December 31, 2021, CDC will withdraw the request to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel, the assay first introduced in February 2020 for detection of SARS-CoV-2 only. CDC is providing this advance notice for clinical laboratories to have adequate time to select and implement one of the many FDA-authorized alternatives."[33]

164. The CDC also admitted that the PCR test cannot differentiate between SARS-CoV-2 and influenza viruses.

165. For the abovementioned reasons, any past reliance on PCR testing "case" numbers in relation to risk assessment in any risk-benefit analysis should be viewed with extreme caution.

[33] https://www.cdc.gov/csels/dls/locs/2021/07-21-2021-lab-alert-Changes_CDC_RT-PCR_SARS-CoV-2_Testing_1.html

W. New Zealand COVID-19 in children 5-11 years of age

166. Town Affidavit at Appendix GT-3, page 4, b states:

> *"In the current Delta outbreak in New Zealand (data to 19 November 2021), children aged 5-11 made up 14.9% of cases (1,003/6,714). Eight of these children were hospitalised but none were admitted to ICU. Of those who were hospitalised, all but one had a pre-existing condition and three were in hospital for less than six hours. As a comparison, between 16 June and 13 November 2021 in Sydney, 14,154 cases (19.4%) were aged 0-11 years and not eligible for vaccination. Of these cases, 632 were hospitalised, 9 were in ICU, and 0 patients died. It was not mentioned whether any of these cases had pre-existing conditions or comorbidities. The Sydney data further demonstrates that COVI D-19 is relatively mild in most young children as despite accounting for 19.4% of cases in Sydney since 16 June, they account for only 5.9% of hospitalisations, 0.6% of ICU admissions, and no deaths [8]."*

167. This type of data is of limited usefulness in determining the risk of COVID-19 in children aged 5-11. I say this for the following reasons:

a) A positive PCR test which is the basis for identifying a "case" does not determine the presence or absence of disease ie it is not diagnostic for COVID-19.

b) A positive PCR test cannot distinguish between a viable living virus and a part of a virus which cannot replicate.

c) A positive PCR test cannot distinguish between a person with a high level of viral infection or a very low level of viral infection.

d) The reason why the "cases" were admitted to hospital or ICU is unknown. Children are often hospitalised for various serious pre-existing conditions or even for "social reasons" and these should not be counted as a COVID-19 case.

168. Unless it is known that the child was admitted to hospital or ICU due to COVID-19 not with COVID-19, reliance upon this type of data to justify the administration of gene-based vaccines to children 5-11 should be considered highly unreliable.

169. In the New Zealand tally of cases quoted above (see paragraph 166.), I note that no child died in relation to COVID-19 as was the case in Australia (see table at paragraph 93. above) once again affirming the view that COVID-19 is extremely rarely, if ever, fatal in young children.

170. As an appropriate and meaningful example of the important need to view unqualified "case" numbers and hospitalisations (such as those presented by Dr. Town) with some scepticism, I point to the caveat placed on the Table 1 "case" numbers of COVID-19 morbidity in children under 12 years of age by the TGA evaluator (page 10) which reads:

"The report notes that not all cases of hospitalisation are related to disease severity 'as cases may be hospitalised for reasons other than clinical COVID-19 related care' (for example, this includes 'social admissions' of children when parents are hospitalised with COVID-19)."

X. Mutagenic and genotoxcity

171. Town Affidavit at page 11, paragraph 39, Dr. Town states:

"Messenger RNA vaccines do not contain any of the virus that causes COVID-19 nor do they affect or interact with a person's DNA or genes — mRNA vaccines never enter the nucleus of the cell which is where our DNA is kept. Nor are mRNA vaccines gene therapy."

172. I disagree with this statement for 3 reasons:

a) No data exists to support the claim that the mRNA vaccines never enter the nucleus of the cells.

b) The New Zealand Data Sheet (Version: pfdcovii10222) which is the officially approved comprehensive information on the Pfizer Comirnaty vaccine states:

"Preclinical safety data -
Genotoxicity/Carcinogenicity

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

Genotoxicity and mutagenicity pre-clinical in-vitro safety testing specifically investigates interaction of the therapeutic agent with the genetic material in the nucleus of cells. These studies were not done.

c) A common definition of "gene therapy" is - an experimental treatment that involves introducing genetic material into a person's cells to fight or prevent disease. The Pfizer COVID-19 COMIRNATY "vaccine" delivers mRNA genetic material into a person's cells to make the spike protein and therefore should correctly be classed as a form of "gene therapy".

173. The submitted Crown affidavits make no mention of the need for Pfizer to produce pre-clinical genotoxicity and mutagenicity safety testing in future in relation to the Pfizer COVID-19 vaccine as part of the ongoing Provisional Consent requirements. In my opinion, this is a serious oversight on the part of the New Zealand drug regulator.

174. In considering the safety of any new therapeutic, especially genetic therapeutics such as the COVID-19 vaccines, among the highest priority for safety evaluation would be consideration of both genotoxicity and mutagenicity (carcinogenicity) – this would especially apply in this case where it was envisaged to administer these products to healthy individuals of all ages worldwide.

175. Pfizer and other gene-based COVID-19 "vaccine" manufacturers presented their products as "vaccines" to drug regulators even though they do not fit the definition of a vaccine in that they are now known neither to prevent infection or transmission of infection like conventional vaccines. This had significant impact on reducing the usual requirements for safety testing.

176. The World Health Organisation WHO Technical Report Series, no. 927m 2005 Annex 1, WHO Guidelines on nonclinical evaluation of vaccines[34] page 50 section 4.2.3 states: *"Genotoxicity studies are normally not needed for the final vaccine formulation"*. But these guidelines were drafted well before the invention of the mRNA vaccines which are the subject of this affidavit and applied to conventional vaccines – not gene-based products.

177. Theoretically, the gene-based vaccines may have the ability to reverse transcribe (ie incorporate itself or in part) into the DNA of human cells of the body and the Spike Protein produced by these vaccines might impair the innate DNA damage repair systems of the body.

178. Drug regulators around the world have accepted official product information statements which acknowledge the omission of this important pre-clinical safety data.

179. Provisional Consent for COMIRNATY (10ug/0.2mL was provided on 16 December 2021. Since then (18 January 2022) new and important in-vitro genetic data has been published which raises the theoretical possibility that the mRNA contained in the Pfizer gene-based vaccine may be reverse transcribed into one's DNA around the body (including a wide variety of tissues and organs including eggs in the ovary) contrary to the assumptions of the New Zealand drug regulator and other drug regulators. While this research was done on an in-vitro human liver cell line the potential safety implications for current and future generations are of great relevance and significance and drug regulators should be demanding immediate further investigations.[35]

180. This new information has been considered to be of such importance that several international vaccine experts have called for the withdrawal of the Pfizer COMIRNATY vaccines from the world market. Following an extensive critical review of the immunological and metabolic consequences associated with the mRNA based COVID-19 vaccines,

[34] https://cdn.who.int/media/docs/default-source/biologicals/annex1nonclinical.p31-63.pdf?sfvrsn=d11d7789_3&download=true

[35] M. Aldén, F. Olofsson Falla, D. Yang, M. Barghouth, C. Luan, M. Rasmussen, Y. De Marinis. (2022) *Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line.* Current Issues in Molecular Biology 44: 1115–1126. https://doi.org/10.3390/cimb44030073.

some have concluded these vaccines should be withdrawn due to their potential adverse effects.[36]

181. Furthermore, in relation to risk-benefit, it has been reported that "based on publicly available official UK and US data, all age groups under 50 years old are at greater risk of fatality after receiving a COVID-19 inoculation than an unvaccinated person is at risk of a COVID-19 death.[37]

182. This revelation follows an earlier report indicating that the spike protein produced by the Pfizer mRNA vaccine does in fact go into the nucleus of cells and disrupts fundamental cellular processes involved in DNA repair. This raises serious potential safety issues regarding a diminished ability of the body to prevent the rise of cancers.[38] Neither of these observed genetic type molecular effects are expected in relation to conventional vaccines. It is unclear if these concerns contributed to the Swedish drug regulatory decision announced 27 January 2022:

"STOCKHOLM, Jan 27 (Reuters) -

Sweden has decided against recommending COVID vaccines for kids aged 5-11, the Health Agency said on Thursday, arguing that the benefits did not outweigh the risks.

"With the knowledge we have today, with a low risk for serious disease for kids, we don't see any clear benefit with vaccinating them,"[39]

183. It is also unknown if the Danish drug regulator's recent decision to cease its gene-based vaccination program is related to concerns regarding genotoxicity.[40]

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[36]Seneff, S and Nigh, G; International Journal of Vaccine Theory, practice and Research: 2(1), May 10, 2021 - https://ijvtpr.com/index.php/IJVTPR/article/view/23

[37]Dopp, K and Seneff, S. 13 Feb. 2022 *COVID-19 and All-Cause Mortality Data by Age Group Reveals Risk of COVID Vaccine-Induced Fatality is Equal to or Greater than the Risk of a COVID death for all Age Groups Under 80 Years Old as of 6 February 2022.* https://www.skirsch.com/covid/Seneff_costBenefit.pdf

[38] H. Jiang, Y.-F. Mei. (2021) SARS–CoV–2 Spike Impairs DNA Damage Repair and Inhibits V(D)J Recombination In Vitro. *Viruses* **13**:2056 https://doi.org/10.3390/v13102056

[39]https://www.reuters.com/world/europe/sweden-decides-against-recommending-covid-vaccines-kids-aged-5-12-2022-01-27/

[40]https://news.sky.com/story/covid-19-denmark-suspends-covid-vaccination-programme-with-health-chiefs-saying-virus-under-control-12600593?fbclid=IwAR2xIYS6Dil45imXz0FIp7JB19JaVNovUgeN8VmYG0mhP5hiE6GJ4zHNnXM

184. The Swedish and Danish drug regulatory agencies have long been considered to rank among the most competent regulatory agencies in the world and is highly regarded.

185. The issue of potential mutagenicity and genotoxicity is of high importance and received attention at Australian Senate Estimates on Tuesday 1 June 2021 (Community Affairs Legislation Committee, page 53).[41]

186. In relation to questioning of Prof. Skerritt (head of the Australian TGA) by Senator Malcolm Roberts on mRNA COVID-19 vaccines such as the Pfizer gene-based COMIRNATY vaccine on the potential for the mRNA to enter the nucleus of cells and cause potentially serious genetic adverse events which may affect future generations, the following question was put and Prof. Skerritt responded:

"Senator ROBERTS: How long before we know the intergenerational effects?

Dr Skerritt: There is no evidence at all from animal or human studies that the RNA vaccines, if you're talking about them, incorporate into the genetic material of human beings. They wouldn't have received regulatory approval, and that includes by much bigger regulators such as the FDA, if these bits of mRNA incorporated into the human genetic material. In fact, medicines that incorporate into human genetic material and are inherited are currently not permitted in most major countries, including Australia."

187. The statement by Prof. Skerritt was made prior to the publications referred to above indicating that there is now laboratory evidence that mRNA contained in the Pfizer COVID-19 vaccine can enter the nucleus of cells and potentially integrate into human genetic material. This statement by Prof. Skerritt highlights the importance of this discovery and represents perhaps the most compelling evidence of all to reject the use of this vaccine in children on safety grounds.

[41] https://parlinfo.aph.gov.au/parlInfo/download/committees/estimate/074f811f-4fa9-49b2-a2d5-f8dc2b74d47d/toc_pdf/Community%20Affairs%20Legislation%20Committee_2021_06_01_8809_Official.pdf;fileType=application%2Fpdf#search=%22committees/estimate/074f811f-4fa9-49b2-a2d5-f8dc2b74d47d/0000%22 page 53

188. It is my opinion that if the New Zealand drug regulatory authority was aware of this genomic laboratory information prior to consenting to grant Provisional Consent to the Pfizer product on 16 December 2021 for children 5-11, that serious consideration should have been given to withholding this approval. In my opinion, the options now are either to withdraw this Provisional Approval or alternatively the product should be issued a black box warning and only be available to children with relevant and significant co-morbidities who may be at special risk and available on a limited basis by prescription following consultation with a doctor.

Conclusion

189. The reasons why I consider the use of the Pfizer COVID-19 gene-based vaccine in children 5-11 to be unsafe, can be summarised as follows:

a) COVID-19 most commonly is either asymptomatic in children or mildly symptomatic resembling a common cold and requires no treatment and poses no significant health risk. From a statistical point of view, the risk of mortality in this age group due to COVID-19 is virtually nil.

b) The gene-based COVID-19 vaccines, including Pfizer COVID-19 COMIRNATY vaccine for children, have been reported to be associated with serious and significant adverse effects including myocarditis (and other cardiovascular events) especially in younger aged boys. The striking reported incidence of death within 24-48 hours following administration of the gene-based vaccines across the population warrants concern and a re-assessment of risk-benefit, especially in children. In my opinion, the death of a single child due to the known cardiovascular adverse effects of the gene-based "vaccines" is a price to high to pay for the use of these therapeutic agents.

c) There are no long-term safety data on the gene-based vaccines and the potential for integration of the genetic material contained in these vaccines to integrate into the body's DNA, and possibly passed on to future generations, cannot be excluded because such safety studies have not been conducted. This is particularly important in relation to gene-based therapies.

d) The risk of serious COVID-19 appears diminishing with time while the potentially serious adverse effects associated with the gene-based vaccines remains as high as ever. This demands a reassessment of the initial risk-benefit analysis in light of this information.

e) Contrary to initial assumptions, the gene-based "vaccines" like Pfizer COMIRNATY "vaccine" are neither reliably nor substantially effective

in either preventing infection or preventing transmission of infection. There is no viable argument, based on recent data, that children should be vaccinated to protect any vulnerable segment of the population (eg the elderly).

190. This failure to reliably or substantially prevent infection and transmission of the virus was known at the time Medsafe Provisionally Approved the Pfizer gene-based COMIRNATY "vaccine" to children aged 5-11 and this fact should have been compelling evidence for the drug regulator not to approve this gene-based "vaccine" for this age group.

191. On balance, in my opinion, the risk-benefit assessment does not support the administration of a Pfizer gene-based COMIRNATY vaccine to children aged 5-11 in light of the known potentially serious acute adverse effects and unknown potential serious long-term effects in this age group.

192. I consider the provisional approval decision for the paediatric vaccine made on 16 December 2021 to be wrong. In my opinion, the Provisional Consent was based on inadequate and flawed information. There was no need to have children aged 5-11 "vaccinated" against COVID-19 at all given their natural immunity and the known limited effects of COVID-19 on this age group. The decision to approve the vaccine and then to have it administered to children have put children who receive the vaccine at risk. Children would be in a better position in terms of their immediate and long-term health and well-being by not having this drug injected into their bodies.

Affirmed at CAMBERAY)
this 2nd day of May 2022)
before me: Peter Halim Fam, Lawyer)

[Person of appropriate office or occupation that is able to take oaths or affirmations in the jurisdiction that you are in at the time of swearing/affirming this affidavit]

EXHIBIT "A"

EXHIBIT STAMP

This is the exhibit marked with the letter "A" referred to in the annexed affidavit of Phillip Michael Altman affirmed at NSW, Australia this 2nd day of May 2022.

.....

A person appropriate to witness a statement in the jurisdiction in which it is being affirmed.

[redacted]

CURRICULUM VITAE
April 2020

[redacted]

TERTIARY QUALIFICATIONS

Bachelor of Pharmacy (Honours)	Sydney University	1970
Master of Science	Sydney University	1972
Bachelor of Science	Seattle, WA, USA	1974
Doctor of Philosophy	Sydney University	1981

SUMMARY OF POSITIONS WITHIN THE AUSTRALIAN PHARMACEUTICAL INDUSTRY

Director – Clinical & Regulatory Affairs	Viralytics Ltd	2007-2012
Pharmaceutical Consultant	consulting	1998-present
Managing Director	Pharmaco International (Omnicare)	1986-98
General Manager (Sydney)	Institute of Drug Technology	1985
Head, Medical Department	Merrell Dow Pharmaceuticals	1982-85
Scientific Affairs Manager	Hoechst Roussel	1981
PhD candidate	Sydney University	1978-1981
Scientific Affairs Manager	Searle Laboratories	1976-1978
Clinical Research Associate	Searle Laboratories	1974-1976

MEMBERSHIPS

- Founder and Life member of the Association of Clinical and Regulatory Scientists (ARCS) serving the Australian pharmaceutical, medical device and biotechnology industries.

GENERAL EXPERIENCE

Dr. Altman has more than 30 years experience in clinical research and regulatory affairs having worked in senior positions for several multinational companies and as a senior industry consultant within his own company Pharmaco Pty. Ltd. – one of Australia's first contract research organisations (CROs).

Regulatory affairs activities included the assessment and compilation of registration dossiers including aspects relating to organic chemistry, pharmaceutical chemistry, pharmaceutics, pharmacokinetics, quality control and manufacturing for novel chemical entities, generic drugs and non-prescription products.

He has been involved in more than a hundred clinical trials (including Phase I, II, III and IV) and has been personally responsible for the market approval of numerous new drugs and dosage forms since joining the pharmaceutical industry in 1974. Dr. Altman has consulted to many of the leading Australian biotech companies at one time or another and is experienced in setting R&D strategy, developing detailed research plans, the design and supervision of clinical research projects and the generation of documentation to meet international registration requirements.

Dr. Altman was co-author of the medical and pharmaceutical training program used by pharmaceutical representatives in the Australian pharmaceutical industry. He co-founded and is a Life Member the largest professional body of pharmaceutical industry scientists involved in clinical research and regulatory affairs (Association of Regulatory and Clinical Scientists to the Australian Pharmaceutical Industry Ltd. - ARCS) which now has more than 2000 members.

Dr. Altman has acted as an expert witness in matters relating to pharmaceutical formulation patent disputes and in relation to criminal cases involving drugs and/or alcohol. Experience has been gained over 30 years in evaluating pharmaceutical formulations for drug registration in Australia, including aspects related to bioavailability and sustained release pharmacokinetics. Recent clinical research activities have involved the design, management and reporting of pharmacokinetic clinical trials involving a solid dose oral formulation and an inhaled formulation (see recent papers).

Senior Clinical and Regulatory Pharmaceutical Industry Consultant
1998-present

As Director of Altman Biomedical Consulting Pty. Ltd., Dr. Altman currently consults for several companies and provides clinical trial and regulatory services and management advice. In this capacity, Dr. Altman provides critical analysis of new projects, advises companies on the best strategic approach to develop new products, constructs R&D plans and budgets, manages, supervises and reports on the research projects . Dr. Altman also manages all the regulatory issues and requirements throughout the research programs to ensure all work conduct adheres to the required codes of Good Clinical Practice, Good Manufacturing Practice and ICH guidelines.

Smaller companies or start-up companies may particularly benefit from the support of Altman Biomedical Consulting in that comprehensive and detailed advice covering product development and research can be obtained in order to allow companies to assess scientific risk and to plan future research and budget needs.

Dr. Altman has conducted audits of contract research facilities to ensure that any contracted work is conducted to the highest international standards.

Dr. Altman provides expert witness services in relation to therapeutic goods and is experienced in drafting affidavits in relation to patent and other courtroom matters.

Dr. Altman advises public companies involved in drug development and occasionally participates as a Board member for public companies. Dr. Altman was until 2015 a non-executive Director of Viralytics Ltd. which developed a live virus therapy (CAVATAK) for the treatment of melanoma.

Altman Biomedical Consulting networks with data managers, statisticians, formulation experts, medical device engineers, CROs and various hospital departments linked to academic units in relation to therapeutic trials and diagnostic products.

Pharmaco Pty. Ltd.
Managing Director
1986-1998

Dr. Altman is a pharmacologist and established one of the first full service clinical research organisations in Australia (Pharmaco International) in 1986. Within 12 years the staff of Pharmaco International grew to include clinicians, pharmacologists, nurses, pharmacists, regulatory and health economic staff.

Pharmaco was acquired by IBAH, a multinational CRO employing 1200 staff worldwide and Dr. Altman was retained as Managing Director of the Australian IBAH office (now known as Omnicare) during the transition period.

Dr. Altman consulted to more than 30 major international pharmaceutical, biotech and medical device companies including Abbott, Allergan, Alphapharm, Astra, Bayer, Biotech Australia, Boehringer Ingelheim, Bristol Myers Squibb, CSL, Lilly, Fauldings, Glaxo, Sterling, SmithKline Beecham, Janssen Cilag, Johnson & Johnson, Lederle, Mundipharma, Novartis, Novo Nordisk, Organon, Peptech, Pfizer, Reckitt & Coleman, Roche, Sanofi, Serono, 3M, Wyeth and many others.

Dr. Altman work extended to the design, conduct and reporting of Phase I-IV clinical trials in relation to anti-microbial, anti-viral, anti-cancer, anti-rheumatic, hormonal, contraceptive, analgesic, anti-ulcer, anti-hypertensive, anti-arrhythmic, hypolipidaemic, anti-psychotic, anti-ulcer, anti-histamines, anti-depressant, narcotic, steroidal, vaccine and dermatological therapeutic agents.

Dr. Altman provided regulatory advice to both Australian and overseas companies with regard to drugs, medical devices and biotech products including new drug registration, amended or varied registrations, approval of new indications, revised product information approval, labelling and appeals to the Minister.

Pharmaco Pty. Ltd. was the first full service CRO in Australia offering clinical, regulatory, health economic, statistical and data management support to client companies.

General Manager (Sydney)
Institute of Drug Technology
1985

- Dr. Altman opened the Sydney Office of IDT
- acquired business for IDT
- liaised with the IDT laboratories on research projects
- provided regulatory consulting to several multinational pharmaceutical companies.

Clinical Research & Regulatory Affairs Director
Head, Medical Department
Merrell Dow Pharmaceuticals
1982-85

- reported to the Managing Director
- supervised the activities of a team of clinical research and regulatory staff
- responsible for adherence to corporate guidelines for the conduct of clinical trials
- responsible for investigator negotiation, clinical trial budgets and planning, clinical trial monitoring, transmission of data to headquarters and reporting
- responsible for registering new drugs, expanding the approved indications of existing drugs, obtaining approval for new dosage forms and amending product information documentation
- supervising the drug information function
- supervising the adverse event reporting system
- approving medical literature and advertising
- training the field sales force
- responsible for public affairs
- participate in the development of new local non-prescription products

Scientific Affairs Manager
Hoechst Roussel
1981

- responsible for the evaluation of data packages for all new products
- responsible for compiling NDF-4 new drug submissions, answering TGA questions on these submissions and obtaining final approval
- responsible for the drafting of approved Product Information and assisting the Medical Director to gain TGA approval for these documents
- responsible for obtaining approval of new or revised dosage forms of existing drugs
- assisting the Medical Director in the training of field sales representatives
- collating adverse event reports
- responding to telephone inquiries from health professionals and the public

PhD candidate
Sydney University
1978-1981

- develop and implement a research plan to synthesise, isolate, purify and test in-vitro and in-vivo the pharmacological activity of a new class of digitalis-like cardiotonic drugs with lower toxicity profiles than currently known.
- In-vitro pharmacology involved the isolated perfused guinea pig heart while in-vivo work concentrated on the open-chest anaesthetised dog preparation within the School of Medicine.
- toxicology work was conducted within the School of Pharmacy
- tutoring in pharmaceutics, organic chemistry and pharmaceutical chemistry
- this research led to the development of a series of digitoxigenin glucosides with high potency and low toxicity with potential clinical application

Scientific Affairs Manager
Clinical Research Associate
Searle Laboratories
1974-1978

- managing the company's library literature
- coordinating the adverse event reporting and interfaced with health professionals and the public
- monitoring clinical trials
- compiling regulatory submissions for the Australian TGA for new drugs and new dosage forms of existing drugs
- obtained amended Poisons Scheduling for several products
- training of field sales representatives
- protocol design and negotiation with investigators
- approval of advertising material
- drafting of product information documents

Recent papers:

Journal of Clinical Virology 42 (2008) 22–26
Comparison of a novel HPV test with the Hybrid Capture II (hcII)
and a reference PCR method shows high specificity and
positive predictive value for 13 high-risk human papillomavirus infections
Cristina Baleriola, Douglas Millar, John Melki, Neralie Coulston,
Phillip Altman, Nikolas Rismanto, William Rawlinson

Cherry CL, Hoy JF, Altman PM, Rowe JS, Krum H, Mills M, Lewin SR and Altman PM
Current HIV Research, 2008, 6, 272-276.
Phase 1 single dose studies to optimize the pharmacokinetics of DG17, a novel HIV-protease inhibitor pro-drug, using sodium bicarbonate and ritonavir

KA Grieve, PM Altman, JS Rowe, JA Staton and VMJ Oppenheim
A randomized, double–blind, comparative efficacy trial of three head lice treatment options:
Malathion, pyrethrins with piperonyl butoxide and MOOV Head Lice Solution.
Pharmacist, 26:9: Sept. 2007 p 738-743.

Brooke Berry, Phillip Altman, James Rowe, and Jack Vaisman.
Comparison of Pharmacokinetics of Vardenafil Administered Using an Ultrasonic Nebuliser for Inhalation versus a Single 10mg Oral Tablet. In press, J. Sex. Med. (2009)

Simon T. Lake, Phillip M. Altman, Jack Vaisman and Russell S. Addison
Validated LC-MS/MS assay for the quantitative determination of vardenafil in human plasma and its application to a pharmacokinetic study
Biomedical Chromatography (in press) 2010

Steve Barker and Phillip Altman
A randomised, assessor blind, parallel group comparative efficacy trial of three products for the treatment of head lice in children - melaleuca oil and lavender oil, pyrethrins and piperonyl butoxide, and a "suffocation" product.
BMC Dermatology 2010, **10**:6/1471-5945/10/6

Steve Barker and Phillip Altman
An ex vivo, assessor blind, randomised, parallel group, comparative efficacy trial of the ovicidal activity of three pediculicides after a single application - melaleuca oil and lavender oil, eucalyptus oil and lemon tea tree oil, and a "suffocation" pediculicide
BMC Dermatology 2011, 11:14 doi:10.1186/1471-5945-11-14

Phillip Altman
The Who, How and Why of COVID-19
Quadrant Magazine 25 July 2021

Phillip Altman
A Total Lack of Therapeutic Perspective
Quadrant Magazine 22 Aug. 2021

Phillip Altman
Comparison of ivermectin and molnupiravir
BIRD-group.org
28 October 2021