NOTICE OF FILING

Details of Filing

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File Title:	ANTHONY LEITH ROSE & ORS v THE SECRETARY OF THE DEPARTMENT OF HEALTH AGED CARE, BRENDAN MURPHY & ORS
Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA

Registrar

Important Information

This Notice has been inserted as the first page of the document which has been accepted for electronic filing. It is now taken to be part of that document for the purposes of the proceeding in the Court and contains important information for all parties to that proceeding. It must be included in the document served on each of those parties.

The date of the filing of the document is determined pursuant to the Court's Rules.

Form 17

Rule 8.05(1)(a)

Amended Statement of Claim

Amended pursuant to *Federal Court Rules 2011* – r. 16.51(1).

No. NSD349 of 2023

Federal Court of Australia

District Registry: NSW

Division: GENERAL

ANTHONY LEITH ROSE and others

Applicants

THE SECRETARY OF THE DEPARTMENT OF HEALTH AND AGED CARE, BRENDAN MURPHY and others

Respondents

PART A – INTRODUCTION

GROUP MEMBERS

1. The Applicants bring this proceeding as a representative proceeding pursuant to Part IVA of the *Federal Court of Australia Act 1976* (Cth):

    a) in their own right; and

    b) on behalf of all natural persons, being persons who at any time up to and including the date on which this Statement of Claim is filed **("the Group Members")**:

        1 were injected with one or more of the following products identified as

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("the Vaccines"):

(1) any of the following Vaccines sponsored by Pfizer Australia Pty Ltd, by which a Group Member is also a **Pfizer Sub-Group Member**:

a) "COMIRNATY" product containing active ingredient BNT162b2 messenger ribonucleic acid mRNA sponsored by Pfizer Australia Pty Ltd **("the Pfizer Vaccine")**, at any time on or after:

i) 25 January 2021 in persons 16 years of age or older;

ii) 23 July, 2021 in persons 12 years of age or older;

b) the Pfizer Vaccine product produced in the formulation for paediatric use in children aged 5 to 11 years of age sponsored by Pfizer Australia Pty Ltd **("the Pfizer Child Vaccine")** at any time on or after 6 December 2021 in persons 5 to 11 years of age;

c) The Pfizer Bivalent vaccine product (Comirnaty) Bivalent Original/Omicron BA.1), tonzinameran/riltozinameran, ("**The Pfizer Bivalent Product**") at any time on or after 27 October 2022 in people aged 18 years and older;

d) The Pfizer Bivalent vaccine product (Comirnaty Bivalent Omicron BA.4/BA.5) tozinameran and famtozinameran) ("**The Pfizer Bivalent BA 4/5 Product**") at any time on or after 20 January 2023 in people aged 12 years and older.

(2) any of the following Vaccines sponsored by AstraZeneca Pty Ltd, by which a Group Member is also an **AstraZeneca Sub-**

Group Member:

a) "VAXZEVRIA" product containing active ingredient ChAdOx1-S sponsored by AstraZeneca Pty Ltd **("the AstraZeneca Vaccine")** at any time on or after 16 February 2021 in persons 18 years of age or older;

(3) any of the following Vaccines sponsored by Moderna Australia Pty Ltd, by which a Group Member is also a **Moderna Sub-Group Member:**

a) "SPIKEVAX" product containing active ingredient Elasomeran sponsored by Moderna Australia Pty Ltd **("the Moderna Vaccine")** at any time on or after 9 August 2021 in persons 18 years of age or older;

b) the Moderna Vaccine product produced in the formulation for paediatric use in children:

i) on or after 4 September, 2021 in persons aged 12 years or older **("the Moderna Adolescent Vaccine")**;

ii) on or after 22 February, 2022 aged 6 to 11 years of age **("the Moderna Child Vaccine")**; and

iii) on or after 21 October, 2022 in infants aged 6 month to 5 years of age **("the Moderna Infant Vaccine")**;

(4) on or after, as to:

a) the Pfizer Vaccine - 25 January 2021;

b) the Pfizer Child Vaccine - 3 December 2021;

c) the AstraZeneca Vaccine – 15 February, 2021;

d) the Moderna Vaccine - 9 August 2021;

e) the Moderna Child Vaccine – 17 February, 2022;

f) the Pfizer Bivalent vaccine -– 27 October 2022;

g) the Pfizer Bivalent BA.4/5 vaccine – 20 January 2023.

(5) in Australia; and

(6) by a suitably qualified:

a) medical practitioner;

b) health professional; or

c) any other person legally qualified or authorised to administer the Vaccines; and

2 suffered a Serious Adverse Event either partly or wholly by reason of injection with one or more of the Vaccines, such Serious Adverse Event being one or more of the following events **("a Vaccines Induced Caused Adverse Event")**:

(1) death;

(2) a life-threatening event;

(3) an event which required in-patient hospitalisation;

(4) an event which prolonged existing hospitalisation;

(5) an event which resulted in persistent or significant disability or incapacity, including:

a) permanent impairment of a body function; or

b) permanent damage to a body structure;

(6) an event which necessitated medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure;

(7) caused a congenital anomaly, birth defect or stillbirth;

(8) was a medically important event;

(9) was an event that made one or more of the outcomes above more likely; or

(10) was an event that required intervention to prevent one or more of the above outcomes, including events that required intensive treatment in an emergency department or at home but did not result in hospitalisation.

2. The following persons are not Group Members for purposes of this proceeding:

a) any current Minister of the Commonwealth of Australia, a State or Territories; or

b) any judicial officer of the Commonwealth of Australia, a State or Territories.

3. The claims advanced by the Applicants, on their own behalf, and on behalf of Group Members, in this proceeding, include claims for:

a) personal injury; and

b) pure economic loss.

4. As at the time of the commencement of this proceeding, there are seven or more persons who are Group Members having claims against each of the Respondents as pleaded and particularised in the Statement of Claim herein.

COMMON QUESTIONS OF FACT AND LAW

5. The questions of law or fact common to the claims of Group Members in this proceeding are (adopting the definitions pleaded in the Statement of Claim):

    a) whether the factual matters pleaded herein at paragraphs 10 to 13, 17 to 24, 26 to 232; 235, 237 to 247, 251 to 254, 256 and are true as findings of fact;

    b) whether at all material times the Secretary possessed the authority and undertook the responsibilities and functions alleged in paragraph 10;

    c) whether at all material times Skerritt possessed the authority and undertook the responsibilities and functions alleged in paragraph 11;

    d) whether at all material times the Chief Medical Officer possessed the authority and undertook the responsibilities and functions alleged in paragraph 12;

    e) whether at all material times Hunt possessed the authority and undertook the responsibilities and functions alleged in paragraph 13;

    f) whether at all material times in relation to the acts and omissions pleaded in this statement of claim, the Respondents acted:

        1 in the performance or exercise in relation to their functions, duties or powers under the Act or the Regulations;

        2 purportedly in the performance or exercise in relation to their functions, duties or powers under the Act or the Regulations.

    g) whether the material acts and omissions of each of the Respondents occurred as alleged herein as:

        1 the Approvals;

        2 the Continuing Approvals;

3 the Known Serious Vaccines Risks and Conduct – Approvals;

4 the Known Serious Vaccines Risks and Conduct – Continuing Approvals;

5 the Misleading Vaccines Statements;

6 Respondents Control of Therapeutic Goods;

7 the Reckless Failures – Approvals;

8 the Reckless Failures – Continuing Approvals;

h) whether the material knowledge was held by each of the Respondents as alleged in:

1 the Known Serious Vaccines Risks and Conduct – Approvals;

2 the Known Serious Vaccines Risks and Conduct – Continuing Approvals;

3 the Misleading Vaccines Statements;

4 the Reckless Failures – Approvals;

5 the Reckless Failures – Continuing Approvals;

6 Respondents' Knowledge of Public Reliance;

7 Public's Reasonable Expectation and Reliance;

8 the Public Expectation of Skill;

9 the Known Gravity of the Approvals;

10 the Known Vulnerability of the Australian Public;

11 the Respondents Duty;

12 the Approvals Breach;

i) whether the Approvals were undertaken by any or all of the Respondents extraneous to any power provided under:

1 the Act and/or the Regulations;

2 at all.

j) whether the Continuing Approvals were undertaken by any or all of the Respondents extraneous to any power provided under:

1 the Act and/or the Regulations;

2 at all;

k) whether it was reasonably foreseeable that the following may cause or contribute to harm to the Group Members:

1 the Approvals constituting the Approvals Breach;

2 the Continuing Approvals constituting the Continuing Approvals Breach;

l) whether but for the Approvals the Group Members would not have taken one or more of the Vaccines;

m) whether but for the Continuing Approvals the Group Members would not have taken one or more of the Vaccines;

n) whether the Approvals were undertaken by the Respondents with:

1 knowledge that such was:

(1) extraneous to any power under the Act; and

(2) likely to cause harm to the Group Members;

2 further or alternatively, reckless indifference:

(1) to whether such was extraneous to any power under the Act; and

(2) to the likelihood of harm to the Group Members;

o) whether the Continuing Approvals were undertaken by the Respondents with:

1 knowledge that such was:

(1) extraneous to any power under the Act; and

(2) likely to cause harm to the Group Members;

2 further or alternatively, recklessly indifference:

(1) to whether such was extraneous to any power under the Act; and

(2) to the likelihood of harm to the Group Members;

p) whether the Respondents owed the Respondents Duty to the Group Members;

q) whether the Approvals Breach occurred;

r) whether the Continuing Approvals Breach occurred;

s) whether the Approvals constituting the Approvals Breach caused or contributed to injury, loss or harm to the Group Members;

t) whether the Continuing Approvals constituting the Continuing Approvals Breach caused or contributed to injury, loss or harm to the Group Members;

u) whether the Misfeasance occurred;

v) whether and to what extent the Commonwealth is vicariously liable for the actions (tortious or otherwise) of the Public Officers alleged in the proceedings.

APPLICANTS

6. The First Applicant, Anthony Leith Rose **("Mr Rose")**:

a) is a Group Member of the Moderna Sub-Group;

b) was born on 7 October, 1976 in New South Wales;

c) is unmarried, formerly married;

d) has two children;

e) is an Australian citizen;

f) resides in New South Wales;

g) received an injection of a single dose of the Moderna Vaccine **("Mr Rose Vaccination")**:

1 by a medical health professional;

2 on 8 October, 2021;

3 in Sydney, New South Wales;

h) Mr Rose Vaccination caused Mr Rose to suffer by 9 October, 2021, chronic and ongoing **("the Rose Injuries")**:

1 severe cognitive impairment;

2 severe chest pain;

3 severe headaches;

4 shortness of breath;

5 painful left arm;

6 leg weakness;

7 vision changes;

8 altered cardiac function; and

9 severe chronic fatigue.

7. The Second Applicant, Antonio Derose **("Mr Derose")**:

a) is a Group Member of the AstraZeneca Sub-Group;

b) was born on 7 November, 1957 in Italy;

c) is unmarried, formerly married;

d) has 3 children;

e) is an Australian permanent resident;

f) resides in South Australia;

g) received an injection of a single dose of the AstraZeneca Vaccine **("Mr Derose Vaccination")**:

1 by a medical health professional;

2 on 9 October, 2021;

3 in Adelaide, South Australia;

h) Mr Derose Vaccination caused Mr Derose to suffer by 18 October, 2021,

chronic and ongoing **("the Derose Injuries")**:

1 Acute Disseminated Encephalomyelitis;

2 lower back pain;

3 lower limb numbness and weakness;

4 neurogenic bladder and bowel;

5 inability to walk unassisted;

6 wheelchair dependency;

7 left lower leg venous thrombosis

8. The Third Applicant, Gareth O'Gradie **("Mr O'Gradie")**:

a) is a Group Member of the Pfizer Sub-Group;

b) was born on 19 September, 1981;

c) is married;

d) has 2 children;

e) is an Australian citizen;

f) resides in Victoria;

g) received an injection of a single dose of the Pfizer Vaccine **("Mr O'Gradie Vaccination")**:

1 by a medical health professional;

2 on 24 July, 2021;

3 in Melbourne, Victoria

h) Mr O'Gradie Vaccination caused Mr O'Gradie to suffer by 31 July, 2021 **("the O'Gradie Injuries")**:

1 chronic;

(1) myopericarditis requiring pericardiectomy;

(2) pericarditis;

(3) myocarditis;

(4) lethargy;

(5) shortness of breath;

(6) back pain;

(7) psychological illness:

(8) anxiety;

(9) depression;

(10) PTSD;

(11) social isolation.

2 chronic from treatment:

(1) disfiguring scarring;

(2) numbness of the chest wall due to median sternotomy for pericardiectomy;

(3) steroid induced diabetes;

(4) injection site reactions to immunosuppressive injection

therapy

3 acute:

(1) chest pain;

(2) palpitations;

(3) shortness of breath; and

(4) fever.

9. Each and every one of the Applicants is capable of suing:

a) in their own right; and

b) on behalf of the Group Members.

PART B - RESPONDENTS

THE FIRST RESPONDENT

10. At all material times, the First Respondent, the Secretary of the Department of Health and Aged Care **("the Secretary")**:

a) is identified in the person of Brendan Murphy;

b) was secretary of the Department of Health and Aged Care (formerly the Department of Health) being a department of the Australian Government executive **("the Department")**;

c) represented and acted for the Commonwealth in his role as secretary of the Department;

d) was "Secretary" as defined by and pursuant to s. 3 of the *Therapeutic Goods Act 1989* (Cth), and thereby Secretary for the purposes of:

1 the *Therapeutic Goods Act 1989* (Cth) **("the Act")**;

2 the *Therapeutic Goods Regulations 1990* (Cth) **("the Regulations")**;

e) maintained the Australian Register of Therapeutic Goods **("the Register")**:

1 required by s.9A(1) of the Act to be for the purpose of compiling information related to, and providing evaluation of therapeutic goods for use in humans;

2 purportedly pursuant to the Act and Regulations;

f) dealt with the matters to which the Act relates;

g) was appointed to the role of Secretary by the minster responsible for the Department;

h) directed and was responsible for the functions of:

1 the Department;

2 the Therapeutic Goods Administration **("the TGA")** acting pursuant to the Act;

i) undertook the functions of the TGA and the Department by:

1 direct action and directive;

2 by directions to authorised persons empowered to act in accordance with the Act by authority of the Secretary;

j) and pursuant to whose instructions the following were required to act or customarily acted:

1 TGA Members, officers and staff;

2 the Department officers and staff.

k) was an employee, officer, representative, and acting on behalf of the Commonwealth;

l) was a Commonwealth Officer as defined by s. 3 of the Act;

m) in all acts and omissions doing so purportedly pursuant to and insofar as the duties and authorities conferred on him:

1 as an employee or officer of the Commonwealth; and

2 by legislation, including the Act and Regulations.

THE SECOND RESPONDENT

11. At all material times until 18 April, 2023, the Second Respondent, John Skerritt **("Skerritt")**:

a) led the TGA acting purportedly to the powers conferred under the Act and the Regulations;

b) directed and was responsible for the functions of the TGA consistently with the direction of the Secretary;

c) undertook the functions of the TGA and the Department by:

1 direct action and directive;

2 directions to authorised persons empowered to act in accordance with the Act by authority of the Secretary;

d) was a person pursuant to whose instructions TGA Members, officers and staff were required to act or customarily acted;

e) dealt with the matters to which the Act relates;

f) was Deputy Secretary of Health Products Regulation Group (HPRG) which:

1 is part of the Department;

2 includes the whole of the TGA.

g) duly authorised by the Secretary as a person:

1 authorised to exercise powers under the Act pursuant to s. 7A of the Act;

2 as an authorised officer to exercise powers under the Regulations;

h) was a member of the HPRG Executive body;

i) had direct responsibility for the overall management of:

1 the TGA; and

2 the ODC.

j) was the most senior officer within the TGA:

1 to whom TGA Members reported;

2 pursuant to whose instructions TGA Members, officers and staff were required to act or customarily acted;

3 with responsibility for the conduct of the TGA.

k) was an employee, officer, representative, and acting on behalf of the Commonwealth;

l) was a Commonwealth Officer as defined by s. 3 of the Act;

m) in all acts and omissions doing so purportedly pursuant to and insofar as the duties and authorities conferred on him:

1 as an employee or officer of the Commonwealth; and

2 legislation, including the Act and Regulations.

THE THIRD RESPONDENT

12. At all material times, the Third Respondent, the Chief Medical Officer **("the Chief Medical Officer")**:

a) was identified in the person of Professor Paul Kelly;

b) represented and acted for the Commonwealth in his role as Chief Medical Officer;

c) was the principal medical advisor to:

1 the Minister of the Department

2 the Department; and

3 the Australian Government;

d) was directed by and reported to the Secretary;

e) dealt with the matters to which the Act relates;

f) was directly responsible for the division of the Department:

1 called the Office of Health Protection and Response Division;

2 providing advices relating to:

(1) epidemiology;

(2) infectious disease; AND

(3) immunisation of the Australian population;

g) was tasked with assisting the Australian Government and Australian

population to:

1 understand how coronavirus spreads through the community; and

2 what the Australian population and Australian Government could do to stop the spread of coronavirus;

h) was an employee, officer, representative, and acted on behalf of the Commonwealth;

i) was a Commonwealth Officer as defined by s. 3 of the Act;

j) in all acts and omissions doing so purportedly pursuant to and insofar as the duties and authorities conferred on him:

1 as an employee or officer of the Commonwealth; and

2 legislation, including the Act and the Regulations.

THE FOURTH RESPONDENT

13. At all material times the Fourth Respondent, Greg Hunt **("Hunt")**:

a) was minister for the Department until 23 May, 2022;

b) was an employee, officer, representative, and acting on behalf of the Commonwealth;

c) was a Minister for the purposes of the Act;

d) was the Minister responsible for administration of the Act;

e) dealt with the matters to which the Act relates;

f) was a Commonwealth Officer as defined by s. 3 of the Act;

g) in all acts and omissions doing so purportedly pursuant and insofar as to the duties and authorities conferred on him:

1 as an employee or officer of the Commonwealth; and

2 legislation.

THE FIFTH RESPONDENT

14. At all material times, the Fifth Respondent, the Commonwealth:

a) was and is liable in for the actions and omissions in their respective capacities as employees and officers of the Commonwealth of **("the Public Officers")**:

1 the Secretary;

2 Skerritt;

3 the Chief Medical Officer; and

4 Hunt;

ACTIONS THROUGH THE TGA

15. At all material times the Public Officers when acting through the body of the TGA either directly or by exercising acts or omissions by the grant of authority to or direction of any employee, officer, contractor or servant of the TGA that person was at all times:

a) acting purportedly pursuant to power granted under the Act;

b) the person acting:

1 for the purposes of the allegations of acts and omissions in this pleading; and

2 in fact acting to facilitate and bring about that act or omission.

RESPONDENTS' LIABILITY

16. Each act or omission pleaded by reference to the personal Respondents identified in this proceeding was an act or omission:

    a) carried out by them pursuant to the duties and authorities conferred on them as employees or officers of the Commonwealth;

    b) wherein the Commonwealth is responsible in law for the actions of those persons.

THE DEPARTMENT

17. The Department was at all material times and is:

    a) responsible for **("the Department Functional Responsibilities")**:

        1 the health of the Australian population including the Group Members;

        2 the Australian health system;

        3 the health and wellbeing of the Australian population;

        4 the priorities of the government of the Commonwealth.

        5 the overall administration of the Act and the Regulations.

    b) a department of the Government of Australia;

    c) regulating medicines and medical devices in Australia, including the Vaccines, through the approved functions of the TGA under the Act;

    d) comprised of departments which included the HPRG;

    e) employing at all material times:

        1 the Secretary;

2 Skerritt.

Particulars

The Department Functional Responsibilities are contained in and publicly declared by the Department to be the responsibilities of the Department in documents produced by the Department in published to the Department Website at https://www.health.gov.au/.

https://www.health.gov.au/about-us/what-we-do/regulation-and-compliance

https://www.health.gov.au/about-us/the-australian-health-system

TGA

18. The TGA was at all material times:

a) a part and a division of:

1 the Department; and

2 the Health Products Regulation Group **("the HPRG")** being a sub-division of the Department;

b) a statutory body empowered in its functions by:

1 the Act;

2 the Regulations.

c) empowered by the Act and the Regulations to provide for the establishment and maintenance of a national system of controls of therapeutic goods used in Australia regardless of the place of production, including the Vaccines, in respect of their:

1 safety;

2 efficacy;

3 quality.

d) directed in its daily functions by Skerritt, in his position as the Deputy Secretary of the HPRG;

e) acting in all of its conduct under the direction and authority of the Respondents being:

1 Skerritt;
2 the Secretary;
3 Hunt; and
4 The Commonwealth.

f) operating as the Australian regulatory authority in respect of therapeutic goods including the Vaccines;

g) regularly carrying out and tasked with conducting assessment and monitoring activities to ensure therapeutic goods available in Australia, including the Vaccines:

1 are of an acceptable standard; and

2 with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances.

h) possessed of, and publicly declared by the TGA to be possessed of, the following responsibilities relevant to the Vaccines authorisation and use in Australia **("the TGA Functional Responsibilities")**:

1 the evaluation of applications to approve new medicines and vaccines for supply in Australia, including the Vaccines, for their:

(1) safety;

(2) efficacy;

(3) quality;

(4) risk-benefit profile.

2 undertaking safety monitoring of medicines and vaccines approved for supply in Australia after they are on the market, including the Vaccines, for their ongoing:

(1) safety;

(2) efficacy;

(3) quality;

(4) risk-benefit profile.

3 regulation of therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products;

4 ensuring that therapeutic goods available for supply in Australia are safe and fit for their intended purpose;

5 creation and maintenance of the Register for the purpose of compiling information in relation to, and providing for evaluation of, therapeutic goods for use in humans;

6 evaluation of applications to approve new medicines for supply in Australia;

7 safety monitoring of medicines and vaccines approved for supply in Australia after they are on the market by:

(1) pre-market assessment; and

(2) post-market monitoring and enforcement of standards including withdrawal of a product from use.

8 undertaking risk assessment of new medicines as a primary function in the process by application of the TGA's scientific and clinical expertise to its decision-making to ensure that the benefits of a product outweigh any risk;

9 in assessing the level of risk taking account of:

(1) side effects;

(2) potential harm through prolonged use;

(3) toxicity; and

(4) the seriousness of the medical condition for which the product is intended to be used;

10 managing the risks of approval of therapeutic products including vaccines by:

(1) identifying, assessing and evaluating the risks posed by therapeutic products;

(2) applying any measures necessary for treating the risks posed; and

(3) monitoring and reviewing risks over time.

11 adopting a risk-benefit approach by balancing:

(1) assurances to consumers that the products they take are safe for their intended use; and

(2) providing access to products that are essential to their health needs.

12 obtaining and using risk information in relation to a therapeutic product including vaccines in determining:

(1) whether to approve a medication for supply; and

(2) the conditions that might be imposed on that approval.

13 in direct proportion to the level of risk the medicine poses to the consumer:

(1) increasing the level of TGA regulatory control; and
(2) determines how and whether consumers can access the medicine by exercising TGA controls or approvals.

14 determining a therapeutic product's risk by assessing whether:

(1) the product contains a substance or substances:

a) scheduled in the Poisons Standard;

b) previously unknown or untested in humans:

i) for the purpose proposed; or

ii) at all.

(2) the product's use can result in significant adverse effects;

(3) the product is used to treat life-threatening or very serious illnesses.

15 the regulation of medicines available to the Australian population by:

(1) classifying the medicine based on different levels of risk to consumer of the medicine;

(2) implementing appropriate regulatory controls for the manufacturing processes of those medicines;

(3) assessing and evaluating medicines for and based upon quality, safety and efficacy where the medicine:

a) is assessed as having a higher level of risk;

b) consequently and typically subject to supply and consumption by prescription only.

16 act in the event of evident safety or efficacy issues with approved and registered medicines to:

(1) closely monitor the safety of the product;

(2) withdraw the product from:

a) the Register;

b) access to the general population.

Particulars

The TGA Functional Responsibilities are contained in and publicly declared by the Department and the TGA to be the responsibilities of the TGA in documents produced by the Department and the TGA in published to the TGA Website at https://www.tga.gov.au/.

https://www.tga.gov.au/products/covid-19/covid-19-vaccines/covid-19-vaccine-approval-process

https://www.tga.gov.au/vaccines-overview

https://www.tga.gov.au/sites/default/files/covid-19-vaccine-safety-monitoring-plan.pdf

i) undertaking, and publicly declared to be undertaking, inter alia, the following functions relevant to the Vaccines and authorisation and use in

Australia **("the TGA Functions")**:

1 evaluating new prescription medicines;

2 approving or rejecting medicines based upon evaluation;

3 approving applications to market biologicals and generic medicines in Australia;

4 providing internal scientific advice to support the decisions made by the Medicines Regulation Division;

5 evaluating toxicological and pharmaceutical chemistry aspects of therapeutic products;

6 providing internal expertise in the biological sciences;

7 overseeing medicines and vaccines to ensure they maintain an appropriate level of quality, safety and efficacy following entry into the Australian marketplace;

8 evaluating and authorising clinical trials for therapeutic products;

9 monitoring and managing medicine shortages;

10 supporting the Governments COVID-19 vaccine compensation scheme;

11 conducting laboratory testing, quality assessment and test procedure development in disciplines such as:

(1) microbiology;

(2) immunobiology;

(3) molecular biology;

(4) biochemistry;

(5) chemistry;

(6) biomaterials engineering;

12 contributing to post market monitoring and the evaluation of a range of therapeutic products for market authorisation including vaccines;

13 ensuring manufacturers of medicines meet appropriate quality standards by:

(1) physically inspecting manufacturing facilities in Australia and abroad;

(2) providing clearances for facilities where suitable inspections have been carried out by comparable overseas regulators;

(3) coordinating therapeutic product recalls when considered necessary;

(4) providing internal technical advice to support Medicines Regulation Division's decisions including on matters relating to:

a) manufacturing practice; and

b) quality management;

14 providing efficient, best practice regulatory operations;

15 communications with the public and health professionals through websites, social media, media releases, direct communications, and responding to direct enquiries.

Particulars

The TGA Functions are contained in and publicly declared by the Department and the TGA to be the functions of the

TGA in documents produced by the Department and the TGA in published to the TGA Website at https://www.tga.gov.au/.

https://www.tga.gov.au/about-tga/corporate-information/tga-structure

PART C - THE VACCINES

COVID AND THE VIRUS

19. SARS-CoV-2 **("the Virus")** is known to be a virus that causes the disease known as Coronavirus Disease (COVID-19) **("Covid")**.

APPROVAL OF THE VACCINES

20. The Respondents acting through the TGA granted approval for provisional registration for each of the Vaccines pursuant to and as defined by s. 23AA of the Act as follows **("the Approvals")**:

    a) the Pfizer Vaccine **("the Pfizer Approval")**:

        1 for use in persons 16 years of age or older;

        2 approved on 24 January 2021;

        3 entered onto the Register: 25 January, 2021;

        4 sponsored by Pfizer Australia Pty Ltd **("Pfizer")**;

    b) the Pfizer Vaccine **("the Pfizer Adolescent Approval")**:

        1 extension of the Pfizer Approval for indicated use of the Pfizer Vaccine in persons 12 years of age or older;

        2 approved on 22 July, 2021;

        3 entered onto the Register on 23 July, 2021;

4 sponsored by Pfizer;

c) the Pfizer Child Vaccine **("the Pfizer Child Approval")**

1 extension of the Pfizer Approval and change to formulation (excipients) for indicated use of the Pfizer Vaccine in children aged 5 years to 11 years;

2 approved on 3 December, 2021;

3 entered onto the Register on 6 December, 2021:

4 sponsored by Pfizer;

d) the AstraZeneca Vaccine (**"the AstraZeneca Approval"**)

1 for use in persons 18 years of age or older;

2 approved on 15 February, 2021;

3 entered onto the Register on 16 February, 2021;

4 sponsored by AstraZeneca Pty Ltd (**"AstraZeneca"**).

e) the Moderna Vaccine (**"the Moderna Approval"**)

1 for use in persons 18 years of age or older;

2 approved on 9 August, 2021;

3 entered onto the Register on 9 August, 2021:

4 sponsored by Moderna Australia Pty Ltd (**"Moderna"**).

f) the Moderna Adolescent Vaccine (**"the Moderna Adolescent Approval"**)

1 extension of the Moderna Approval for indicated use of the Moderna

Vaccine in persons 12 years of age or older;

2 approved on 3 September, 2021;

3 entered onto the Register on 4 September, 2021;

4 sponsored by Moderna.

g) the Moderna Child Vaccine (**"the Moderna Child Approval"**)

1 extension of the Moderna Approval for indicated use of the Moderna Vaccine in persons 6 years of age or older;

2 approved on 17 February, 2022;

3 entered onto the Register on 22 February, 2022;

4 sponsored by Moderna.

h) the Moderna Infant Vaccine (**"the Moderna Infant Approval"**)

1 extension of the Moderna Approval for indicated use of the Moderna Vaccine in persons 6 months of age or older;

2 approved on 19 October, 2022;

3 entered onto the Register on 21 October, 2022;

4 sponsored by Moderna.

21. Each and every one of the Approvals:

a) remains in effect from the date of the respective Approvals until the time of the commencement of these proceedings by reason of the Respondents positive failure or refusal to **("the Continuing Approvals"):**

1 suspend the Approvals;

2 cancel the Approvals;

b) was granted by the Respondents:

1 either directly or by conduct in their respective positions acting directly supportive of, in pursuance of, and in agreement with the grant such application for the relevant Approval made by the Sponsor to the Secretary **("the Applications")**;

2 purportedly pursuant to the Act.

22. Pfizer, Moderna and AstraZeneca **("the Sponsors")** undertook the following studies **("the Sponsors Trials")** from which the resultant data obtained was provided to and relied upon by the Respondents prior to the Approvals in granting the Approvals **("the Sponsors Study Data")**:

Pfizer

a) Pfizer undertook Nonclinical Trials in respect of the Pfizer Vaccine comprised of **("the Pfizer Nonclinical Trial")**:

1 17-day intramuscular toxicity study of BNT162B2 (v9) in wistar rats with 3-week recovery. Study number: 20GR142. Sponsored by Pfizer. 13 November, 2020 https://icandecide.org/wpcontent/uploads/2023/03/125742_S1_M4_20gr142_nsdrg.pdf **("the Pfizer Toxicity Study")**

2 a combined fertility and developmental study (including teratogenicity and postnatal investigations) of BNT162b1, BNT162b2 and BNT162b3 by intramuscular administration in the wistar rat. Sponsored by BioNTech SE. Study report 10 December, 2020 https://www.tga.gov.au/sites/default/files/foi-2289-01.pdf **("the Pfizer Reproductive Study")**.

3 a repeat dosing study of three LNP-Formulated RNA platforms (BNT162b1, BNT162b2, BNT162b3) encoding viral proteins by repeat intramuscular administration to wister han rats. Study report

1 July 2020. Study number 38166. Sponsored by Pfizer https://www.tga.gov.au/sites/default/files/foi-3093-02.pdf ("**the Pfizer Repeat Dosing Study**")

4 a study of vaccine immunogenicity of BNT162b2 (V9) in mice. Study R-20-0085. Sponsored by Pfizer. https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf ("**the Pfizer Immunogenicity Study**")

5 a study of vaccine immunogenicity of BNT162b2 (V8) in mice. Study R-20-0054. Sponsored by Pfizer. https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf ("**the Pfizer Immunogenicity (V8) Study**")

6 a study Characterising the immunophenotype in spleen and lymph node of mice treated with SARS-CoV-2 vaccine candidates. Study R-20-0112. Sponsored by BioNTech. https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf ("**the Pfizer Immunophenotype Study**")

7 a study evaluating Immunogenicity and Evaluation of Protection against SARS-CoV-2 Challenge in Rhesus Macaques for BNT162b2 (V9). Sponsored by Pfizer. Study No. VR-VTR-10671. https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf ("**The Pfizer Immunogenicity and Protection Study**")

b) a phase 1/2/3, placebo-controlled, randomised, observer-blind, dose-finding study to evaluate the safety, tolerability, immunogenicity and efficacy of SARS-CoV-2 RNA vaccine candidates against Covid-19 in healthy individuals. Study number: C4591001. Trial ID NCT04368728. Study start date: 29 April, 2020. Sponsored by BioNTech SE, Collaborator: Pfizer. https://clinicaltrials.gov/ct2/show/NCT04368728 **("the Pfizer Clinical Trial");**

c) a phase 1, open-label dose-finding study to evaluate safety, tolerability, and immunogenicity and phase 2/3 placebo-controlled, observer-blinded safety, tolerability, and immunogenicity study of a SARS-CoV-2 RNA vaccine candidate against Covid-19 in healthy children and young adults. Study Number: C4591007. Trial ID NCT04816643. Commenced 24

March, 2021. Sponsored by BioNTech SE, Collaborator: Pfizer. https://clinicaltrials.gov/ct2/show/NCT04816643
("the Pfizer Child Trial");

d) a study to evaluate the safety, tolerability, efficacy and immunogenicity of BNT162b2 boosting strategies against Covid-19 in participants >12 years of age. Study Number: C4591031. Trial ID: NCT04955626. Commenced 9 July, 2021. Sponsored by BioNTech SE, Collaborator: Pfizer. https://clinicaltrials.gov/ct2/show/NCT04955626
("the Pfizer Booster Trial")

Moderna

e) a study to evaluate efficacy, safety, and immunogenicity of mRNA-1273 vaccine in adults aged 18 years and older to prevent Covid-19. Study Number: mRNA-1273-P301. Trial ID: NCT04470427. Commenced 27 July, 2020. Sponsored by Moderna TX, Inc. https://clinicaltrials.gov/ct2/show/NCT04470427
("the Moderna Clinical Trial")

f) a study to evaluate the safety, reactogenicity, and effectiveness of mRNA-1273 vaccine in adolescents 12 to <18 years old to prevent Covid-19 (TeenCove). Study Number: mRNA-1273-P203. Trial ID: NCT04649151. Commenced 2 December, 2020. Sponsored by Moderna TX, Inc. https://clinicaltrials.gov/ct2/show/NCT04649151
("the Moderna Adolescent Trial")

g) A study to evaluate safety and effectiveness of mRNA-1273 Covid-19 vaccine in healthy children between 6 months of age and less than 12 years of age". Study Number: mRNA-1273-P204. Trial ID: NCT04796896. Commenced 15 March, 2021. Sponsored by Moderna TX, Inc. https://clinicaltrials.gov/ct2/show/NCT04796896
("the Moderna Child Trial")

h) Delayed heterologous SARS-CoV-2 vaccine dosing (boost) after receipt of EUA Vaccines. Study Number: 21-0012. Trial ID: NCT04889209. Commenced May 17, 2021. Sponsored by National Institute of Allergy and Infectious Diseases (NIAID).

https://clinicaltrials.gov/ct2/show/NCT04889209
("the Moderna Booster Trial")

AstraZeneca

i) AstraZeneca undertook Clinical Trials in respect of the AstraZeneca Vaccine comprised of **("the AstraZeneca Clinical Trial")**:

1 a study of a candidate Covid-19 vaccine (COV001). Study Number: COV001. Trial ID: NCT04324606. Commenced 27 March, 2020. Sponsored by: University of Oxford. https://clinicaltrials.gov/ct2/show/NCT04324606**;**

2 Investigating a vaccine against Covid-19. Study Number: COV002. Trial ID: NCT04400838. Commenced 26 May, 2020. Sponsored by University of Oxford. https://clinicaltrials.gov/ct2/show/NCT04400838;

3 A study of a candidate Covid-19 vaccine (COV003). Study Number: COV003. Trial ID: NCT04536051. Commenced 2 September, 2020. Sponsored by: University of Oxford. https://clinicaltrials.gov/ct2/show/NCT04536051;

4 COVID-19 vaccine (ChAdOx1 nCoV-19) trial in South African adults with and without HIV-infection. Study Number: ChAdOx1 nCoV-19_ZA_phI/II v4.1 . Trial ID: NCT04444674. Commenced 23 June, 2020. Sponsored by: University of Oxford. https://clinicaltrials.gov/ct2/show/NCT04444674.

TRIAL PROTOCOLS

23. The following trial protocols were produced by the Sponsors and provided to the Respondents prior to the Approvals as the purported basis for the conduct of the of the Clinical Sponsors Trials and upon which the Respondents relied in granting the Approvals:

a) A phase 1/2/3, placebo-controlled, randomized, observer-blind, dose-finding study to evaluate the safety, tolerability, immunogenicity, and

efficacy of SARS-CoV-2 RNA vaccine candidates against Covid-19 in healthy individuals. Protocol Number C4591001, Trial ID NCT04368728. Final version dated Nov, 2020. Sponsored by BioNTech SE, Collaborator: Pfizer.
https://cdn.pfizer.com/pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf
Earliest version dated 15 April, 2020
https://www.nejm.org/doi/suppl/10.1056/NEJMoa2034577/suppl_file/nejmoa2034577_protocol.pdf
("the Pfizer Trial Protocol")

b) A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older. Protocol Number: mRNA-1273-P301. Dated 20 August, 2020. Sponsored by: ModernaTX, Inc.
https://covid19crc.org/wp-content/uploads/2020/09/mRNA-1273-P301-Protocol-2020.pdf
("the Moderna Trial Protocol")

c) A phase III randomised, double-blind, placebo-controlled multicentre study in adults to determine the safety, efficacy and immunogenicity of AZD1222, a non-replicating ChAdOx1 vector vaccine, for the prevention of Covid-19. Trial ID: NCT04516746. Dated 17 September, 2020. Sponsored by AstraZeneca.
https://s3.amazonaws.com/ctr-med-7111/D8110C00001/52bec400-80f6-4c1b-8791-0483923d0867/c8070a4e-6a9d-46f9-8c32-cece903592b9/D8110C00001_CSP-v2.pdf
("the Trial Protocol")

TGA APPROVAL DOCUMENTS

24. The Respondents produced, *inter alia*, the following documents relating to the matters, data and conclusions made and relied upon by them in granting the Approvals, including by reference to the Sponsors Study Data **("the TGA Vaccine Approval Documents")**:

PFIZER

a) Clinical Evaluation Report – Prescription Medicines Authorisation Branch. Active substance: BNT162b2 [mRNA] COVID-19 vaccine. Product Name: COMIRNATY. Sponsor: Pfizer Australia. 8 January, 2021.
("the Pfizer Clinical Evaluation Report")

b) Nonclinical Evaluation Report – BNT162b2 [mRNA] COVID-19 vaccine (COMIRNATY). Sponsor: Pfizer Australia Pty Ltd. January 2021.
https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf
("the Pfizer Nonclinical Evaluation Report")

c) Delegate's Overview and Request for ACV's Advice. Active Ingredient: BNT162b2 [mRNA]. Proprietary Product Name: Comirnaty Covid 19 vaccine. 11 January, 2021.
https://www.tga.gov.au/sites/default/files/foi-2389-01.pdf
("the Pfizer Delegate's Overview")

d) Comirnaty. Published 25 January, 2021.
https://www.tga.gov.au/resources/auspmd/comirnaty
("the Pfizer Decision Summary")

e) Australian Product Information – Comirnaty (Tozinameran) Covid-19 Vaccine dated 22 July, 2021
https://www.tga.gov.au/sites/default/files/covid-19-vaccine-pfizer-australia-comirnaty-bnt162b2-mrna-pi.pdf
("the Pfizer Product Information")

f) Comirnaty Covid-19 Vaccine Consumer Medicine Information (CMI) Summary.
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2021-CMI-02443-1
("the Pfizer Consumer Medicine Information")

g) Australian Public Assessment Report for BNT162b2 (mRNA). Sponsor: Pfizer Australia Pty Ltd. January 2021.
https://www.tga.gov.au/sites/default/files/auspar-bnt162b2-mrna-210125.pdf

("the Pfizer Original AUSPAR")

h) Australian Public Assessment Report for BNT162b2 (mRNA). Sponsor: Pfizer Australia Pty Ltd. July 2021. https://www.tga.gov.au/sites/default/files/auspar-bnt162b2-mrna-210722.pdf
("the Pfizer 12-15 Year Olds Extension AUSPAR")

i) Australian Public Assessment Report for BNT162b2 (mRNA). Sponsor: Pfizer Australia Pty Ltd. October 2021. https://www.tga.gov.au/sites/default/files/auspar-bnt162b2-mrna-211029.pdf
("the Pfizer Booster for Adults >18 Years AUSPAR")

j) Australian Public Assessment Report for Tozinameran (mRNA Covid-19 vaccine). Sponsor: Pfizer Australia Pty Ltd. December 2021. https://www.tga.gov.au/sites/default/files/auspar-tozinameran-mrna-covid-19-vaccine-211207.pdf
("the Pfizer 5-11 Year Olds Extension AUSPAR")

k) Australian Public Assessment Report for Tozinameran. Sponsor: Pfizer Australia Pty Ltd. January 2022. https://www.tga.gov.au/sites/default/files/auspar-tozinameran-220128.pdf
("the Pfizer Booster for 16-17 Year Olds AUSPAR"

l) Australian Public Assessment Report for Tozinameran. Sponsor: Pfizer Australia Pty Ltd. April 2022. https://www.tga.gov.au/sites/default/files/auspar-tozinameran-220408.pdf
("the Pfizer Booster for 12-15 Year Olds AUSPAR")

m) Australian Public Assessment Report for Comirnaty COVID-19 vaccine. Sponsor: Pfizer Australia Pty Ltd. September 2022. https://www.tga.gov.au/sites/default/files/2022-10/auspar-comirnaty-20221010.pdf
("the Pfizer Booster for 5-11 Year Olds AUSPAR")

n) Australian Public Assessment Report for Comirnaty COVID-19 Vaccine. Sponsor: Pfizer Australia Pty Ltd. October 2022.

https://www.tga.gov.au/sites/default/files/2022-10/auspar-tozinameran-221012.pdf
("the Pfizer 6 Months - 5 Year Olds Extension AUSPAR")

MODERNA

o) Australian Product Information – Spikevax (Elasomeran) Covid-19 Vaccine.
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2021-PI-01968-1&d=20230410172310101
("the Moderna Product Information")

p) Spikevax Covid-19 Vaccine Consumer Medicine Information (CMI) Summary.
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2021-CMI-01982-1
("the Moderna Consumer Medicines Information")

q) Spikevax. Published 9 August, 2021.
https://www.tga.gov.au/resources/auspmd/spikevax
("the Moderna Decision Summary")

r) Australian Public Assessment Report for Elasomeran. Sponsor: Moderna Australia Pty Ltd. August 2021.
https://www.tga.gov.au/sites/default/files/auspar-elasomeran.pdf
("the Moderna Original AUSPAR")

s) Australian Public Assessment Report for Elasomeran. Sponsor: Moderna Australia Pty Ltd. September 2021.
https://www.tga.gov.au/sites/default/files/auspar-elasomeran-210903.pdf
("the Moderna 12-17 Year Olds Extension AUSPAR")

t) Australian Public Assessment Report for Elasomeran. Sponsor: Moderna Australia Pty Ltd. December 2021.
https://www.tga.gov.au/sites/default/files/auspar-elasomeran-mrna-1273-211208.pdf
("the Moderna Booster for >18 Year Olds AUSPAR")

u) Australian Public Assessment Report for Elasomeran. Sponsor: Moderna Australia Pty Ltd. February 2022.
https://www.tga.gov.au/sites/default/files/auspar-elasomeran-220221.pdf
("the Moderna 6-11 Year Olds Extension AUSPAR")

v) Australian Public Assessment Report for Elasomeran. Sponsor: Moderna Australia Pty Ltd. July 2022.
https://www.tga.gov.au/sites/default/files/2022-08/auspar-elasomeran-220727.pdf
("the Moderna 6 months and Older Extension AUSPAR")

w) Australian Public Assessment Report for Elasomeran. Sponsor: Moderna Australia Pty Ltd. November 2022.
https://www.tga.gov.au/sites/default/files/2022-11/auspar-spikevax-20221108.pdf
("the Moderna Booster for >12 Year Olds AUSPAR")

ASTRAZENECA

x) Clinical Evaluation Report - Prescription Medicines Authorisation Branch. Active Substance: ChAdOx1-S. Product name: ChAdOx1 CoV-19. Sponsor: Astra Zeneca. 27 January, 2020.
https://www.tga.gov.au/sites/default/files/foi-2494-05.pdf
("the AstraZeneca Clinical Evaluation Report")

y) Nonclinical Evaluation Report – ChAdOx1-S Covid-19 Vaccine (Covid-19 Vaccine AstraZeneca). Sponsor: AstraZeneca. January 2021.
("the AstraZeneca Nonclinical Evaluation Report")

z) Delegate's Overview. Active ingredient: ChAdOx1-S. Proprietary product name: Covid-19 vaccine AstraZeneca. Sponsor: AstraZeneca. 28 January, 2021.
https://www.tga.gov.au/sites/default/files/foi-2494-01.pdf
("the AstraZeneca Delegate's Overview")

aa) Advisory Committee on Vaccines ACV 19 Minutes on Item 2.1 ChAdOx1-S. Product name: Covid-19 vaccine AstraZeneca. Sponsor: AstraZeneca Pty Ltd. February 2021.

https://www.tga.gov.au/sites/default/files/foi-2494-04.pdf
("the ACV AstraZeneca Minutes")

bb) Australian Product Information – Vaxzevria (previously Covid-19 Vaccine AstraZeneca) (ChAdOx1-S) solution for injection, dated 16 February, 2021.
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2021-PI-01194-1
("the AstraZeneca Product Information")

cc) Vaxzevria (previously Covid-19 Vaccine AstraZeneca) Consumer Medicine Information (PI) Summary.
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2021-CMI-01195-1
("the AstraZeneca Consumer Medicines Information")

dd) Covid-19 Vaccine AstraZeneca. Published 16 February, 2021.
https://www.tga.gov.au/resources/auspmd/covid-19-vaccine-AstraZeneca
("the AstraZeneca Decision Summary")

ee) Australian Public Assessment Report for ChAdOx1-S – Proprietary Product Name: Covid-19 Vaccine AstraZeneca. Sponsor: AstraZeneca Pty Ltd. February 2021.
https://www.tga.gov.au/sites/default/files/auspar-chadox1-s-covid-19-vaccine-AstraZeneca-210215.pdf
("the AstraZeneca Original AUSPAR")

ff) Australian Public Assessment Report for ChAdOx-1-S – Proprietary Product Name: Vaxzevria. Sponsor: AstraZeneca Pty Ltd. February 2022.
https://www.tga.gov.au/sites/default/files/auspar-chadox-1-s-220217.pdf
("the AstraZeneca Booster in >18 Year Olds AUSPAR")

PART D - THERPAEUTIC GOODS ADMINISTRATION AND THE ACT

25. The Act:

a) is an Act of the Commonwealth providing for a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic

goods in Australia;

b) s. 5 - binds the Crown in the right of the Commonwealth in civil proceedings.

THE ACT - GUIDING OBJECTS

26. The Act relevantly contained the following provisions at the relevant times in respect of the objects of the Act, applicable to the Approvals and use of the Vaccines in Australia **("the TGA's Statutory Purpose")**:

a) s. 4(1)(a) - an object of the Act is to provide for the establishment and maintenance of a national system of controls relating to the following in respect of therapeutic goods used in Australia:

1 quality;

2 safety;

3 efficacy;

4 timely availability.

THE ACT - REGISTER

27. The Act relevantly contained the following provisions at the relevant times in respect of the establishment and conduct of the Register, applicable to the Approvals and use of the Vaccines in Australia **("the Register's Statutory Purpose")**:

a) s. 9A(1) - the Secretary is to maintain the Register, for the purpose of:

1 compiling information regarding therapeutic goods for use in humans;

2 providing for evaluation of therapeutic goods for use in humans.

b) s. 9A(2)(aa) - the Register to contain a part for provisionally registered goods.

PROVISIONAL DETERMINATION – REGISTRATION OF VACCINES

28. The Act relevantly contained the following provisions at the relevant times in respect of a provisional application and determination by the Secretary in respect of the registration of vaccines upon the Register, applicable to the Approvals and use of the Vaccines in Australia:

a) s. 22C(1) - a person may make an application to the Secretary for a provisional determination relating to (as prescribed by reg. 10K of the Regulations) **("Provisional Determination Application")**:

1 a new prescription medicine; and/or

2 a new indications medicine.

b) s. 22D(1) – the Secretary must decide to make, or to refuse to make, the determination in response to a Provisional Determination Application **("Provisional Determination")**;

c) s. 22D(2) – the Secretary may make the determination after receiving the Provisional Determination Application only if the Secretary is satisfied that all of the following criteria are met in relation to the medicine (as prescribed by reg. 10L of the Regulations) **("the Provisional Determination Criteria")**:

1 an indication of the medicine is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition;

2 there is no therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except provisionally registered goods) or if one or more that there is preliminary clinical data demonstrating that the medicine is likely to provide a significant improvement in the efficacy or safety of the treatment, prevention or diagnosis of the condition compared to those goods;

3 there is preliminary clinical data demonstrating that the medicine is

likely to provide a major therapeutic advance;

4 the person who made the application has provided sufficient evidence of the person's plan to submit comprehensive clinical data on the safety and efficacy of the medicine before the end of the 6 years that would start on the day that provisional registration of the medicine would commence if the Secretary were to provisionally register the medicine.

THE ACT - REGISTRATION OF VACCINES

29. The Act relevantly contained the following provisions at the relevant times in respect of the registration of vaccines upon the Register, including provisionally, applicable to the Approvals and use of the Vaccines in Australia:

a) s. 23 - a person may make an application to the Secretary for registration or listing of therapeutic goods **("Registration Application")**;

b) s. 23AA(1) - if a person makes a Registration Application and a Provisional Determination relating to the person, the medicine and the indication to which the Registration Application relates is in force when the application is made the application is taken to be an application for provisional registration of the medicine **("Provisional Registration")**;

c) s. 25(1)(d)(i) – the Secretary must evaluate the vaccine for Provisional Registration by having regard to whether, based on preliminary clinical data the following has been satisfactorily established **("the Provisional Registration Statutory Standard")**:

1 the safety of the vaccine for the purposes for which it is to be used;

2 the efficacy of the vaccine for the purposes for which it is to be used;

d) s. 25(3) – after evaluation of the vaccine in accordance with s. 25 including the Provisional Registration Standard, the Secretary must register the vaccine or not register the vaccine on the Register.

THE ACT - REQUIREMENT FOR GENE TECHNOLOGY REGULATOR ADVICE

30. The Act relevantly contained the following provisions at the relevant times in respect of the Secretary's obligation to seek advice in respect of a Registration Application, applicable to the Approvals and use of the Vaccines in Australia:

    a) s. 30C(2)(b) – where the vaccine has been Provisionally Registered, the Secretary must give written notice to the Gene Technology Regulator requesting the Gene Technology Regulator to give advice about the application **("Requirement to Seek Gene Technology Regulator Advice")**.

    b) s. 30E – the Secretary must ensure that the advice received by the Secretary pursuant to the Requirement to Seek Gene Technology Regulator Advice is taken into account in making a decision on the application for Registration that the advice relates to **("Requirement to Consider Gene Technology Regulator Advice").**

LAPSING REGISTRATION APPLICATION – INACCURATE OR MISLEADING INFORMATION

31. The Act relevantly contained the following provisions at the relevant times in respect of the lapsing of a Registration Application, including provisionally, applicable to the Approvals and use of the Vaccines in Australia:

    a) s. 24(2)(b) – a Registration Application lapses if it contains information that is inaccurate or misleading in a material particular:

        1 including information given under s. 31 of the Act; and

        2 the failure to give information consisting of individual patient data in relation to the vaccine is required under s. 31 of the Act.

PROVISIONAL DETERMINATION – REVOCATION

32. The Act relevantly contained the following provisions at the relevant times in respect of the revocation of provisional application and determination by the Secretary in respect of the registration of vaccines upon the Register, applicable to the Approvals

and use of the Vaccines in Australia:

a) s. 22F(1) - the Secretary may revoke a Provisional Determination if the Secretary is satisfied that the Provisional Determination Criteria are no longer met in relation to the medicine **("the Provisional Determination Revocation Criteria")**;

SECRETARY'S POWER TO REQUIRE INFORMATION OR DOCUMENTS

33. The Act relevantly contained the following provisions at the relevant times in respect of the power of the Secretary to require from the person applying for or having received Registration Approval, applicable to the Approvals and use of the Vaccines in Australia.

a) s. 8(1) - the Secretary may request that a person who has imported into Australia or has supplied in Australia therapeutic goods give to an officer of the Department within a reasonable period information required concerning the goods':

1 composition;

2 indications;

3 directions for use or labelling of the goods; or

4 advertising material relating to the goods;

b) s.31(1) – the Secretary may require from a person whom is an applicant under a Registration Application or in relation to a Registered medicine registered currently or in the preceding 5 years any information or documents as provided for under s. 31(1) of the Act **("the TGA Power to Obtain Information")**.

SECRETARY'S POWER TO SUSPEND OR CANCEL REGISTRATION

34. The Act relevantly contained the following provisions at the relevant times in respect of the power of the Secretary to suspend or cancel Registration of a vaccine, applicable to the Approvals and use of the Vaccines in Australia **("the Secretary's**

Power to Suspend or Cancel"):

a) s.29D(1) - the Secretary may suspend the registration or listing of a registered vaccine if:

1 the Secretary is satisfied that there is a potential risk of death, serious illness or serious injury if the vaccine continues to be included in the Register; and

2 it is likely that the person will, within the period of the suspension, be able to take the action necessary to ensure that the therapeutic goods would not cause a potential risk of death, serious illness or serious injury if the therapeutic goods were to continue to be included in the Register; or

3 the Secretary is satisfied that it is likely that there are grounds for cancelling the registration or listing of the goods under paragraph 30(1)(da), (e), (ea), (f), (fa), (fb) or (g) or subsection 30(1A), (1C), (1D) or (2) of the Act.

b) s. 30(1)(d) - the Secretary may cancel the registration of a vaccine if it appears to the Secretary that failure to cancel the registration or listing would create an imminent risk of death, serious illness or serious injury **("the Cancellation Standard")**.

DELEGATION OF THE MINISTER'S OR SECRETARY'S POWERS

35. The Act relevantly contained the following provisions at the relevant times in respect of the power of the Minister or the Secretary to delegate all or any of their powers and functions under the Act, applicable to the Approvals and use of the Vaccines in Australia **("the Secretary's Power to Delegate")**:

a) s. 57(1) - the Minister or the Secretary may, by signed instrument, delegate to an officer of the Department; an officer of an authority of the Commonwealth that has functions in relation to therapeutic goods, an APS employee in an Agency (within the meaning of the Public Service Act 1999) that has functions in relation to therapeutic goods; a person occupying or acting in an office, or holding an appointment, declared by the regulations

to be an office or appointment the occupant or holder of which may be a delegate under this section or a person seconded to the Department from those places provided for at sub-section (d), all or any of his or her powers and functions under this Act.

OBLIGATION TO ACT IN ACCORDANCE WITH STATUTE

36. The Respondents were required at all times when purporting to or actually exercising powers, functions and discretion under the Act, to act in accordance with the statutory obligations and principles pleaded herein at paragraphs 25 to 35 **("the Statutory Obligations")**.

PART E - TGA REGULATORY APPROVAL PROCESS AND POLICIES

TGA POLICY - VACCINES APPROVAL & REGULATION

37. The Respondents from at least May, 2019 and current at the time of the Approvals publicly declared that the TGA and they functioned under the following policies in respect of definition, approval and regulation of vaccines in Australia, including the Vaccines **("the TGA Vaccine Regulation Policy")**:

    a) the TGA is responsible for assessing vaccines and other medicines before they can be used in Australia;

    b) the TGA will only register a vaccine for use in Australia if its benefits are much greater than its risks;

    c) the TGA defines vaccines as medicines that:

        1 protect you against specific diseases;

        2 protect you and the people around you from serious and life-threatening diseases;

    d) the TGA rigorously assesses vaccines for safety, quality and efficacy before they can be used in Australia;

e) the TGA only uses the best available scientific evidence to assess the risks and benefits of each vaccine before approval;

f) the TGA's evidence requirements in assessing and approving vaccines for use are based on international guidelines developed by the European Medicines Agency;

g) the TGA carefully assesses the results of clinical trials and the way in which the trials were conducted;

h) the TGA before approving a vaccine requires well-designed trials:

1 of a sufficient length;

2 with a sufficient number of people who represent the people for whom the vaccine is intended;

i) the TGA requires before approving a vaccine that that the results of trials must demonstrate that the benefits of the vaccine greatly outweigh the risks;

j) the TGA's decision of whether to register a vaccine for use in Australia is informed by the advice of the Advisory Committee on Vaccines;

k) the TGA monitors vaccines for safety after they are supplied in Australia;

l) the TGA receives adverse event reports in relation to approved vaccines from consumers, health professionals, the companies who supply vaccines, and state and territory health departments;

m) the TGA publishes reports of adverse event reports in relation to approved vaccines in the publicly available Database of Adverse Event Notifications (DAEN);

n) the TGA maintains that reporting Serious Adverse Events is mandatory for the companies who supply vaccines in Australia which must also develop and implement risk management plans for their vaccines;

o) if the TGA suspects that there is a problem with a vaccine the TGA:

1 will launch an investigation;

2 may suspend use of the vaccine during the investigation;

3 notify the community of safety concerns through the publication of alerts on the TGA website;

p) before it registers any vaccine for use in Australia the TGA considers every ingredient in a vaccine for:

1 safety;

2 quality; and

3 efficacy.

Particulars

TGA Policy Document - "TGA Vaccine Overview – How the TGA defines, approves and regulates vaccines in Australia May 2019"
https://www.tga.gov.au/vaccines-overview

TGA - DEFINITION OF THE VACCINES

38. The Respondents through the TGA has defined the Vaccines for regulatory purposes as:

a) biologicals; and

b) new biological entities.

Particulars

The Pfizer Original AUSPAR – pg. 7, 9, 30.
The Moderna Original AUSPAR – pg. 7, 10.
The AstraZeneca Original AUSPAR – pg. 7, 9, 10.

PART F - TGA POLICIES

TGA POLICY - PROVISIONAL APPROVAL

39. The Respondents from at least August, 2018 publicly declared that the TGA and they functioned under the Act according to the following policy in respect of the process for provisional registration of vaccines by the TGA in Australia, including the Vaccines **("the TGA Provisional Approval Policy")**:

    a) the TGA can provisionally register medicines;

    b) the TGA, where provisionally registering vaccines, does so on the basis of preliminary clinical data which must demonstrate that the benefit of early availability of the vaccine outweighs the risk inherent in the fact that additional data are still required.

    c) any applicant and application to the TGA for provisional registration of a vaccine must satisfactorily establish the vaccine's:

        1 safety;

        2 efficacy;

        3 a positive risk/benefit balance based upon preliminary clinical data.

    d) in order for the TGA to establish safety and efficacy of a vaccine, the preliminary clinical evidence provided by the applicant in support of the provisional registration application must be sufficient to allow the benefits of the vaccine to be assessed against the risks identified by the evidence;

    e) the TGA will re-assess risks related to the absence of evidence through data provided at a later stage as part of the confirmatory data;

    f) the confirmatory data obtained by the TGA must confirm the relationship between:

1 outcomes predicted by the surrogate endpoint or other preliminary data in relation to the safety and efficacy of the vaccine; and

2 the clinical benefit as demonstrated by direct clinical outcomes.

g) in an application for provisional approval of a vaccine the TGA actively seeks the submission from the applicant of:

1 reports from acceptable overseas regulators to supplement the provisional submission for registration;

2 reports including where the vaccine has been conditionally registered overseas.

h) in addition to the standard requirements for registration of a vaccine, the TGA will base its decision to grant time-limited provisional registration of a vaccine upon the TGA's assessment of whether:

1 the preliminary clinical data satisfactorily establishes the safety and efficacy of the vaccine;

2 the quality of the vaccine has been satisfactorily established; and

3 the TGA is satisfied with the sponsor's plan to submit comprehensive clinical data on the safety and efficacy of the vaccine:

(1) before the end of the provisional registration period; and

(2) starting on the day that registration would commence.

Particulars

TGA Policy Document - "Provisional Registration Process – For prescription medicines with provisional determination" 2 August, 2018.
https://www.tga.gov.au/resources/resource/guidance/provisional-registration-process

TGA POLICY – ADVERSE EVENTS IDENTIFICATION

40. The Respondents from at least December 2017 and from the time of the Approvals publicly declared that the TGA and they functioned under the Act according to the following policy in respect of the identification of adverse events and serious threats to public health associated with approved biologicals in Australia, including the Vaccines, which states that **("the TGA Adverse Events Identification Policy"):**

    a) for biovigilance, and adverse event is defined as **("TGA Defined Adverse Event")**:

        1 any undesirable medical event that occurs during or after the administration or use of a biological;

        2 undesirable medical event for which there is at least a reasonable possibility of a causal relationship between the use of the biological and the event, which is thereby:

            (1) considered an adverse event related to the biological;

            (2) reportable;

    b) a spontaneous report is an unsolicited communication by a health professional or consumer to a sponsor, manufacturer, regulatory authority or other organisation that describes one or more suspected TGA Defined Adverse Events in a patient who was given a biological;

    c) any spontaneous report of a TGA Defined Adverse Event by health professionals, patients or consumers are considered to be related adverse events as they convey the suspicions of the person reporting the information that there is a causal relationship **("the TGA Presumed Adverse Event Causality")**.

Particulars

TGA Policy Document - Identifying adverse events and serious threats to public health - Australian requirements and recommendations - 13 December 2017

https://www.tga.gov.au/resources/publication/publications/biovigilance-responsibilities-sponsors-biologicals/identifying-adverse-events-and-serious-threats-public-health

TGA POLICY - ADVERSE EVENTS REPORTING

41. The Respondents from at least August, 2021 publicly declared that the TGA and they functioned under the Act according to the following policy in respect of the reporting of adverse events associated with approved vaccines in Australia, including the Vaccines which states that **("the TGA Adverse Events Reporting Policy")**:

    a) all adverse events arising in approved vaccines:

        1 are risk assessed and entered into the appropriate database for future reference;

        2 are used by TGA to identify safety signals;

    b) a safety signal in a vaccine:

        1 is a 'flag' for a possible safety concern;

        2 when identified by the TGA, the TGA undertakes a detailed evaluation to establish the possible role of the vaccine in causing the adverse event.

    c) if the TGA identifies a safety concern relating to a vaccine:

        1 the TGA can take regulatory action to ensure that the vaccine continues to have for its intended use acceptable:

            (1) safety;

            (2) efficacy/performance; and

            (3) quality.

2 the TGA seeks to ensure that health professionals and the public are aware of:

(1) the safety concern; and

(2) any changes to the availability and recommended use of the product.

d) actions that the TGA can take in response to a safety concern include:

1 informing health professionals and consumers through alerts and articles in publications such as Medicines Safety Update;

2 requiring changes to product labelling, or adding warnings, precautions and adverse event information to the Product Information and Consumer Medicine Information;

3 cancelling the registration of the product, or limiting the population in which it can be used;

4 requiring the sponsor to undertake post-marketing studies to investigate the safety concern if more information is needed before a judgment can be made about the need for further action.

Particulars

TGA Policy Document - "TGA Reporting Adverse Events August 2021": https://www.tga.gov.au/resources/resource/guidance/reporting-adverse-events#:~:text=All%20adverse%20events%20are%20risk,for%20a%20possible%20safety%20concern

TGA POLICY - SAFETY MONITORING

42. The Respondents from at least 9 February, 2021 publicly declared that the TGA and they functioned under the Act according to the following policy in respect of the

process for provisional registration of vaccines by the TGA in Australia, including the Vaccines **("the TGA Safety Monitoring Policy")**:

a) the TGA's decision to approve a new vaccine is always made on the basis that the benefits outweigh the risks for the group of people in which it is intended to be used;

b) clinical studies that are conducted before vaccines are approved by the TGA provide extensive information about the safety of the vaccine;

c) the TGA:

1 is the Government body responsible for ensuring that medicines and vaccines supplied in Australia continue to meet the required standards of:

(1) safety;

(2) effectiveness; and

(3) quality for their intended use;

2 is responsible for the oversight of sponsors of vaccines and medicines who are legally responsible for monitoring the safety, quality and effectiveness of their products.

d) the rapid development of COVID-19 vaccines due to the urgent global need to effectively combat this pandemic has meant that the typical regulatory approval and production processes are being expedited;

e) the provisional approval pathway…..allows for temporary registration of promising new medicines and vaccines where the need for early access outweighs the risks;

f) information from ongoing clinical trials and safety studies will continue to be collected and analysed after provisional approval;

g) the TGA, other international regulators, and vaccine sponsors will also continuously review safety and effectiveness information collected from use in mass vaccination programs worldwide;

h) the TGA aims to:

1 strengthen the existing vaccine vigilance system for early detection and investigation of suspected side effects;

2 enable it to:

(1) manage any emerging safety issues arising in approved vaccines; and

(2) maintain public confidence in the immunisation program.

i) the TGA's objectives are:

1 timely:

(1) collection and management of reports of Vaccine AEFI;

(2) detection and investigation of vaccine safety signals;

(3) action to address any vaccine safety signals;

(4) communications that:

a) inform the public of emerging vaccine safety information; and

b) support public confidence in vaccines.

2 close collaboration and coordination of effort with other vaccine safety stakeholder groups.

3 enhanced reporting of Adverse Events Following Immunisation with approved vaccines;

4 enhanced vaccine safety signal detection and investigation;

5 understanding Covid-19 vaccine safety profiles;

6 enhanced capacity and capability for investigating individual reports of Adverse Events Following Immunisation with approved Covid 19 vaccines;

7 enhanced cumulative data reviews for each approved Covid 19 vaccine;

8 active surveillance of vaccine adverse events through AusVaxSafety;

9 ongoing analysis of clinical studies and reports;

10 the production of monthly safety summary reports;

11 worldwide environmental scanning for safety material in relation to Covid vaccines by ongoing review of worldwide:

(1) medical literature; and

(2) data.

12 ongoing review of worldwide safety signals in Covid vaccines including sharing information on Covid vaccine safety signals between international regulators;

13 receiving expert advice including from:

(1) the ACV; and

(2) ATAGI.

j) signal detection:

1 involves identifying patterns of adverse events associated with a particular medicine or vaccine that warrant further investigation;

2 may arise from:

(1) a previously unrecognised safety issue;

(2) a change in the frequency or severity of a known safety issue;

(3) identification of a new ‘at risk’ group.

k) when a safety signal in relation to an approved medicine or vaccine is identified, the TGA will conduct a thorough investigation:

1 to determine what, if any, action is required;

2 with the aim to determine whether vaccination could be the cause of the adverse event;

3 which includes assessment of the ‘background rate’ of the adverse event in the population to see if the reported rate is higher than expected;

l) when a safety concerns in relation to an approved medicine or vaccine arises, the TGA:

1 may use:

(1) legislative provisions to achieve effective and timely regulatory action in response to emerging Vaccine safety concerns;

(2) non-regulatory action that may help to address or reduce the risk of a safety concern.

2 must communicate the safety concerns in a timely way to:

(1) consumers;

(2) health professionals; and

(3) media.

m) The TGA must collaborate actively with in safety monitoring activities of approved vaccines:

1 national vaccine safety stakeholders including:

(1) ATAGI;

(2) ACV;

(3) NCIRS;

(4) SAEFVIC; and

(5) AEFI-CAN.

2 international entities including:

(1) ICMRA;

(2) overseas regulators; and

(3) the WHO global advisory committee on vaccines working group.

43. The National Centre for Immunisation Research and Surveillance advised on 11 May, 2021 the following procedure adopted by the TGA and known at that time to the Respondents for the reporting and investigation of adverse events following vaccination with the Vaccines **("National Vaccines Adverse Events Reporting Procedure")**:

a) reports of adverse events related to the Vaccines can be made by anyone to:

1 the TGA; or

2 when prompted with a survey via the AusVaxSafety system.

b) further investigations are made by the state health department and the TGA if within days to weeks after vaccination with the Vaccines:

1 a person dies; or

2 has a serious event needing hospitalisation.

c) the relevant health department and TGA gather as much information as possible about the person including:

1 their medical history;

2 risk factors;

3 any medications they are on;

4 details and timing of the vaccine;

5 hospitalisation records;

6 any laboratory test results and

7 whether they have subsequently recovered or have any ongoing issues.

d) the investigation process necessarily involves liaising with the person's:

1 treating general practitioner;

2 treating medical specialists;

3 hospital at which they received treatment post-vaccination.

e) an expert panel of doctors is convened:

1 to discuss a serious case in detail;

2 which often includes the treating doctor to discuss the case and may advise extra tests that may help them understand the event.

f) a full clinical dossier is subsequently provided to the TGA:

1 which then further reviews the case;

2 decides whether a group of independent expert advisors, known as a Vaccine Safety Investigation Group ("VSIG") is needed to review the case in detail; and

3 assess if the relevant Vaccine(s) caused the adverse event.

g) VSIG often includes independent medical experts in:

1 vaccine safety;

2 infectious diseases;

3 haematology;

4 public health and vaccine confidence;

5 other medical specialists; and

6 a consumer representative.

h) an independent panel of advisers:

1 meet to review the case in detail;

2 review the clinical details of the event;

3 report to the TGA.

i) the TGA subsequently uses an internationally accepted method to rate the level of certainty of a link between the serious event and the relevant vaccine.

j) the TGA subsequently:

1 publishes the results of these independent assessments on its website, which is accompanied by:

(1) a summary of the case; and

(2) extra clinical advice for doctors.

2 provides the results of the assessment back to:

(1) the state or territory health department; and

(2) treating doctor.

Particulars

National Centre for Immunisation Research and Surveillance Website page: How do we actually investigate rate COVID-19 vaccine side-effects? https://www.ncirs.org.au/how-do-we-actually-investigate-rare-covid-19-vaccine-side-effects

TGA AEFI REPORTING STANDARD

44. The Department publicly declares the following to be the basis of reporting adverse events to the TGA in respect of Adverse Events Following Immunisation, as to when a vaccine recipient should or should not report an AEFI to the state and territory AEFI contacts:

a) they should be reported:

1 when a recipient has concerns about an adverse event that:

(1) appears to be getting worse;

(2) does not fit the common reactions for that vaccine.

2 in cases of anaphylaxis.

b) they do not need to report low-grade fever or pain at the spot where the needle went in as they are usually mild and short-lived;

45. The TGA publicly declares that as to the reporting of suspected side effects associated with a Covid vaccine, this should be reported by the consumer in circumstances where:

a) they are worried about the side effect;

b) they suspect the side effect is related to the Vaccine;

c) they seek advice from a health professional; and

d) either they or their doctor believe that a COVID-19 vaccine has caused the side effect, especially when:

1 unexpected; or

2 significant.

e) In confluence, the TGA and the Department publicly promote and seek reporting of AEFI only where **("the AEFI Reporting Standard")**:

1 the adverse event is temporally associated with receiving the Vaccine;

2 either they or their doctor or both suspect or believe that the AEFI is related to the Vaccine;

3 the AEFI is significant and/or unexpected.

Particulars

"Reporting and managing adverse vaccination events". https://www.health.gov.au/topics/immunisation/immunisation-information-for-health-professionals/reporting-and-managing-adverse-vaccination-events

"Reporting suspected side effects associated with a COVID-19 vaccine". https://www.tga.gov.au/products/covid-19/covid-19-vaccines/covid-19-vaccine-safety-monitoring-and-reporting/reporting-suspected-side-effects-associated-covid-19-vaccine

TGA POLICY – SAFETY ALERTS

46. The Respondents from at least prior to the Approvals, publicly declared that the TGA functioned under the Act according to the following policy in respect of information for consumers and health professionals relating to possible risks or action needed, including the Vaccines **("the TGA Safety Alert Policy")**:

    a) safety alerts are triggered by any potential safety problem linked to a medicine **("Safety Alerts")**;

    b) Safety Alerts' purpose is to notify and inform the Australian public about:

        1 a possible risk for a health product;

        2 an action needed to be taken in respect of a health product;

    c) safety alerts are defined as including:

        1 known safety problems;

        2 changes in the reporting pattern of known problems;

        3 new problems; and

4 coincidental events.

d) Safety Alerts may be in the form of:

1 safety advisories;

2 alert/advisories; and

3 monitoring communications;

e) Safety Alerts advices should be followed by the public;

f) at the time the safety concern manifesting the Safety Alert is detected, the TGA may not know if the concern is really caused by the medicine.

Particulars

TGA Policy Document - TGA Safety Alerts
https://www.tga.gov.au/news/safety-alerts

TGA POLICY ON COVID INFORMATION - CONSUMERS AND HEALTH PROFESSIONALS

47. The Respondents from at least 28 September, 2021, publicly declared that the TGA and they functioned under the Act according to the following policy in respect of information for consumers and health professionals relating to Covid vaccines, including the Vaccines **("the TGA Safety Covid Information Policy")**:

a) the TGA will formally evaluate the information provided by the Covid vaccine's sponsor which includes data on:

1 clinical studies;

2 non-clinical/toxicology studies;

3 chemistry;

4 manufacturing;

5 risk management; and

6 other information.

b) the TGA's evaluation of Covid vaccines is also informed by the advice of the Advisory Committee on Vaccines, being an independent committee of external experts;

c) the decision to approve a new vaccine is always made by the TGA on the basis that the benefits outweigh the risks for the intended population;

d) the TGA considers the safety, quality and effectiveness of every ingredient in a vaccine before registering the vaccine for use in Australia;

e) the TGA carefully assesses:

1 the results of clinical trials of the Covid vaccines; and

2 the way in which those trials were designed and conducted including:

(1) if they were conducted for a sufficient amount of time; and

(2) if there were enough participants in the trial that represented the people for whom the vaccine is intended;

f) an evaluation of the Covid vaccines under the provisional pathway is:

1 is still a full review of the safety, efficacy, risks and benefits of the vaccines; and

2 is not in the nature of an emergency use authorisation.

g) in the provisional approval process for the Covid vaccines, the TGA requires that the following be made available to all healthcare professionals and consumers those vaccines:

1 a comprehensive Consumer Medicine Information (CMI) leaflet; and

2 a comprehensive Product Information (PI) document.

h) the TGA will before and after any approval of a Covid vaccine:

1 meet regularly with international regulators to discuss the development of Covid vaccines;

2 utilise work-sharing arrangements with comparable international regulators to expedite the evaluation of any new vaccines without compromising on strict standards of:

(1) safety;

(2) quality; and

(3) effectiveness.

i) the TGA's safety monitoring processes for Covid vaccines are well established and include:

1 reviewing and analysing reports of suspected Covid vaccine adverse events submitted by health professionals and consumers;

2 requiring pharmaceutical companies to have risk management plans for their supplied Covid vaccines;

3 working with international regulators to assess significant Covid vaccine adverse events detected overseas;

4 working with state and territory health departments and clinical experts to ensure a coordinated approach

5 reviewing medical literature and other potential sources of new safety information in respect of Covid vaccines;

6 pharmaceutical companies also have legal obligations to monitor, collect, manage and report on safety data;

7 monitoring of approved Covid vaccines will be ongoing including:

(1) quick evaluation of new information as soon as it becomes available;

(2) ensuring that the benefits of Covid vaccines continue to outweigh the risks; and

(3) taking appropriate action to safeguard the health and safety of the Australian public.

8 even when a suspected side effect of a vaccine is serious:

(1) it is possible - even likely - that it may not have been caused by the vaccine;

(2) the timing may be coincidental;

(3) there is an expected 'background rate' of coincidental adverse events;

(4) the TGA investigates the reports it receives to determine if there is a genuine safety concern related to the vaccine.

j) whilst undertaking every effort to expedite the availability of one or more Covid vaccines, the TGA's rigorous safety standards will not be compromised.

k) if the TGA suspects that there is a safety issue with a Covid vaccine the TGA will immediately conduct a thorough investigation of the issue;

l) if the TGA determines that the safety concern is significant it will respond appropriately including:

1 requiring the sponsor to add warnings to the Product Information for the Covid vaccine;

2 providing safety information to vaccine providers;

3 making changes to labelling or packaging;

4 in very serious cases suspend use of the vaccine during the investigation;

5 notify the community of safety concerns through alerts published on:

(1) the TGA website; and

(2) state and territory health department websites.

Particulars

TGA Policy Document – "COVID-19 vaccine: Information for consumers and health professionals" https://www.tga.gov.au/products/covid-19/covid-19-vaccines/covid-19-vaccine-information-consumers-and-health-professionals.

TGA POLICY - SPONSOR PHARMACOVIGILANCE POLICY

48. The Respondents from at least 19 January, 2021, publicly declared that the TGA and they functioned under the Act according to the following policy in respect of the Sponsors Pharmacovigilance System relating to Covid vaccines, including the Vaccines **("the TGA Sponsors Pharmacovigilance Policy")**:

a) the TGA Pharmacovigilance Policy must:

1 be followed by all Sponsors;

2 be ensured by the TGA to in fact have been followed by the Sponsors.

b) the Sponsor's pharmacovigilance system must ensure that it:

1 allows all pharmacovigilance requirements described in the TGA's policies and applicable legislation to be met;

2 allows investigation and reporting of product quality issues associated with Covid vaccines:

(1) Serious Adverse Events; and

(2) significant safety issues.

3 allows critical analysis of:

(1) adverse events associated with Covid vaccines; and

(2) other safety and quality information;

4 allow the taking of any action necessary to mitigate an identified safety issue in the approved Covid vaccines.

c) the Sponsors must identify and collect all information related to the safety of their vaccines from all possible sources, including:

1 spontaneous reports of adverse reactions including consumer reports to:

(1) the Sponsor; or

(2) to people who work for or have a contractual relationship with the Sponsor;

2 internet and social media reports;

3 reports from non-medical sources;

4 solicited reports, such as from post-registration studies or post-market initiatives;

5 reports in international and local literature;

6 individual adverse drug reaction reports in the TGA's Database of Adverse Event Notifications (DAEN).

7 gathering sufficient information to scientifically evaluate reports of adverse reactions and any other safety issues associated with the medicine;

8 validating suspected adverse reactions and report them to us within the required time frame.

d) the Sponsor must report adverse reactions associated with the Covid vaccines:

1 if they are considered serious;

2 even if the Sponsor does not agree with the reporter's assessment of the cause.

e) for regulatory purposes, spontaneous reports:

1 are considered to have implied causality;

2 where it is not clear whether a causal association is suspected:

(1) are presumed to mean that the Covid vaccine and the adverse event are possibly related; and

(2) meet the definition of an adverse reaction, unless the reporter explicitly states otherwise.

f) the Sponsor must exercise due diligence in ensuring that reports of adverse events associated with the Covid vaccine are complete and are of high quality:

1 because reports provided by consumers may often lack sufficient clinical detail required for assessing causality or seriousness; and

2 by accurately recording, clarifying, analysing and following up on any information received.

g) the Sponsors must:

1 obtain as much information as necessary to determine the nature and seriousness of the adverse reaction to the Covid vaccine; and

2 seek the reporter's voluntary informed consent to contact the treating doctor for medical confirmation of the adverse reaction and any additional relevant information;

3 if consent is not obtainable use clinical judgement to:

(1) assess how serious the reaction was from the available information; and

(2) guide the subsequent handling of it.

4 if the adverse reaction is serious:

(1) make additional attempts as reasonable either to:

a) obtain the reporter's voluntary consent to contact the treating doctor; or

b) ask the consumer to provide relevant medical documentation to allow you to assess causality.

h) the Sponsors must:

1 regularly screen internet such as websites, webpages, blogs, vlogs, social networks, internet forums, chat rooms and health portals) or digital media you own, fund, manage or are responsible for, for potential reports of suspected adverse reactions;

2 if they become aware of an adverse experience on an internet or digital site that it does not sponsor:

(1) review the available information; and

(2) attempt to follow up the report to determine if it must be reported to the TGA.

3 make reasonable attempts to contact the reporter wherever possible to:

(1) confirm the event and patient details; and

(2) collect any additional information;

i) international and local scientific and medical literature are a significant source of information for monitoring:

1 the safety profile of the vaccines; and

2 benefit-risk balance of the vaccines;

3 particularly in relation to the detection of new safety signals or emerging safety issues.

j) the Sponsors must:

1 undertake regular and no less than weekly systematic literature review of widely used reference databases such as Medline, Excerpta Medica or Embase, including those that contain the largest number of articles about:

(1) the vaccine;

(2) all of vaccine's active ingredients; and

(3) the vaccine's properties.

2 monitor ongoing safety and efficacy studies relating to the Covid vaccine including non-human teratogenicity and/or carcinogenicity studies for any relevant safety findings;

3 review and assess both worldwide and relevant local scientific and medical literature articles including abstracts from meetings and draft manuscripts to identify, report and record adverse reaction reports and significant safety issues.

4 follow up and validate any Serious Adverse Events that are reported in the literature:

(1) by contacting the study's author to obtain further information where possible;

(2) specifically any information needed to assess causality and patient identifiers.

k) proper pharmacovigilance in respect of the Covid vaccine requires that:

1 the Sponsors collect information on adverse reactions and significant safety issues; and

2 critically analyse and evaluate such information to monitor the on-going benefit-risk profile of the vaccine.

l) proper safety monitoring activities by the Sponsors requires:

1 a review of cumulative safety issue cases:

(1) in order to allow for a comprehensive review of potential safety issues;

(2) because safety issues may come from one or multiple sources which may suggest:

a) a new risk; or

b) a change in the nature of a known risk associated with the vaccine.

2 where identifying a safety signal that may change the benefit–risk balance of the vaccine, reporting:

(1) the matter to the TGA as a significant safety issue; and

(2) any actions the Sponsor proposes to take, or justification for no further action.

Particulars

TGA Policy Document - "TGA Pharmacovigilance System – Australian Recommendations and Requirements January 2021" https://www.tga.gov.au/resources/resource/guidance/pharmacovigilance-responsibilities-medicine-sponsors/your-pharmacovigilance-system - dated 19 January, 2021.

49. The Respondents from at least 19 January, 2021, publicly declared that the TGA and they functioned under the Act according to the following policy in respect of the Pharmacovigilance System of sponsors relating to Covid vaccines, including the Vaccines **("the TGA Sponsors Pharmacovigilance Policy 2")**:

a) the TGA Pharmacovigilance Policy 2 must:

1 be followed by all Sponsors;

2 be ensured by the TGA to in fact have been followed by the Sponsors.

b) spontaneous reports of adverse events are considered to be adverse reactions i.e. a noxious and unintended response to a medicine, for regulatory purposes;

c) a significant safety issue:

1 is a new safety issue or validated signal considered by the Sponsor in relation to their vaccine which requires urgent attention of the TGA;

2 can be identified by ongoing review and analysis of all information that is pertinent to the vaccine's:

(1) safety; or

(2) benefit-risk balance;

3 includes:

(1) safety-related actions by comparable international regulatory agencies;

(2) changes in the nature, severity or frequency of known serious adverse reactions which are medically significant;

(3) detection of new risk factors for the development of a known adverse reaction or a new serious adverse reaction that may impact on the safety or benefit-risk balance of the medicine;

(4) series of reports of similar or linked adverse reactions reported at the same time;

(5) an unusual and significant lack of efficacy occurring in or outside Australia that may have implications for public health;

(6) major safety findings from a newly completed non-clinical study, post-registration study or clinical trial that may impact the benefit-risk balance of the medicine;

(7) a signal of a possible teratogenic effect or of significant hazard to public health;

(8) safety issues related to any raw materials used in the medicine that may impact the safety of the medicine and/or have implications for public health;

(9) safety issues due to misinformation in the product information or label that may impact the safety of the medicine;

(10) safety issues related to use outside the approved indication or intended use that may impact the safety or benefit-risk balance of the medicine.

4 where reported by the Sponsor to the TGA:

(1) is used by the TGA to take appropriate action;

(2) may be the basis of:

a) further safety information to the public;

b) updates to product information documents and labels;

c) the imposition of additional risk management interventions or pharmacovigilance activities;

d) removal of the vaccine from the market.

5 is to be, where doubted by the Sponsor, treated as significant.

d) the Sponsor must report the following to the TGA:

1 expected and unexpected serious adverse reactions associated with the use of the vaccine that occurred in Australia;

2 expected and unexpected serious adverse reactions associated with the use of the vaccine that occurred in Australia and were reported in the published international or local scientific and medical literature;

3 all clinical and medically relevant follow-up information related to serious adverse reaction reports related to the vaccine occurring in Australia;

4 all serious adverse reaction reports which must be:

(1) validated;

(2) followed up as necessary; and

(3) submitted to the TGA within the 15 calendar day time frame;

5 all significant safety issues related to the vaccine within 72 hours of awareness;

6 all serious adverse reaction cases occurring in Australia that are identified through screening the worldwide literature:

(1) as soon as possible; and

(2) no later than 15 calendar days from receipt.

e) in respect of reports involving pregnancies where the embryo or foetus could have been exposed to the vaccine, the Sponsor must:

1 make reasonable attempts to follow up all individual cases;

2 collect information on the outcome of the pregnancy and development of the child after birth;

3 collect as much information as possible to enable assessment of the causal relationship between any reported adverse event(s) and exposure to the vaccine;

4 consider whether the vaccine may have been taken prior to conception or during pregnancy;

5 take into account whether any active substance or one of the metabolites in the vaccine has a long half-life;

6 report pregnancies that result in abnormal outcomes suspected to be related to the vaccine as serious adverse reactions, including:

(1) congenital anomalies or developmental delay in the foetus or the child;

(2) foetal death and spontaneous abortion;

(3) serious adverse reactions in the neonate.

7 report suspected serious adverse reactions in infants following exposure to the vaccine in breastmilk in accordance with the reporting requirements for serious adverse reactions;

8 report any signal of a possible teratogenic effect, such as a cluster of similar abnormal outcomes, as a significant safety issue.

f) the Sponsor must:

1 record and follow up all reports of a lack of therapeutic efficacy in the vaccine;

2 treat reports of unusual or unexpected lack of efficacy in the vaccine must as serious adverse reactions for reporting purposes;

3 assess causality for all solicited reports including AusVaxSafety to decide if it is a serious adverse reaction in which case it must be reported to the TGA.

Particulars

TGA Document – “Pharmacovigilance responsibilities of medicine sponsors - Australian recommendations and requirements”.
https://www.tga.gov.au/sites/default/files/190214_pharmac

ovigilance-responsibilities-medicine-sponsors.pdf. Dated 18 January, 2021.

TGA POLICY - COVID VACCINE APPROVALS

50. The Respondents from at least 6 July, 2021, publicly declared that the TGA and they functioned under the Act according to the following policy in respect of the TGA Approval Process for Covid vaccines, including the Vaccines **("the TGA Covid Vaccine Approvals Policy")**:

    a) the TGA's decision to grant provisional registration to the Covid vaccines is based on a number of factors including the established vaccine's:

        1 safety;

        2 quality; and

        3 effectiveness, for intended use.

    b) the TGA, after approval of the Covid vaccine:

        1 will continue to play an active role in the ongoing monitoring of any vaccines available in Australia including the Vaccines; and

        2 has robust procedures in place to investigate any potential new safety issues in vaccines, including the Vaccines.

    c) the TGA's vaccine safety monitoring system can rapidly detect, investigate and respond to any emerging safety issues identified for Covid vaccines;

    d) post-market monitoring of safety and efficacy issues in respect of the Covid vaccines by the TGA relies upon:

        1 reviewing and analysing adverse events reports;

        2 working with international regulators; and

3 reviewing medical literature, media and other potential sources of new safety information.

Particulars

TGA Document - "TGA Covid Vaccine Approval Process July 2021" Dated 6 July, 2021. https://www.tga.gov.au/products/covid-19/covid-19-vaccines/covid-19-vaccine-approval-process.

TGA POLICY - COVID VACCINE EVIDENCE

51. The Respondents from at least 4 December, 2020, publicly declared that the TGA and they functioned under the Act according to the following policy in respect of evidence relating to Covid vaccines, including the Vaccines **("the TGA Covid Vaccine Evidence Policy")**:

a) the TGA will rigorously evaluate the totality of scientific and clinical evidence provided by sponsors of Covid vaccines as well as other evidence available, including that which may be specific to other countries;

b) the TGA will only authorise a Covid vaccine if its benefits outweigh the risks, based on the required evidence provided by sponsors;

c) the TGA will require a high level of evidence from the sponsor prior to approval of any Covid vaccine;

d) the TGA will continually monitor approved Covid vaccines for safety, efficacy and quality;

e) the TGA will not register a Covid vaccine unless it is demonstrated that the vaccine prevents Covid disease:

1 through well-conducted clinical trials in humans;

2 by the Sponsor.

f) before approving any Covid vaccine the TGA must consider:

1 the availability of alternative vaccines and treatments;

2 the status of the pandemic; and

3 the epidemiology of the Virus in Australia and worldwide.

g) before the TGA approves any Covid vaccine:

1 clinical trials must:

(1) demonstrate that the vaccine:

a) very significantly reduces the incidence of Covid disease in people who are vaccinated with the vaccine compared to a control group of people who did not receive the vaccine; and

b) reduces the transmission of disease between individuals, including from asymptomatic to uninfected individuals;

(2) be based upon a reduction in the rate of symptomatic laboratory-confirmed Covid infections;

2 sponsors must demonstrate robust evidence of safety;

h) after approval of a Covid vaccine:

1 the TGA will monitor the continued evidence of safety of the vaccine;

2 evidence of Covid vaccine safety will require a database:

(1) to detect infrequent side effects;

(2) which must adequately monitor the safety of the Covid vaccines;

3 participants in clinical trials must be followed for a median of at least 2 months after receiving their final Covid vaccine dose;

4 participants in clinical trials must be followed up for a median of 6 months to assess the potential risks of:

(1) late-onset adverse events; and

(2) vaccine-associated enhanced respiratory disease.

5 participants in clinical trials must continue to be followed:

(1) for at least 1 year; and

(2) ideally longer to assess the duration of protection and longer-term safety of the Covid vaccine;

6 the TGA must access the follow-up data from the:

(1) clinical studies;

(2) non-clinical studies;

(3) studies assessing the risk of vaccine-associated enhanced respiratory disease.

7 the TGA must:

(1) continuously monitor, assess and strengthen Covid vaccine safety to ensure that the benefits of the vaccine continue to outweigh the risks; and

(2) collaborate in monitoring the safety and effectiveness of Covid vaccines to:

a) assess new safety issues; and

b) take quick action to mitigate risks.

(3) work closely on an ongoing basis with health care professionals, public health authorities, vaccine sponsors to monitor and assess the safety of Covid vaccines after authorisation.

i) continuing trials of the Covid vaccines by sponsors is essential to providing robust evidence of long-term safety and protection against the Virus which may not be adequately demonstrated through post-authorisation surveillance studies.

Particulars

TGA Document – "Access Consortium statement on COVID-19 vaccines evidence" Dated 4 December, 2020.
https://www.tga.gov.au/access-consortium-statement-covid-19-vaccines-evidence.

ADOPTED STANDARDS & POLICIES - EUROPEAN MEDICINES AGENCY

52. Prior to the Approvals, the Respondents adopted and continues to have adopted in respect of their functions under the Act the following policies and principles produced and published by the European Medicines Agency relevant to the Approvals and the continuing use of the Vaccines **("the Adopted EMA Policies")**:

a) Guideline Nonclinical Testing For Inadvertent Germline Transmission Gene Transfer Vectors dated 16 November, 2006;

b) Guideline M3(R2) Nonclinical Safety Studies For Conduct of Human Clinical Trials and Marketing Authorisation For Pharmaceuticals dated December, 2009;

c) Guideline M4S Registration of Pharmaceuticals For Human Use dated 20 February 2003;

d) Guideline on Clinical Evaluation of New Vaccines dated 18 October 2006;

e) Guideline on Clinical Evaluation of Vaccines dated March 2017 (since updated – current update agreed by Vaccine Working Party January 2020);

f) Guideline on Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk dated July 2017;

g) Guideline S2(R1) on Genotoxicity Testing and Data Interpretation Pharmaceuticals Intended For Human dated June 2012;

h) Note for Guidance On Preclinical Pharmacological and Toxicological Testing of Vaccines dated 17 December, 1997;

i) Guideline on Strategies to Identify and Mitigate Risks for First-in-Human and Early Clinical Trials with Investigational Medicinal Products dated 20 July, 2017;

j) Guideline on the Need for Nonclinical Testing in Juvenile Animals of Pharmaceuticals for Paediatric Indications dated 24 January, 2008;

k) Guideline on Adjuvants in Vaccines for Human Use dated January, 2005;

l) Guideline on Good Pharmacovigilance Practices (GVP) dated December, 2013.

MITIGATING RISK IN FIRST-IN-HUMAN MEDICINES – ADOPTED EMA POLICY

53. The Respondents adopted prior to the Approvals in respect of their functions under the Act the EU Guideline on strategies to identify and mitigate risks for first-in-human

and early clinical trials with investigational medicinal products published on 20 July, 2017, which expressly states that **("First In Human Medicine Policy")**:

a) toxicity can be the result of exaggerated pharmacological actions which should not be ignored when establishing a safe starting dose for humans;

b) the exposures at which these toxicities are observed should be considered for the definition of the dose escalation range to be investigated in humans;

c) an evaluation as to whether the target organs identified in the non-clinical studies warrant particular monitoring in the CT should be undertaken;

d) serious toxicity should lead to a more cautious approach when setting doses and applying risk mitigation strategies in the clinical setting;

e) when serious toxicity or mortality is observed, these effects if not been possible to clarify within the studies undertaken:

1 require follow up studies to determine:

(1) the cause of death; or

(2) the mechanism of toxicity and

2 must be examined for relevance to:

(1) the clinical trial design; or

(2) safety monitoring plan.

f) usually driven by exposures where serious toxicity/mortality is observed.

Particulars

European Medicines Agency - 20 July 2017. Rev. 1 Committee for Medicinal Products for Human Use (CHMP) - "Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products". Pg. 10.

https://web.archive.org.au/awa/20220816022520mp_/https:/www.ema.europa.eu/en/documents/scientific-guideline/guideline-strategies-identify-mitigate-risks-first-human-early-clinical-trials-investigational_en.pdf.

SAFETY SURVEILLANCE – ADOPTED EMA POLICY

54. The Council for International Organisations for Medical Sciences (CIOMS) Guide on Vaccine Safety Surveillance referenced in the EMA Guideline on good pharmacovigilance practices stated as from January, 2017 and known to and adopted by the Respondents prior to the Approvals **("EMA Pharmacovigilance Practice Policy")**:

    a) it is the responsibility of each national regulatory authority (NRA) to assure the safety of vaccines licensed in its country;

    b) safety surveillance is a fundamental pharmacovigilance tool used to assess the safety of licensed vaccines and to promptly identify and address any unexpected safety concerns arising from their use;

    c) the cornerstone of vaccine pharmacovigilance is passive surveillance …. In passive surveillance systems, the primary responsibility for identification and reporting AEFIs falls upon the health care provider, the patient, or the patient's family or carers.

    d) the role of those responsible for overseeing the passive surveillance system focuses primarily on assuring the accuracy and completeness of reports that are received, and on analysis of the AEFI reports for necessary action.

    e) Following vaccine introduction in a country, there may be a need for Active Vaccine Safety Surveillance because:

        1 a concern has arisen on account of a safety signal detected through passive surveillance;

        2 a new population or circumstance (e.g. expanded use in an outbreak setting) may benefit from timely impact assessment;

3 International or local concerns have been raised about the vaccine's safety;

4 each of the above may prompt stakeholders to question:

(1) whether passive surveillance is sufficient; or

(2) if indeed Active Vaccine Safety Surveillance would be warranted; and

(3) whether additional data would be needed to inform the benefit-risk assessment for the vaccine's use.

f) Spontaneous reporting pharmacovigilance:

1 offers the potential for detecting rare events because of the broad pool of reporters;

2 using a passive surveillance system allows a case series to be assembled to detect:

(1) patterns of adverse events connected with vaccines; and

(2) possible associations between a vaccine and an adverse event.

Particulars

EMA Guideline on good pharmacovigilance practices https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-product-population-specific-considerations-i-vaccines_en.pdf

Council for International Organisations for Medical Sciences (CIOMS) - Guide to Active Vaccine Safety Surveillance, Geneva 2017.

https://cioms.ch/wp-content/uploads/2020/04/240WEB-CIOMS-Guide-AVSS-20170202-protected.pdf
(Page 2, 9, 20)

PHARMACOVIGILANCE - APPROVALS AND REPORTING – ADOPTED EMA POLICY

55. Pharmacovigilance approvals and reporting guidelines specific to vaccines and directly applicable to the Vaccines published in or about February, 2013, known to and adopted by the Respondents at the time of the Approvals in respect of their functions under the Act states as requirements of good pharmacovigilance in the testing, analysis and approval of vaccines including the Vaccines **("Pharmacovigilance in Vaccine Approvals Policy")**:

    a) robust systems and procedures must be in place to continuously monitor quality, safety and efficacy of vaccines;

    b) a high level of safety is required for vaccines and tolerance to risk is low because vaccines, as in the case of the Vaccines:

        1 are usually administered to otherwise healthy individuals, often very young or vulnerable;

        2 may be administered to a large fraction of the population and vaccination is mandatory in some countries;

    c) the risk-benefit balance of many vaccines:

        1 is dynamic and may change over time which may impact on pharmacovigilance activities;

        2 is such that the balance of risks and benefits may shift such that:

            (1) the risk may outweigh the benefits over time; and

            (2) the tolerance to the risks of vaccines is decreased.

    d) factors affecting risk-benefit balance include:

1 efficacy and effectiveness in vaccination programmes;

2 biological variability.

e) vaccines are highly complex multi-component products manufactured from biological systems that are inherently variable over time and between Sponsors;

f) the safety, quality and efficacy of vaccines are as dependent on the product-specific manufacturing process as on the inherent profile of active antigens and excipients;

g) clinical trials must be constructed to:

1 detect common and uncommon adverse reactions and to address long-term risks by utilising appropriate sample size and duration;

2 only be limited such that inclusion and exclusion criteria are relevant to the target population for vaccination;

h) risk to the developing foetus from vaccination of the mother with an inactivated vaccine during pregnancy:

1 means that live attenuated vaccines are contraindicated in pregnant women due to the known or suspected risk of transplacental infection of the foetus;

2 should be discussed, including data collected in the post-authorisation phase if available.

i) additional pharmacovigilance activities may be needed in the following circumstances:

1 to establish evidence of safety for novel vaccines or for vaccines with a novel adjuvant, in order to:

(1) assess the risk of occurrence of rare or delayed onset adverse reactions, local or systemic;

(2) detect occurrence of auto-immune diseases and immune-mediated reactions resulting from a synergistic action of the adjuvant and the biologically active antigen;

2 to assess the effectiveness of the vaccine, especially where pre-authorisation data are limited;

3 to investigate clusters of reported adverse events/reactions;

4 where spontaneous reports raise concerns that a higher than expected rate of vaccine failures and breakthrough infections in certain risk groups exists;

j) a pregnancy register may be needed to address risks of the vaccine in pregnant women to allow identification of spontaneous abortions, stillbirths and congenital malformations with an adequate duration of follow-up of the offspring;

k) where adverse events of special interest (AESIs) are presented in the safety specification as important potential risks and baseline/background incidence rates of those AESIs in the target population are not available, it may be necessary to design a study to collect this information in order to provide rapid answers to vaccine safety concerns emerging from spontaneous reports of suspected adverse reactions;

l) plans for post-authorisation efficacy studies (PAES) may include the assessment of vaccine efficacy/effectiveness and immunogenicity in order to get additional information on waning immunity, long-term protection, cross-protective efficacy/effectiveness and the most appropriate use of the vaccine;

m) the potential for local and systemic adverse reactions should be analysed for different doses of the vaccine and also across different vaccination schedules by summarisation of the following data in the PSUR:

1 reports of:

(1) vaccine failure; and

(2) lack of efficacy/effectiveness;

(3) vaccination errors;

(4) vaccination anxiety-related reactions such as syncope;

(5) literature data with information relevant to other similar vaccines and vaccine components such as stabilisers, preservatives and adjuvants.

n) when a new or changing risk is identified, the regulatory body must:

1 re-evaluate the benefit of the medicinal product using all available data, such benefits including prevention of:

(1) the target disease;

(2) severity of symptoms;

(3) hospitalisation;

(4) complications;

(5) effect of target disease on offspring (in case of vaccination of pregnant women); and

(6) any other clinical outcome relevant for individual patients;

2 estimate the impact of the new or changing risk on the benefit-risk balance of the vaccine.

o) non-clinical studies and experimental investigations should be considered to address safety concerns and to elucidate the aetiology of an adverse reaction including:

1 virological;

2 bacteriological;

3 immunological experiments; and

4 other methods.

p) a safety signal:

1 is information arising from one or multiple sources which suggests:

(1) a new potentially causal association; or

(2) a new aspect of a known association between an intervention and an event; or

(3) a set of related events that is judged to be of sufficient likelihood to justify verificatory action;

2 includes observations and experiments;

3 in vaccines may also relate to:

(1) evidence of reduced efficacy or effectiveness;

(2) vaccine failures; and

(3) quality deviations with potential impact on:

a) safety;

b) efficacy; or

c) effectiveness (which may be batch-specific).

q) a safety signal:

1 can arise from a single report of a Serious Adverse Event if there is a possible causal association to the vaccine which review of:

(1) adequate information on the clinical course of the event (time to onset, signs and symptoms, results of relevant laboratory and diagnostic tests, evolution, and treatment of the event);

(2) medical history;

(3) vaccination history;

(4) co-medication; and

(5) details of the vaccine(s) administered (including brand name, batch number, route of administration and dose).

2 is based upon contextual information, such relevant data being:

(1) the number of reported cases of a similar event; and

(2) the probability of occurrence of the event in a non-vaccinated population of the same age category calculated from:

a) clinical trials; and

b) observational studies.

(3) if adequate data is available, the number of vaccinated individuals of the same age category, the observed and expected numbers of cases should be estimated.

r) in mass vaccination programs which involve large exposure over a relatively short time period, safety signal detection:

1 should be as real-time as possible;

2 inform decision-making as the vaccination progresses;

3 occurs by quickly analysing and communicating the significance of spontaneously reported adverse reactions;

4 requires rapid:

(1) identification of possible new signals;

(2) assessment of the likelihood that the number of reports may be consistent with the expected background incidence in the vaccinated cohort, and thereby possibly coincidental.

s) the safety profile of a vaccine may differ substantially within the target population (for example, higher risks in the youngest age groups) which should be addressed by:

1 calculating the disproportionality of the risk of those vaccines as compared to the background risk for illness in a similar age-specific group;

2 examining the results of statistical methods using both comparator groups; and

3 using reports for other vaccines as the comparator group with a stratification made at least by age.

t) when there is little time to validate safety signals it is essential to make best use of suspected adverse reaction reports as:

1 although such analyses cannot exclude risks or determine causality:

(1) they can put suspected adverse reaction reports into context; and

(2) should be used as a routine tool for real-time surveillance;

2 they can be used in safety signal validation;

3 in the absence of robust epidemiological data, they can be used in preliminary signal evaluation.

u) the shorter the time that has elapsed between the vaccination procedure and the event, the more likely it is to be perceived as a safety trigger and subsequently be reported;

v) events that are expected, common and mild, or occur late after vaccination, are less likely to be reported;

w) given uncertainties around the observed number of adverse events cases sensitivity analyses should be applied in statistical analyses accounting for:

1 the levels of diagnostic certainty;

2 the level of vaccine exposure;

3 the background incidence rates;

4 properly assumed levels of under-reporting of adverse events;

5 numbers of confirmed and non-confirmed cases (using several categories of diagnostic certainty as appropriate);

6 numbers of vaccinated individuals or vaccine doses administered; and

7 confidence intervals of incidence rates.

x) appropriate follow-up of serious suspected adverse reactions is essential, including data on possible alternative causes;

y) safety signal evaluation requires attention to the following matters:

1 the incidence of the natural disease in the target population for vaccination and its seasonality;

2 additives and excipients used for the production, inactivation, preservation, and stabilisation of the vaccine;

3 past experience with similar vaccines, adjuvants and types of antigens, in order to identify adverse reactions which are unexpected and for which a causal relationship remains to be elucidated;

4 distinction between suspected adverse reactions to the vaccine and those reflecting the clinical picture of the disease for which vaccination has been given (e.g. rash following measles vaccination);

5 public information (public campaign, press) that may favour certain reports in some periods.

z) the principle of public health protection:

1 is particularly relevant in situations such as the approval of vaccines for healthy children, particularly in case of a localised adverse event incident;

2 requires in those circumstances consideration of a vaccine batch recall or quarantine:

(1) in the absence of the full facts; and

(2) evidence and before the assessment of the issue is finalised.

aa) when considering a batch recall or quarantine where indicated following the relevant adverse event the following matters are to be considered:

1 detailed description of the cases presented in CIOMS format with narrative;

2 any additional information as appropriate including:

(1) laboratory results;

(2) autopsy reports;

(3) literature.

3 the characteristics of the adverse event including:

(1) severity;

(2) expectedness (new adverse reaction vs. increased frequency of a known adverse reaction);

(3) outcome;

4 the characteristics of patients presenting the adverse event including:

(1) age;

(2) concomitant diseases;

(3) concomitant vaccination;

5 the crude number of cases and reporting rate or incidence rate of the adverse event in the vaccinated population using actual vaccine usage data rather than sales data and observed vs. expected calculations of the event observed;

6 the time and space clustering of cases, e.g. cases reported by a single hospital, physician or region;

7 the geographical distribution (both spatial and numbers of doses used) of the suspected batch(es);

8 the manufacturing records of the suspected batch(es) (certificates of analysis, information on deviations observed at in-process controls or manufacturing steps, documentation of recent changes to the manufacturing process);

9 the storage and administration conditions of the suspected batch(es);

10 re-analysis of retained samples of the suspected batch(es), focusing, if necessary, on additional parameters to those required for the release of the product;

11 investigation of any other available source of information that may promptly provide information on similar events (including batch-related information) and provide a preliminary assessment of all available data within a short timeframe.

bb) for single fatal adverse events, particularly where the cause of death is unknown, the reporting rate of the event relative to both the usage of the vaccine batch and the expected age-specific all-cause mortality should be considered before deciding on a recall or quarantine action;

cc) regulatory authorities must engage in:

1 appropriate communication about the benefit-risk balance and safe use of vaccines by regulators to:

(1) the target population;

(2) vaccinated individuals;

(3) parents / carers;

(4) healthcare professionals;

(5) health policy makers; and

(6) the general public;

dd) Principles and guidance on safety communication entails:

1 transparency;

2 providing explicit information in lay language to the public regarding the use of vaccines which is fundamental to the communication approach;

3 public confidence in vaccination programs being only attained by implementation of and knowledge that systems are in place to ensure complete and rapid assessment and to take precautionary measures if needed;

4 safety communication about vaccines may also profit from describing key functions of the pharmacovigilance systems;

5 communication about vaccine should include:

(1) informing vaccinators and healthcare professionals on the management of vaccine-related anxiety and associated reactions, particularly in individuals with special conditions:

a) including pregnancy, puberty, immunosensitive conditions, general anxiety or other mood disorders, epilepsy;

b) for the purpose of quantifying safety concerns, relevant background rates, by age group and sex;

c) of up-to-date signs and symptoms which are present in adverse events, whether:

i) known to be causally related;

ii) suspected to be causally related or

iii) likely to be coincidental.

d) preparing standard frequently needed explanations tested by representatives of likely target audiences;

e) addressing concerns raised by the public by proactively communicating results of benefit-risk evaluations;

f) ensuring appropriate communication with the public and in particular the media which should be monitored;

g) giving information to the media in a timely and meaningful manner.

Particulars

Guideline on good pharmacovigilance practices (GVP) Product- or Population-Specific Considerations I: Vaccines for prophylaxis against infectious diseases. HMA Heads of Medicines Agencies and European Medicines Agency as an agency of the European Union. Dated 9 December, 2013. Pg. 4,5,6,8,12-20. https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-product-population-specific-considerations-i-vaccines_en.pdf.

MONITORING OF DATA IN CLINICAL TRIALS – ADOPTED EMA POLICY

56. Guidelines requiring the establishment of data monitoring committees in drug clinical studies directly applicable to the Clinical Trials and the Vaccines published in or about 2005, known to and adopted by the Respondents in respect of their functions under the Act at the time of the Approvals states **("Clinical Trials Oversight Policy")**:

a) it is important to ensure that a trial:

1 continues for an adequate period of time;

2 is not stopped too early to answer its scientific questions;

b) an independent Data Monitoring Committee (DMC):

1 is appointed as a group of experts external to a study that reviews accumulating data from an ongoing clinical trial to serve the task of answering scientific questions;

2 should in general have the predominant purpose of monitoring safety in the study data;

3 might also assess other aspects of a clinical trial including:

(1) study integrity; and

(2) study design.

4 should be set up in relation to a study:

(1) upon consideration of:

a) the vaccine's indication;

b) study endpoints;

c) study duration;

d) study population.

(2) where there is:

a) a lack of available knowledge about the drug;

b) the drug concerns a life-threatening disease usually the implementation, indicated:

i) from an ethical point of view;

ii) whether or not:

1. the treatment aims to reduce mortality or morbidity; or

2. is intended to relieve the patients' situation.

c) would only in very rare cases not be necessary where there exists the circumstances of:

i) a lack of available knowledge about the drug; or

ii) the drug concerns a life-threatening disease usually the implementation.

Particulars

European Medicines Agency Pre-authorisation Evaluation of Medicines for Human Use London, 27 July 2005 - Doc. Ref. EMEA/CHMP/EWP/5872/03 COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP) - GUIDELINE ON DATA MONITORING COMMITTEES. Pg. 3-4. https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-data-monitoring-committees_en.pdf

57. At all material times in performance of powers, functions and discretion under the Act, the Respondents were reasonably expected and obliged to adhere to those policies published by and/or adopted by the TGA by any of the Respondents pleaded at paragraphs 38 to 56 (inclusive) herein where acting under the Act **("the TGA Policies")**:

a) with reasonable care; and

b) in good faith.

PART F - OTHER INTERNATIONAL VACCINE APPROVAL STANDARDS

US COVID VACCINES APPROVALS STANDARD

58. The Respondents knew from at least October 2020 and prior to the Approvals, the published policy that the U.S. Department of Health and Human Services stipulated in relation to investigational vaccines being developed for the prevention of Covid, emergency use approval of those vaccines **("the US Covid Vaccine Approval Standard")**:

    a) must consider the totality of the available scientific evidence relevant to the product;

    b) requires a determination that:

        1 the vaccine's benefits outweigh its risk based on data from at least one well-designed Phase 3 clinical trial;

        2 the Vaccines' safety and efficacy must be demonstrated in a clear and compelling manner.

Particulars

The Respondents knew of these factual matters as the following document had been published to them at that time - U.S. Department of Health and Human Services, Food and Drug Administration, and Center for Biologics Evaluation and Research policy document "Emergency Use Authorization for Vaccines to Prevent COVID-19 Guidance for Industry" dated October, 2020, pg. 3-4.

59. The Respondents were required at all times to, and the Group Members reasonably expected that they would, act in consideration of and with regard to the obligations and principles contained in the US Covid Vaccine Approval Standard **("the US Policy Consideration Obligations")**.

UK COVID VACCINES APPROVALS STANDARD

60. The Respondents knew from at least 7 January, 2021 and prior to the Approvals, the published policy of that the UK Government stipulated in relation to investigational vaccines being developed for the prevention of Covid **("the UK Covid Vaccine Approval Standard")**:

a) in approving any Covid vaccines:

1 each country will consider:

(1) the availability of other vaccines and treatments;

(2) the status of the pandemic; and

(3) the epidemiology of disease in each regulatory jurisdiction.

2 clinical trials should show that a candidate vaccine very significantly reduces the incidence of Covid:

(1) in a group of people who are vaccinated, compared to a control group of people who don't receive the vaccine, effectively being the Absolute Risk Reduction Rate;

(2) based on a reduction in the rate of symptomatic laboratory-confirmed Covid Virus infections;

3 vaccines should also reduce the transmission of disease between individuals, including from asymptomatic to uninfected individuals;

4 only a trial that has a sufficient number of participants who develop severe COVID-19 disease in the control group would provide relevant data to support that the vaccine is effective;

Particulars

The Respondents knew of these factual matters as the following document had been published to them

at that time - “Policy paper Access Consortium statement on COVID-19 vaccines evidence”. Published 7 January 2021. UK Government. https://www.gov.uk/government/publications/access-consortium-statement-on-covid-19-vaccines-evidence/access-consortium-statement-on-covid-19-vaccines-evidence.

KNOWN RECOMMENDATIONS FOR TGA - NOT IMPLEMENTED

61. On or about July, 2010, the Western Australian Government conducted an independent ministerial review **(“the Stokes Report”)** into the public health response into the adverse events to the seasonal influenza vaccine, from which the following observations, conclusions and recommendations were made, and the Respondents knew were made before the Approvals, which were never adopted by the TGA **(“the Known Recommendation Implementation Failures”)**:

    a) that there must be achieved and maintained a separation of functions between licensing and regulation and monitoring and surveillance so that the process is open and transparent especially to those whom they serve, namely the public;

    b) the reporting system should incorporate a “flag system” so that when an AEFI occurs in a pattern outside the accepted norm an alert is immediately issued;

    c) an accurate and timely web-based mechanism should be facilitated by recording and making publicly available on any given day the batch number of the vaccine;

    d) consumer information accompanying the Vaccine for recipients must divulge side effects discovered in testing;

    e) vaccination providers, as well as parents and adult patients are also consumers of the vaccination product and thereby vaccination providers, especially family practitioners where observing an increasing number of AEFIs must:

1 report those matters;

2 inform parents and consumers of those possible complications in an appropriate manner.

f) more information than previously given must be provided about the content, testing and safety of vaccines being supplied to the public, especially when a new vaccine is introduced;

g) where there appears to be an emerging issue of AEFI, an early warning must be sent to:

1 vaccination providers including medical practitioners;

2 the public in the form of well-constructed information to keep them informed.

h) product Information must include information about the content, testing and safety of vaccines being supplied to the public to enable informed decisions about the vaccine before administration;

i) intensive surveillance is required to follow up with one in ten recipients (randomised) to ensure adverse events are identified, recorded appropriately and case managed;

j) communication regarding alerts or raising the level of surveillance should be targeted to emergency departments, Healthdirect, and GPs, all of whom would see or hear of patients with adverse reactions to the vaccine;

k) a simple method to report AEFI in emergency departments be established to ensure that AEFI are reported in a timely manner;

l) there must be flags put in place to detect early an adverse trend;

m) the Department:

1 appoints a separate body from the TGA to undertake the role of national surveillance and monitoring of AEFI;

2 formally reviews and address any perceived or real concerns in peak bodies with regard to Conflicts of Interest;

3 conduct surveillance for vaccine failures through disease surveillance processes rather than AEFI surveillance processes.

62. With respect to the TGA, the Stokes Report concluded inter alia that:

a) the relationships between the divisions of the TGA and the State were not functional;

b) the passive National surveillance system under the TGA was not robust or adequate;

c) the internal processes of the TGA in the day to day management of AEFI reports and safety signals was unclear at the time of the Report.

Particulars

Public Document published to the Respondents - Government of Western Australia – Department of Health. Ministerial Review into the Public Health Response into the Adverse Events to the Seasonal Influenza Vaccine - Final Report to the Minister for Health – WA July 2010. Professor Bryant Stokes, August 9, 2010. https://www.scgh.health.wa.gov.au/~/media/Files/Corporate/Reports-and-publications/PDF/Stokes_Report.pdf.

PART G - PLEADING

PLEADING KNOWLEDGE

63. In all Instances where a person is alleged in this pleading to have knowledge of a matter, such knowledge is alleged to be:

a) actual knowledge of that person;

b) further or in the alternative, knowledge imputed constructively to the person in the circumstances;

c) further or in the alternative, knowledge that the person ought to have possessed in the circumstances.

PLEADING - AUSTRALIAN PUBLIC

64. In all instances when the "Australian Public" or "Australian Population" is referred to in these pleading, such includes in each and every instance reference expressly to each and all of the Group Members.

PART H - RESPONDENTS KNOWLEDGE OF VACCINES RISK AND CONDUCT

KNOWN ACTUAL THREAT OF COVID TO AUSTRALIAN POPULATION

65. From prior to the Approvals, the Respondents knew of the following established scientific facts in respect of the established risks and threat of Covid infection to the Australian population by reason of the factual matters being widely published worldwide at that time and reasonably available to the Respondents particularised herein **("the Known Actual Threat of Covid")**:

a) the Covid infection case fatality rate estimated by the US Government Center for Disease Control was known to the Respondents at least from May, 2020 and at the time of the Approvals and was:

1 in the overall population - 0.004;

2 in people 0-49 years old – 0.0005;

3 in people 50-64 years old – 0.002;

4 in people 65 years old and over – 0.013.

Particulars

CDC. Coronavirus disease 2019 (COVID-19). COVID-19 Pandemic Planning Scenarios. Updated May 20, 2020.

http://web.archive.org/web/20200709001525/https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html .

b) the statistics produced by the Commonwealth as to the scale of Covid infections in the Australian population was known by the Respondents at the time of the Approvals to be obviously exaggerated because **("the Publicly Inflated Covid Infections")**:

1 there was a known and widespread Australian Government approval and use of the polymerase chain reaction test used to detect purported active cases of Covid infection in Australia and internationally **("the PCR Test")** which:

(1) was uniformly set to cycle threshold value **("CTV")** of greater than 35 which was:

a) so unreasonably sensitive as to produce erroneous results;

b) could and did produce a positive result where:

i) no live virus was present; or

ii) if a fragment of a single viral particle was present;

c) even when set to a CTV of 35 to produce positive results in which a positive culture was present in only 3% of those instances;

d) was at no time intended or purposed by its creator and producer in public health practice to be diagnostic instrument for detection of Covid infection;

e) was wholly unfit for purpose, inappropriate and misleading in its operation for the purpose to which

it was applied as a diagnostic instrument for detection of Covid infection;

(2) frequently provided positive results in persons:

a) with very low viral loads of the Virus;

b) whom were asymptomatic;

c) incapable of transmission of the Virus due to their low viral loads;

(3) in 97% of positive results by PCR testing for the Virus:

a) no Virus was detected in subsequent culture tests;

b) the positive result was false.

(4) was from publicly notified on 21 July, 2021 by the CDC:

a) to be subject to CDC's withdrawal of 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;

b) on the basis of being inappropriate for the stated purpose of testing for infection with the Virus;

(5) is and was at all material times useless as a specific diagnostic tool to identify the Virus;

Particulars

Jaafar R, et al - Correlation Between 3790 Quantitative Polymerase Chain Reaction-Positives Samples and Positive Cell Cultures, Including 1941 Severe Acute Respiratory Syndrome Coronavirus 2 Isolates. Clin Infect Dis. 2021 Jun

1;72(11):e921. doi: 10.1093/cid/ciaa1491. Erratum in: Clin Infect Dis. 2021 Nov 2;73(9):1745. PMID: 32986798; PMCID: PMC7543373.
https://pubmed.ncbi.nlm.nih.gov/32986798/

CDC 07/21/2021: Lab Alert: Changes to CDC RT-PCR for SARS-CoV-2 Testing
https://www.cdc.gov/locs/2021/07-21-2021-lab-alert-Changes_CDC_RT-PCR_SARS-CoV-2_Testing_1.html

External peer review of the RTPCR test to detect SARS-CoV-2 reveals 10 major scientific flaws at the molecular and methodological level: consequences for false positive results November 2020
DOI:10.5281/zenodo.4298004. Pieter Borger
https://www.researchgate.net/publication/346483715_External_peer_review_of_the_RTPCR_test_to_detect_SARS-CoV-2_reveals_10_major_scientific_flaws_at_the_molecular_and_methodological_level_consequences_for_false_positive_results

c) there was a known inflation of the reporting of Covid - related deaths by the Commonwealth known to the Respondents at that time of the Approvals obviously arising because **("the Inflated Covid Deaths")**:

1 the quantum of deaths reported was at all material times misleadingly determined and defined to be causal wherein any person died "with Covid" as opposed to "from Covid" thereby:

(1) allowing for excessive coincidental findings of death unrelated to Covid in a high proportion such that the claimed deaths from Covid were in fact in respect of the most virulent strain of Covid:

a) only 41% causally related to Covid;

b) 2.5 times the actual deaths causally related to Covid;

(2) in no further manner attempted to genuinely ascribe causality of the death to Covid infection;

(3) cited as a basis for true numbers of Covid related deaths in circumstances where in truth that applied process to establish causality was unknown to science;

(4) no statistic has been produced by the Respondents or is known to the Respondents prior to the Approvals or at all as to the number of Australians 'dying from' Covid in circumstances where in truth:

a) the number of Australians reportedly 'dying with' Covid:

i) had co-existing co-morbidities at the time of death in 93% of cases;

ii) were only in 7% of the cases listed with Covid as the sole cause of death;

b) the total number of Australians 'dying from' Covid must be a materially smaller subset of those 'dying with' Covid.

Particulars

"Deaths in children and young people in England after SARS-CoV-2 infection during the first pandemic year". Smith, C et al. 2022. Nature Medicine; Vol 28, 185-192. https://doi.org/10.1038/s41591-021-01578-1.

"COVID infection severity in children under 5 years old before and after Omicron emergence in the US".WANG, L. et al. Posted 13 January, 2022. https://doi.org/10.1101/2022.01.12.22269179

See e.g. NSW COVID-19 WEEKLY DATA OVERVIEW: www.health.nsw.gov.au/coronavirus

d) the Respondents knew that based upon Commonwealth reporting recorded from at on or about the time of the Approvals at 31 January, 2021 and to the present time:

1 that the median age of death from Covid was at that time and remains until the present **("the Known Median Age of Covid Deaths")**:

(1) 81.2 years for males; and

(2) 86.0 years for females;

2 in circumstances where in truth **("the Known Non-Effect of Covid Upon Age Life Expectancy")**:

(1) the known median life expectancy at birth for people born in that same period was:

a) 81.3 years for males; and

b) 85.4 years for females.

(2) the median age of death was:

a) 79 for males; and

b) 85 for females.

(3) the expectation of significant and common co-morbidities amongst those in that age group known to be:

a) entirely causal; or

b) contributory.

Particulars

"Australian Government Department of Health – Data Sheet". https://www.health.gov.au/sites/default/files/documents/2021/02/coronavirus-covid-19-at-a-glance-31-january-2021-coronavirus-covid-19-at-a-glance-31-january-2021.pdf

"ABS Life expectancy hits a new high". Media Release. Released 4/11/2021 https://www.abs.gov.au/media-centre/media-releases/life-expectancy-hits-new-high

"Australian Institute of Health and Welfare. Deaths in Australia" Australian Government. Web report https://www.aihw.gov.au/reports/life-expectancy-death/deaths-in-australia/contents/age-at-death

e) the Respondents knew at the time of the Approvals that based upon Commonwealth reporting by the Australian Bureau of Statistics that **("the Known Actual Circumstances of Covid")**:

1 Covid was only the 38th leading cause of death in Australia in 2020 even adopting the Inflated Covid Deaths;

2 influenza was a significantly greater concern in Australia in that infection with influenza reported by the Australian Bureau of Statistics in 2017:

(1) was the direct cause of 1,183 deaths in that year;

(2) in confluence with pneumonia contributed to 4,369 deaths in that year;

(3) was the 9th leading cause of death in that year;

(4) was the 12th leading cause of death in 2018 at 3102 deaths;

3 the impact of Covid varies materially depending upon the age group;

4 not one person under the age of 50 years in Australia had died from Covid at the time of the Approvals;

Particulars

Australian Government Department of Health (2018) Communicable Diseases Intelligence. Report of the National Influenza Surveillance Scheme 2011 to 2018. Year 2022 Volume 46. Communicable Disease Epidemiology and Surveillance Section
https://doi.org/10.33321/cdi.2022.46.12

Australian Government Department of Health – Data Sheet
https://www.health.gov.au/sites/default/files/documents/2021/02/coronavirus-covid-19-at-a-glance-31-january-2021-coronavirus-covid-19-at-a-glance-31-january-2021.pdf

f) from prior to January 2021 and before the Approvals, the Respondents knew that, with respect to the fatality rate in respect of Covid infection, in fact **("the Known Actual Covid Fatality Rate")**:

1 that the true infection fatality rate for Covid:

(1) across all age groups and strata of the world population at that time were from 0.00 to 0.0154;

(2) an average across all age groups and global populations of 0.002;

(3) a range of less than 0.001 to 0.0058 in city and national populations globally;

(4) 0.0003 in people below 40 years of age;

(5) in people below 70 years of age:

a) ranged from 0.00 to 0.0068;

b) was a median of 0.0005;

(6) was similar to seasonal influenza;

2 that at that time it being known to the Respondents that 94% of the global population was younger than 70 years old;

3 that the infection fatality rate data was established based upon unassailable large scale and widely published scientific seroprevalence testing which determined actual previous Covid infections in the population;

4 the median age of Covid deaths were known by the Respondents at that time to be:

(1) in Australia – 82 years of age;

(2) globally in developed countries to be between 78 and 86 years of age;

5 the Respondents knew at that time that the infection fatality rate of:

(1) seasonal influenza was scientifically determined and known to be usually 0.001;

(2) during the 1918-1919 influenza pandemic was greater than 0.025;

6 the variation in the infection fatality rate of Covid infection varies due to differences in population age structure and the case-mix of infected and deceased patients and other factors.

Particulars

The Known Actual Covid Fatality Rate was well documented and accepted scientifically prior the Approvals including in, for example, the following studies:

1. “Seroprevalence of anti-SARS-CoV-2 IgG antibodies in Kenyan blood donors”. Uyoga, S et al. Nov 2020. Science: Vol 371, Issue 6524. Pp 79-82.
https://www.science.org/doi/10.1126/science.abe1916

2. “High SARS-CoV-2 seroprevalence in health care workers but relatively low number of deaths in urban Malawi” Chibwana, M et al. 2020. Wellcome Open Res, 5:199.
https://wellcomeopenresearch.org/articles/5-199/v1

3. “What do the Delhi and Mumbai Sero-Survey Results Tell US About COVID-19 in India?”. The Wire. 31 July,2020.
https://thewire.in/health/delhi-mumbai-covid-19-coronavirus-seroprevalence-survey-results

4. “Covid-19 far more widespread in Indonesia than official data show: studies”. Reuters. 3 June, 2021.
https://www.reuters.com/world/asia-pacific/exclusive-covid-19-far-more-widespread-indonesia-than-official-data-show-studies-2021-06-03/

5. “Seroprevalence of SARS-CoV-2 in Guilan Province, Iran”. Shakiba, M et al. April 2020. Emerging Infectious Diseases. 2021;27(2):636-638.
https://wwwnc.cdc.gov/eid/article/27/2/20-1960_article

6. “42.4 percent of the residents of Ischgl have antibodies against the corona virus”. The Standard. 25 June, 2020.
https://www.derstandard.at/story/2000118306133/42-4-prozent-der-bewohner-ischgls-haben-antikoerper-gegen-sars

7. “COVID-19 mortality, excess mortality, deaths per million and infection fatality ratio, Belgium, 9 March 2020 to 28 June 2020”. Molenberghs, G et al. 2022. Euro Surveill. 27(7).
https://doi.org/10.2807/1560-7917.ES.2022.27.7.2002060

8. “Estimation of SARS-CoV-2 Infection Fatality Rate by Real-time Antibody Screening of Blood Donors”, Erikstrup, C et al. January 2021. Clinical Infectious Diseases, Volume 72, Issue 2, Pages 249–253, https://doi.org/10.1093/cid/ciaa849

9. “Estimating the infection fatality ratio in England”. The Centre for Evidence-Based Medicine. 21 August, 2020. https://www.cebm.net/covid-19/estimating-the-infection-fatality-ratio-in-england/

10. ”SARS-CoV-2 antibody prevalence in England following the first peak of the pandemic”. Ward, H et al. 2021. Nat Commun 12, 905. https://doi.org/10.1038/s41467-021-21237-w

11. “Infection fatality rate of SARS-CoV2 in a super-spreading event in Germany”. Streeck, H et al. 2020. Nat Commun 11, 5829. https://doi.org/10.1038/s41467-020-19509-y

12. “Humoral immune response to SARS-CoV-2 in Iceland”. Gudbjartsson, DF et al. Oct 2020. New England Journal of Medicine. 383:1724-1734. https://www.nejm.org/doi/full/10.1056/NEJMoa2026116

13. “Age-specific SARS-CoV-2 infection fatality ratio and associated risk factors, Italy, February to April 2020”. Poletti, P et al. 2020. Euro Surveill. 2020;25(31).. https://doi.org/10.2807/1560-7917.ES.2020.25.31.2001383

14. “Infection fatality risk for SARS-CoV-2 in community dwelling population of Spain: nationwide seroepidemiological study”. Pastor-Barriuso, R et al. Nov 2020. BMJ 2020; 371. https://doi.org/10.1136/bmj.m4509

15. “Serology-informed estimates of SARS-CoV-2 infection fatality risk in Geneva, Switzerland”. Perez-Saez, J et al. April 2021. Lancet. VOLUME 21, ISSUE 4, E69-E70. https://doi.org/10.1016/S1473-3099(20)30584-3

16. “Early peak and rapid decline of SARS-Co-V-2 seroprevalence in a Swiss metropolitan region”. Emmenegger, M et al. Posted August 2021. https://www.medrxiv.org/content/10.1101/2020.05.31.20118554v4

17. “Population-based seroprevalence of SARS-CoV-2 is more than halfway through the herd immunity threshold in the State of Maranhão, Brazil”. Mourna da Silva, AA et al. Posted Sept 01, 2020. https://www.medrxiv.org/content/10.1101/2020.08.28.20180463v1

18. “Three-quarters attack rate of SARS-CoV-2 in the Brazilian Amazon during a largely unmitigated epidemic”. Buss, L et al. Dec 2020. SCIENCE. Vol 371, Issue 6526 pp. 288-292 https://pubmed.ncbi.nlm.nih.gov/33293339/

19. “Using serological studies to assess Covid-19 infection fatality rate in developing countries: A case study from one Colombian department”. Alvis Guzman, N et al. Sept 2021. International Journal of Infectious Diseases. Vol 110: p 4-5. https://www.sciencedirect.com/science/article/pii/S1201971221005075

20. “Infection fatality ratios for Covid-19 among noninstitutionalized persons 12 and older: results of a random-sample prevalence study”. Blackburn, J et al. January 2021. Annals of Internal Medicine. https://www.acpjournals.org/doi/10.7326/M20-5352

21. “Covid-19 antibody seroprevalence in Santa Clara County, California”. Bendavid, E et al. April, 2021. International Journal of Epidemiology, Volume 50, Issue 2, Pages 410–419, https://doi.org/10.1093/ije/dyab010

22. “Second round of COVID-19 community testing completed; Miami-Dade County and the University of Miami Miller School of Medicine announce initial findings”. Miami-Dade County News Release. 24 April, 2020. https://www.miamidade.gov/releases/2020-04-24-sample-testing-results.asp

23. “Preliminary results of USC-LA County COVID-19 study released”. University of Southern California Press Room. April 20, 2020.
https://pressroom.usc.edu/preliminary-results-of-usc-la-county-covid-19-study-released/

24. “Infection fatality risk for SARS-CoV-2 in community dwelling population of Spain: nationwide seroepidemiological study”. Pastor-Barriuso, R et al. 2020. BMJ. 371.
https://doi.org/10.1136/bmj.m4509

25. “Global perspective of COVID-19 epidemiology for a full-cycle pandemic”. Ioannidis, J Dec 2020, European Journal of Clinical Investigation. Vol 50, Issue 12.
https://onlinelibrary.wiley.com/doi/10.1111/eci.13423

26. “A systematic review and meta-analysis of published research data on Covid-19 infection fatality rates”. Meyerowitz-Katz, Dec 2020. International Journal of Infectious Diseases. Volume 101, P138-148.
https://www.ijidonline.com/article/S1201-9712(20)32180-9/fulltext

27. “Estimation of SARS-CoV-2 Infection Fatality Rate by Real-time Antibody Screening of Blood Donors”.Erikstrup, C et al. January 2021. Clinical Infectious Diseases, Volume 72, Issue 2, Pages 249–253. https://doi.org/10.1093/cid/ciaa849

28. “Humoral immune response to SARS-CoV-2 in Iceland” Gudbjartsson, DF et al. Oct 2020. New England Journal of Medicine. 383:1724-1734.
https://www.nejm.org/doi/full/10.1056/NEJMoa2026116

29. “Infection fatality rate of COVID-1937 inferred from seroprevalence data”.Ioannidis, J. P. A . 2020. Bulletin of the World Health Organization. 99(1): 19-33F.
https://www.who.int/bulletin/online_first/BLT.20.265892.pdf

30. “Coronavirus (COVID-19) at a glance – 6 August 2020”. https://www.health.gov.au/resources/publications/coronavirus-covid-19-at-a-glance-6-august-2020

31. “1918 Influenza: the mother of all pandemics”. Taubenberger JK, Morens DM. 2006. Emerg Infect Dis. 12(1):15-22. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3291398/#R4

32. “All-cause mortality supports the COVID-19 mortality in Belgium and comparison with major fatal events of the last century”. Bustos 33. Sierra, N et al. Nov 2020. Arch Public Health. 13;78(1):117. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7662738/

“CDC - Weekly Updates by Select Demographic and Geographic Characteristics”. https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm

“COVID-19 epidemiology update: Key updates”. Government of Canada. https://health-infobase.canada.ca/covid-19/epidemiological-summary-covid-19-cases.html

“NHS – COVID-19 Daily Deaths”. https://www.england.nhs.uk/statistics/statistical-work-areas/covid-19-daily-deaths/

“France - COVID-19: epidemiological update of May 7, 2020” https://www.santepubliquefrance.fr/maladies-et-traumatismes/maladies-et-infections-respiratoires/infection-a-coronavirus/documents/bulletin-national/covid-19-point-epidemiologique-du-7-mai-2020

“Germany - Current situation reports, weekly reports and pandemic radar”. https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Situationsberichte/Gesamt.html

"Characteristics of patients who died positive for SARS-CoV-2 infection in Italy". https://www.epicentro.iss.it/coronavirus/sars-cov-2-decessi-italia

"Corona virus: situation in Switzerland". https://www.bag.admin.ch/bag/de/home/krankheiten/ausbrueche-epidemien-pandemien/aktuelle-ausbrueche-epidemien/novel-cov/situation-schweiz-und-international.html

g) as from at least 2 April, 2021, the Respondents knew that it was conclusively determined and verified by data publicly that **("the Known Underestimate of Previous Covid Infection in the Population")**:

1 actual cases of current or previous infection with Covid in the US population was in fact 4,416% or 44.17 times greater than the reported number of Covid cases (53,000 / 1,200);

2 the local infection fatality rate for Covid at that time across all age groups was in fact approximately 0.17%.

Particulars

"Covid-19 Antibody Seroprevalence in Santa Clara County, California". Bendavid et al. April 2021. International Journal of Epidemiology. Vol 50, Issue 2, pages 410-419

h) the risk from Covid was inflated by regulatory authorities by:

1 publication of case fatality rates which erroneously relied upon the number of tested cases known to be significantly less than actual numbers of infections;

2 the number of deaths as a comparator further inflated by the Inflated Covid Deaths;

3 Covid had an actual infection fatality rate known to the Respondents at the time of the Approvals of:

(1) no greater than 0.0057 in the general population;

(2) no greater than 0.0005 in those under the age of 70 years;

(3) far lower than early purely speculative and unsubstantiated estimates.

i) from prior to the Approvals, the Respondents knew, in respect of the question of natural extant or arising immunity from Covid in the general Australian population that **("the Known and Ignored Efficacy of Natural Covid Immunity")**:

1 the Respondents at no point in time prior to the Approvals reasonably considered or studied as an alternative to mass vaccination:

(1) the efficacy and duration of the natural immunity from Covid in people either naturally or following Covid infection **("Natural Immunity")**;

(2) Natural Immunity as a positive consideration within the context of risk-benefit analysis in Approval of any of the Vaccines;

2 the Respondents knew prior to the Approvals that it had been scientifically established prior to the Approvals that:

(1) Natural Immunity is very durable and typically persists for 12-17 years;

(2) the world population has cross-reacting T-cells, B cells and antibodies derived from encounters with previous cold coronaviruses that can recognise and defend against Covid;

3 the four human coronaviruses that cause common colds were at the time of the arrival of the Virus and at the time of the Approvals:

(1) endemic in the world population;

(2) never vaccinated against by humans because no such successful vaccine had ever existed;

4 over 150 scientific studies and evidence on natural immunity as compared to the COVID-19 vaccine-induced immunity had:

(1) been produced; and

(2) disclosed a consensus that immunity caused by COVID infection is robust and long lasting.

5 that it was known by the Respondents before the Approvals in respect of Covid infection that:

(1) at least 40% to 45% of the infections were asymptomatic and in some cohorts the proportion was 96% depending upon:

a) age; and

b) cross-immunity imparted by other viruses such as beta coronaviruses HCoV-OC43 and HCoV-HKU1.

(2) 80% were mild infections.

Particulars

Dr Karina Reiss, Dr Sucharit Bhakdi. Book, “Corona False Alarm? Facts and Figures”. Pages 101-108.

The Known and Ignored Efficacy of Natural Covid Immunity was well documented and accepted scientifically prior the Approvals including in, for example, the following studies:

1. “Covid-19: Do many people have pre-existing immunity?” Doshi, P. September 2020. BMJ: 370. https://doi.org/10.1136/bmj.m3563

2. “Preexisting and de novo humoral immunity to SARs-CoV-2 in humans”. Kevin W NG et al. 2020. Science. 370(6522): 1339-1343. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7857411/

3. “Letter to BMJ: T-cells really are the superstars in fighting COVID-19 - but why are some of us so poor at making them?” King E. Sept 2020 https://www.bmj.com/content/370/bmj.m3563/rr-6

4. “Prevalence of asymptomatic SARS-CoV-2 infection: a narrative review”. Oran DP, Topol, EJ. 2020. Annals of Internal Medicine. 173,362-367. https://doi.org/10.7326/M20-3012

5. “160 Plus Research Studies Affirm Naturally Acquired Immunity to Covid-19: Documented, Linked, and Quoted”. Alexander, PE. October, 2021. Brownstone Institute. https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/

j) that in the circumstances of the scientific factual matters known to the Respondents prior to the Approvals at that time the Respondents knew that:

1 Covid was not a threat to the Australian population such that the Respondents could assume such a low a level of risk arising to the Australian population which could only be met with an even lower level of risk in receiving the Vaccines confirmed by fully, comprehensively, and evidently establishing that the Vaccines are:

(1) safe;

(2) effective;

(3) displaying a positive risk-benefit profile.

2 the Approvals were undertaken as a Provisional Approval by the Respondents upon the purported basis that there was an urgent need for the Vaccines early approval such that if the Vaccines were

not approved in a materially expedited manner **("the False Necessity Basis")**:

(1) millions of the Australian population would die or require hospitalisation due to the Covid infection;

(2) there were no other therapies available in the world known to be capable of therapeutically addressing Covid infection;

(3) mass vaccination was the only way out of the Covid Pandemic;

(4) there was an urgent need for the Vaccines;

(5) the risk – benefit ratio was such that there was a greater harm in failing to approve the Vaccines and make them available without full and proper testing to the public than not.

3 to the extent that any risk-benefit assessment was done in respect of the Vaccines prior to the Approvals, the Respondents:

(1) assumed a level of risk in respect of Covid profoundly controverted by the actual risk of Covid known and disclosed to the Respondents in the Known Actual Threat of Covid, including the False Necessity Basis;

(2) without any proper basis failed or refused to apply the Known Actual Threat of Covid to any risk-benefit analysis in respect of the Vaccines, thereby determining the Approvals:

a) on the basis of known false assumptions, including the False Necessity Basis;

b) in circumstances where in truth the Approvals ought to have been rejected where the Known Actual Threat of Covid was properly considered.

Particulars

TGA Documents indicating that there was an urgent need for the Vaccines in order to prevent widespread serious disease, hospitalisations and deaths from Covid in Australia:

1. The Pfizer Original AUSPAR. Page 9.

2. The Pfizer 12-15 Year Olds Extension AUSPAR. Page 8.

3. The Pfizer 5-11 Year Olds Extension AUSPAR. Page 9,10.

4. The Booster for 12-15 Year Olds AUSPAR. Page 7.

5. The Pfizer 6 months-5 Year Olds Extension AUSPAR. Page 9,10.

6. The Pfizer Booster AUSPAR For Adults >18 Years AUSPAR. Page 9.

7. The Pfizer Booster for 5-11 Year Olds Booster AUSPAR. Page 10,11.

8. The Pfizer Clinical Evaluation Report. Page 9,10.

9. The Pfizer Delegate's Overview. Page 22.

10. The AstraZeneca Delegate's Overview. Page 6.

11. The AstraZeneca Original AUSPAR. Page 9.

12. The AstraZeneca Booster in >18 Year Olds AUSPAR. Page 8.

13. The Moderna 12-17 Year Olds AUSPAR. Page 9.

The False Necessity Basis was purported on the following occasions by the Respondents in their Misleading Statements:

the Skerritt Misleading Vaccines Statements:
7 December, 2021;
1 March, 2022;
1 April, 2022.
the Secretary Misleading Vaccines Statements:
3 February, 2021;
7 March, 2021.
the TGA Misleading Vaccines Statements:
27 May, 2021;
16 September, 2021;
8 November, 2022.

the Misleading Department Vaccines Statements:
23 December, 2021.

PART I – INFORMATION KNOWN TO THE RESPONDENTS PRIOR TO APPROVAL

KNOWN ALTERNATIVE THERAPIES FOR COVID

66. The Respondents knew from at least 10 December, 2020 and before the Approvals, and by reason of their respective positions, circumstances and public knowledge that there were effective therapeutics already available in respect of the effects of Covid **("the Known Alternative Therapies")**:

a) including:

1 antivirals such as:

(1) interferon beta-2a;

(2) molnupiravir;

(3) lopinavir/ritonavir;

(4) remdesivir.

2 steroids such as:

(1) dexamethasone.

3 monoclonal cocktails such as:

(1) tocilizumab (actemra).

4 hyperimmune plasma/convalescent plasma; and

b) known to the Respondents to have been publicly acknowledged by Pfizer at that time.

Particulars

The Known Alternative Therapies were known to the Respondents by reason of the fact that those therapies were publicly known and approved for use in humans for a significant period prior to the Approvals. Further the Respondents had published to them the following document produced by Pfizer making the assertion expressly - Pfizer-BioNTech Covid-19 Vaccine (BNT162, PF-07302048) Vaccines And Related Biological Products Advisory Committee Briefing Document - Meeting Date: 10 December 2020. https://www.Fda.Gov/Media/144246/Download. Page 10.

The existence of the Known Alternative Therapies was known to the Respondents and was well documented and accepted scientifically including in for example the following studies:

1. “Efficacy of various treatment modalities for nCOV-2019:

A systematic review and meta-analysis". Misra, S et al. 2020. Eur J Clin Invest. 50:e13383. https://doi.org/10.1111/eci.13383

2.https://www.recoverytrial.net/news/low-cost-dexamethasone-reduces-death-by-up-to-one-third-in-hospitalised-patients-with-severe-respiratory-complications-of-covid-19 June 2020. Subsequently published in Feb 21 as: "Dexamethasone in Hospitalized Patients with Covid-19". The Recovery Collaborative Group. N Engl J Med. February 25, 2021, 384:693-704

3. "Tocilizumab for treatment patients with COVID-19: Recommended medication for novel disease". Samaee, H et al. December 2020. Int Immunopharmacol. 89(Pt A):107018. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7494278/

4. "Convalescent plasma as a potential therapy for Covid 19". Chen, L et al. April 2020. The Lancet. Vol 20: pp398-400. https://www.thelancet.com/action/showPdf?pii=S1473-3099%2820%2930141-9

KNOWN INHERENT VACCINES RISKS

67. The Vaccines are, and were known by the Respondents at the time of the Approvals to be **("the Known Inherent Vaccines Risks")**:

a) each producing their intended effect in the human body by the introduction of a new or modified gene into the body for the purpose of seeking to immunise against Covid;

b) by universal and conventional definition;

1 not "vaccines", as per the definition of a vaccine at the time of the Approvals;

2 gene therapy products;

c) for the Pfizer and Moderna Vaccines, never evaluated under any gene therapy guidelines;

d) utilizing a pharmacological effect, action, mechanism and purpose which has never before in history been:

1 widely used in a general population;

2 deployed in a fully approved therapeutic product;

e) by reason of their unprecedented nature, experimental;

f) using in their composition a genetic technology which has not been employed for any fully approved drug in history;

g) previously only investigated in relatively early clinical research for possible use in certain cancers and rare genetic disorders;

h) possessing of exceptional and inherent safety risks, by reason of:

1 their novel properties; and

2 widespread intended use;

i) operating in a manner never used previously:

1 by delivery into the human cells of either:

(1) RNA in a lipid nanoparticle; or

(2) DNA genetic material contained in a viral vector;

2 to produce a spike protein:

(1) similar to that found on the surface of the coronavirus as its most toxic element;

(2) in order to provoke an immune response.

j) in respect of the mRNA Vaccines, employing new generation nanoparticle technology using nanoparticles which:

1 are either:

(1) non-viral based; or

(2) viral based;

2 by reason of their small size are:

(1) more readily taken up by the human body than larger sized particles;

(2) able to cross biological membranes and access cells, tissues and organs that larger sized particles normally cannot;

(3) widely and efficiently distributed throughout the human body cells and organs following administration;

(4) cross the blood-brain barrier;

(5) possessive of higher risk and implications in relation to organ and tissue toxicity as compared to conventional vaccines which largely remain at the site of injection;

(6) are associated with long term inflammation:

a) in various tissues and organs; and

b) cardiovascular adverse effects.

k) so unprecedented in their nature and mechanism and purpose so as to be:

1 reasonably expected to take more than 10-12 years to develop due to technical difficulties;

2 having a 5% probability of proving safety and efficacy in even early Phase II clinical trials involving small numbers of individuals; and

3 having a 2% probability of moving to larger Phase III clinical trials and demonstrating safety and efficacy before being considered for marketing.

Particulars

Merriam-Webster definition of vaccine at the time of the Approvals:
"Any preparation of weakened or killed bacteria or viruses introduced into the body to prevent disease by stimulating antibodies against it".
https://languagelog.ldc.upenn.edu/nll/?p=50886

Food and Drug Administration (FDA) Office of Cellular, Tissue, and Gene Therapies' definition of "gene therapy products" include:
"Introducing a new or modified gene into the body to help treat a disease".
https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy

The Known Inherent Risks were well documented and accepted scientifically including in for example the following studies:

1. "Reasons for success and lessons learnt from nanoscale vaccines against COVID-19". Kisby et al. 2021. Nature Nanotechnology. Vol 16: 843-852.
https://www.nature.com/articles/s41565-021-00946-9.pdf

2. "Research Strategies for Safety Evaluation of Nanomaterials, Part II: Toxicological and Safety Evaluation of Nanomaterials, Current Challenges and Data Needs".

2005. Toxicological Sciences, Volume 88, Issue 1, Pages 12–17. https://doi.org/10.1093/toxsci/kfi293

3. "Health and Environmental Alliance Fact Sheet – Nanotechnology and Health Risks". April 2008. https://www.env-health.org/IMG/pdf/17-_NANOTECHNOLOGY_AND_HEALTH_RISKS.pdf

4. 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". Young, R et al. 2018. Gates Open Research. 2:23. https://doi.org/10.12688/gatesopenres.12817.2

The nature and effect of the Vaccines was uncontroversially disclosed to the Respondents through the Sponsors Provisional Applications for Registration through the TGA. That the mechanism of effect of the Vaccines was unprecedented was reasonably and easily evident and ascertainable to and by the Respondents in the context of the available body of known vaccine products worldwide.

KNOWN AND INTENDED WIDESPREAD USE OF THE VACCINES

68. The Respondents knew and intended prior to the Approvals that the Vaccines would upon approval and release to the Australian population be taken by a significant majority of the Australian population as a consequence of **("the Known Widespread Use of Vaccines")**:

    a) the Respondents' determination that the Vaccines, once approved and subsequent to the Approvals, would be as far as possible made available and distributed to the entire Australian population;

    b) the widespread media and government promotional messaging that the Vaccines were:

        1 safe;

2 effective;

3 the only way out of the Covid pandemic for the Australian population.

c) the Approvals being attended by widespread government and private industry promotion of the Vaccines as safe and effective;

d) a reasonable expectation that the Australian public would generally accept that the Vaccines are safe and effective where:

1 approved for registration and public use by the Secretary and the Australian Government;

2 the Respondents public and consistent message that the Vaccines were and are:

(1) safe;

(2) effective;

(3) the only way out of the Covid pandemic for the Australian population.

Particulars

The intent by the Respondents that the Vaccines be used by every member of the Australian population indicated for use of the Vaccines was uncontroversial.

TGA Documents indicating that the Vaccines are the only way to overcome the Covid Pandemic:

1. The Pfizer Original AUSPAR. Page 9.

2. The Pfizer 12-15 Year Olds Extension AUSPAR. Page 8.

3. The Pfizer 5-11 Year Olds Extension AUSPAR. Page 9,10.

4. The Booster for 12-15 Year Olds AUSPAR. Page 7.

5. The Pfizer 6 months-5 Year Olds Extension AUSPAR. Page 9,10.

6. The Pfizer Booster AUSPAR For Adults >18 Years AUSPAR. Page 9.

7. The Pfizer Booster for 5-11 Year Olds Booster AUSPAR. Page 10,11.

8. The Pfizer Clinical Evaluation Report. Page 9,10.

9. The Pfizer Delegate's Overview. Page 22.

10. The AstraZeneca Delegate's Overview. Page 6.

11. The AstraZeneca Original AUSPAR. Page 9.

12. The AstraZeneca Booster in >18 Year Olds

13. AUSPAR. Page 8.

14. The Moderna 12-17 Year Olds AUSPAR. Page 9.

Consistent examples of the messaging of the Respondents associated with the Approvals and the release of the Vaccines to the Australian population are pleaded and particularised herein and defined as the "Misleading Statements of the Respondents".

the Skerritt Misleading Vaccines Statements:

7 December, 2021;

1 March, 2022;

1 April, 2022.

the Secretary Misleading Vaccines Statements:

3 February, 2021;

7 March, 2021.

the TGA Misleading Vaccines Statements:

27 May, 2021;

16 September, 2021;

8 November, 2022.

the Misleading Department Vaccines Statements:

23 December, 2021.

KNOWN TYPICAL APPROVALS TIMELINE

69. The Respondents knew prior to the Approvals by reason of their respective positions, circumstances, and public knowledge **("the Known Vaccine Timeline")**:

a) that a typical vaccine development timeline:

1 takes 5 to 10 years, and sometimes longer to:

(1) assess whether the vaccine is safe and efficacious in clinical trials;

(2) complete the regulatory approval processes; and

(3) manufacture sufficient quantity of vaccine doses for widespread distribution.

2 involves the following stages and time frames:

(1) Animal testing – years;

(2) Phase I - 3 months;

(3) Phase II - 2 years;

(4) Phase III - several years;

(5) Manufacturing;

(6) Approval.

3 that the total amount of time taken for the Approvals from commencement, testing and trials to the time of the Approvals was:

(1) 9 months for the Pfizer vaccine;

(2) 10 months for the AstraZeneca vaccine; and

(3) 17 months for the Moderna vaccine.

Particulars

The Known Vaccine Timeline matters were known to the Respondents as a well-established and known matter of public record.

KNOWN USE AMONGST UNTESTED GROUPS

70. The Respondents knew prior to the Approvals **("the Known Untested Groups")**:

a) it is not usual practice in medicine to use a therapeutic intervention on groups of people on whom the therapeutic intervention has never been tested:

b) the Vaccines were at the time of the Approvals not tested on **("the Untested Groups")**:

1 pregnant women;

2 lactating women;

3 people with autoimmune diseases;

4 people who had prior infection with the disease, specifically Covid;

5 people with polyethylene glycol allergies.

c) the respective Vaccines as approved at the time of the Approvals had not been tested on the Untested Groups;

d) that the Vaccines were each indicated in any case for use by the Untested Groups.

Particulars

The Respondents knew of the factual matters defined as the Known Untested Groups because:

1. the fact that a therapeutic intervention was not used on untested groups is a matter of public record in terms of regulatory historical data.

2. the fact that the Vaccines had not been tested on the Untested Groups before the Approvals was known to the Respondents by reason of their having obtained the entirety of testing data relating to the Vaccines from the Sponsors in granting the Approvals;

3. the Respondents knew that the Vaccines were indicated for the Untested Groups by reason of having issued the Approvals.

KNOWN CORONAVIRUS MODE OF INFECTION

71. It was known to the Respondents prior to the Approvals with respect to the mode of infection of coronaviruses including the Virus and vaccines in respect of coronaviruses that **("the Known Coronavirus Vaccine Issues")**:

a) coronaviruses:

1 spread within an infected organism so as to avoid completely detection or neutralisation by virus-specific antibodies;

2 primarily infect epithelial cells within the lung;

b) it remained unknown as to the coronavirus':

1 exact mechanism of lung injury; and

2 cause of severe disease in humans.

c) vaccine development for coronaviruses is rendered futile and/or hazardous because:

1 the vaccines must either:

(1) induce better immunity than the original virus; or

(2) lessen the disease incurred during a secondary infection;

2 the propensity of the coronaviruses to recombine pose a problem by rendering the vaccine:

(1) useless; and

(2) potentially increasing the evolution and diversity of the virus in the wild.

d) it has been clearly established scientifically that virus vaccination with S protein leads to enhanced disease;

e) due to the lack of effective therapeutics or vaccines for the coronaviruses the best measures to control human coronaviruses are and remain, as opposed to vaccination:

1 a strong public health surveillance system; and

2 rapid diagnostic testing and quarantine when necessary.

f) the data contained in the Pfizer Nonclinical Studies provided to the TGA as a basis for the Pfizer Approval showed:

1 Pfizer Vaccine recipients suffering “immune stimulation and inflammatory response” the TGA (delegate) determined required further scrutiny given the known risk of Antibody-Dependent Enhancement (ADE);

2 the Pfizer Nonclinical Study demonstrating lung histopathological changes in the Pfizer Vaccine recipients;

3 several of the histopathological finding in immunological tissues such as spleen and lymph nodes, as well as increase in temperature, persisted beyond the end of the trial at three weeks;

4 indications of a hyperimmune response in the Pfizer Vaccine recipients accepted by the TGA (delegate) as requiring further review.

Particulars

The scientific facts and conclusions being generally known to the Respondents through scientific studies available to the Respondents since at least 2015 – e.g. Coronaviruses: An Overview of Their Replication and Pathogenesis, Anthony Fehr and Stanley Perlman, pg. 10, 13, 15-16.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4369385/pdf/978-1-4939-2438-7_Chapter_1.pdf.

The Pfizer Nonclinical Trial Data was made available to the TGA prior to the Approvals and summarized by the TGA in the Pfizer Nonclinical Evaluation Report.

KNOWN DEFECTS IN STUDIES AND RAW DATA RELEASE

72. The Respondents knew prior to the Approvals, that the Sponsors **("the Known Study Defects")**:

a) failed to engage in reasonable data transparency because of the confluence in the circumstances of the Approvals of:

1 data transparency being a well-established norm in biomedical research, and

2 the extreme importance of data transparency in the relevant circumstances of the extremely high possibility and risk of harm in the Australian population in the:

(1) use of the novel Vaccines and their respective technologies never before used in a mass vaccination setting;

(2) the broad use of the Vaccines as public health interventions being given to the vast majority of the population;

(3) the comparatively and significantly shorter period of the Approvals.

3 the Australian populations contribution to the funding of the Vaccine Trials and the Approvals apparatus;

b) that the data provided to the Sponsors prior to the Approvals and upon which each of the Approvals was based was so inadequate as to render proper determination of the following impossible in prolific use of the Vaccines:

(1) stratified safety profile of the Vaccines;

(2) the Risk-Benefit Profile of the Vaccines;

(3) the actual necessity of the Vaccines;

(4) the rational basis for use of Vaccines at all.

c) the actual benefit of the Vaccines for determination of a proper risk-benefit analysis could only be determined by proper understanding of death and injury rate of Covid:

1 through comparative analysis of the actual scientifically demonstrated infection fatality rate of Covid at the time of the Approvals for which no accurate data was provided to or considered by the Respondents in granting the Approvals;

2 which proceeded solely upon unsubstantiated, baseless and erroneous assumptions of the Respondents or upon which the Respondents relied at the time of the Approvals:

(1) that millions of deaths from Covid would be caused in the Australian population;

(2) wherein actual infection fatality rate data for Covid at the time of the Approvals evidenced an infection fatality rate similar to seasonal influenza.

Particulars

The Respondents knew of these matters by reason of having received the entirety of the data upon which the Sponsors relied in seeking and the Respondents in granting the Approvals.

KNOWN ABSENCE OF TESTING OR EVIDENCE FOR VACCINES TO PREVENT SERIOUS ILLNESS, FATALITIES OR COVID TRANSMISSION

73. The Respondents knew prior to the Approvals that **("the Known Absence of Testing and Evidence for Vaccine Prevention of Transmission, Serious Illness, or Fatality")**:

a) the Vaccines Clinical Trials were at no time designed to, provide data for, or draw a conclusion as to whether or not the Vaccines were effective to:

1 prevent serious illness arising from Covid infection or at all;

2 prevent death arising from Covid infection or at all; or

3 prevent transmission of Covid between people.

b) there was in fact no evidence provided to the Respondents or otherwise that the Vaccines:

1 prevent serious illness arising from Covid infection or at all;

2 prevent death arising from Covid infection or at all; or

3 prevent transmission of Covid between people.

c) because before the Approvals and presently:

1 the Vaccine Clinical Trials did not reach results of statistical significance to mee the secondary trial endpoint and thereby did not in fact:

(1) detect a reduction in any serious outcome such as hospital admissions, use of intensive care, or deaths;

(2) determine whether the Vaccines can interrupt or prevent transmission of the virus.

2 the Vaccine Clinical Trials did not reach the secondary study endpoints and thereby did not in any manner study or validly conclude, or seek to study or validly conclude:

(1) the safety or efficacy of the Vaccines in respect of:

a) Immunocompromised patients;

b) Pregnant or Breastfeeding Women;

(2) the Vaccines' ability to **("the Efficacy Failures")**:

a) reduce or prevent severe Covid including:

i) admission to hospital or ICU;

ii) death.

b) interrupt, reduce, or prevent entirely transmission of Covid from one person to another.

3 the following Vaccine Clinical Trials had as their protocol a primary endpoint definition of confirmed infection with Covid even with only mild symptoms:

(1) Pfizer Clinical Trial;

(2) Moderna Clinical Trial; and

(3) AstraZeneca Clinical Trial;

4 the Reports of the Vaccine Clinical Trials and the Vaccine Clinical Trials Protocols having been provided to the Respondents prior to the Approvals.

5 the primary endpoint rendering determination of the Efficacy Failures impossible.

Particulars

The relevant testing data evidencing the absence of testing and trial design in respect of the Vaccine Clinical Trials were provided and evident to the Respondents before the Approvals, such data provided for the purposes of the Approvals and relied upon by the Respondents in providing the Approvals.

The Vaccine Clinical Trial Protocols provided to the Respondents prior to the Approvals also evidence to the Respondents the same:

1. PF-07302048 (BNT162 RNA-Based COVID-19 Vaccines) Protocol C4591001. 2020. https://pfe-pfizercom-d8-prod.s3.amazonaws.com/202009/C4591001_Clinical_Protocol.pdf **("the Pfizer Clinical Trial Protocol")**

2. A phase 3, randomized, stratified, observer-blind, placebo-controlled study to evaluate the efficacy, safety, and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine in adults aged 18 years and older [protocol No mRNA-1273-P301]. 2020. http://web.archive.org/web/20201018173405/https://www.modernatx.com/sites/default/files/mRNA-1273-P301-Protocol.pdf **("the Moderna Clinical Trial Protocol")**

3. Clinical Study Protocol - Amendment 2 AZD1222-D8110C00001. 2020. https://s3.amazonaws.com/ctr-med-7111/D8110C00001/52bec400-80f6-4c1b-8791-0483923d0867/c8070a4e-6a9d-46f9-8c32-cece903592b9/D8110C00001_CSP-v2.pdf **("the AstraZeneca Clinical Trial Protocol")**

The Respondents knew of these matters by reason of having received the entirety of the data upon which the Sponsors relied in seeking and the Respondents in granting the Approvals and subsequent to the Approvals including the Vaccines Clinical Trial Data.

The Pfizer Original AUSPAR. Page 34.

The Moderna Original AUSPAR. Pages 56-58.

The AstraZeneca Original AUSPAR. Pages 37, 38.

KNOWN CORRUPTION OF LONGER TERM STUDY DATA BY SPONSORS

74. The Respondents knew within 2 weeks of the Pfizer Approval that the ongoing Pfizer Clinical Study had corrupted and nullified post Pfizer Approval longer term data by intentionally **("the Pfizer Longer Term Trial Corruption")**:

a) commencing to offer the Pfizer Vaccine to placebo recipients:

1 within two weeks of the Approvals;

2 despite the Pfizer Clinical Trial Protocol stipulating a follow-up period of two years;

3 thereby:

(1) eliminating follow-up after a few months of administration;

(2) eliminating the ongoing potential for longer term baseline comparison between Pfizer Vaccine and placebo recipients;

(3) ending the period of randomised follow-up;

(4) limiting understanding of the Vaccines' benefits and harms;

(5) rendering unknown whether the Vaccines can reduce the risk of serious Covid disease;

(6) precluding any further ability to compare adverse events in the Pfizer Vaccine recipients to the placebo recipients.

Particulars

The Respondents knew of these matters by reason of having received the entirety of the data upon which the Sponsors relied in seeking and the Respondents in granting the Approvals and subsequent to the Approvals including the Vaccines Clinical Trial Data.

KNOWN LIMITATION OF STUDY SCALE

75. The Respondents knew prior to the Approvals that the Vaccine Clinical Trials were planned and in fact did limit their Vaccines efficacy analyses to occur **("the Vaccine Longer Term Trial Corruption")**:

a) after just 150 to 160 end point events occurring being the occurrence of:

1 a positive Covid infection confirmation; and

2 any associated symptom regardless of severity;

b) effectively:

1 leading to approval of the Vaccines for use by the majority of the Australian population on the basis of conclusions of efficacy based upon approximately 160 results;

2 applying a disproportionately limited stopping rule in respect of the contemplated widespread and prolific use of the Vaccines;

3 rendering:

(1) the efficacy data provided in respect of the Vaccines in respect of the Approvals to be unreliable;

(2) identification of severe rare adverse events impossible to be determined in the data available to the TGA at the time of the Approvals.

Particulars

The Respondents knew of these matters by reason of having received the entirety of the data upon which the Sponsors relied in seeking and the Respondents in granting the Approvals and subsequent to the Approvals including the Vaccines Clinical Trial Data.

KNOWN MISLEADING CONCLUSION OF PFIZER VACCINE EFFICACY

76. The Respondents knew prior to the Pfizer Approval that its conclusion in or about January 2021 that, based upon the Pfizer Clinical Trial Data, the Pfizer Vaccine achieved a short term vaccine efficacy of 95% against Covid in persons injected with 2 doses of the Pfizer Vaccine **("the Known Misleading Pfizer Efficacy Conclusion")** was a misleading conclusion of the actual efficacy of the Pfizer Vaccine evident upon the Pfizer Clinical Trial Data:

a) the conclusion was claimed to be based upon the Pfizer Clinical Trial having been conducted upon approximately 44,000 subjects wherein the Known Misleading Pfizer Efficacy Conclusion is in fact based upon outcomes reported in only 170 trial participants;

b) there in fact were 43,448 participants wherein:

1 21,720 were in the Pfizer Vaccine group;

2 21,728 were in the placebo group;

c) of that number only 170 subjects tested positive for Covid and developed mild or greater Covid symptoms during the trial period, being the defined confirmed cases endpoint for the study determined by Pfizer and known to the Respondents;

d) of the "confirmed Covid cases":

1 8 were reported in the Pfizer Vaccine group;

2 162 were reported in the placebo group;

e) clinical efficacy of 95% was erroneously concluded and determined by applying these two relative numbers to each other as follows:

1 comparing 8/170 for the Pfizer Vaccine group and 162/170 in the placebo group;

2 inferring from that the Pfizer Vaccine was shown to be 95% effective;

f) wherein in fact:

1 99.07% of the unvaccinated group in the Pfizer Clinical Trial did not develop symptomatic Covid infection;

2 99.95% the Pfizer Vaccine group in the Pfizer Clinical Trial did not develop symptomatic Covid infection;

3 there was scientifically demonstrated and disclosed:

(1) an absolute risk reduction of symptomatic Covid infection of only 0.71% in the Pfizer Vaccine group;

(2) the number of doses of Pfizer Vaccine needed to treat, being the number of doses needed to prevent a single case of symptomatic Covid infection, of 141 doses.

4 the absolute risk reduction and the number needed to treat being the correct and most accurate measure of protection from symptomatic Covid infection which may only present as mild symptoms in an uninfected population over the trial surveillance period;

5 misleadingly, the purported 95% efficacy of the Pfizer Vaccine was, and was known to the Respondents, obtained in circumstances where in truth:

(1) in the Pfizer Clinical trial 3410 “suspected Covid-19 cases” were excluded from the calculation:

a) upon the basis of symptoms being displayed according to the trial protocol but PCR tests were not conducted by Pfizer in the following amounts:

i) 1594 occurring in the vaccine group;

ii) 1816 occurring in the placebo group;

b) undermining the veracity of the efficacy claims, including and particularly the “95% efficacy claim”;

c) but for which, inclusion of those suspected cases results in the following indicated risk reductions in the Pfizer Vaccine:

i) a relative risk reduction accepted by the Respondents as appropriate of only 18.9%;

ii) an absolute risk reduction with the Pfizer Vaccine of only 1.72%;

iii) number of doses needed to treat or needed to prevent a single case of symptomatic Covid infection of 58 doses.

(2) in the Pfizer Clinical Trial 2714 “suspected Covid-19 cases” were excluded from the calculation:

a) upon the basis of symptoms occurring within 7 days of the injection in the following amounts:

i) 1,185 occurring in the Pfizer Vaccine group; and

ii) 1,529 in the placebo group;

b) undermining the veracity of the efficacy claims, including and particularly the “95% efficacy claim”;

c) but for which, inclusion of those suspected cases results in the following indicated risk reductions in the Pfizer Vaccine:

i) a relative risk reduction accepted by the Respondents as appropriate of only of 22.44%;

ii) an absolute risk reduction with the Pfizer Vaccine of only 1.58%;

iii) number of doses needed to treat or needed to prevent a single case of symptomatic Covid infection of 63 doses.

6 in the circumstances the Respondents must have known that the Known Misleading Pfizer Efficacy Conclusion:

(1) was misleading and not an accurate representation of the actual efficacy of the Pfizer Vaccine against Covid;

(2) did not reflect what the Australian population’s general understanding of what 95% efficacy for the Pfizer Vaccine was;

(3) was obviously indicative of the unacceptably low efficacy rate of the Pfizer Vaccine wherein:

a) the Respondents accepted the exclusion of a number of subjects material to efficacy claims:

i) without question or request for further analysis;

ii) despite the extreme disparity in efficacy displayed as between the relative risk reduction and absolute risk reduction;

iii) in circumstances where in truth those excluded numbers profoundly and exponentially exaggerated the asserted efficacy rate of the Pfizer Vaccine.

b) Pfizer's own study protocol indicated those symptoms as:

i) being indicative of Covid infection;

ii) rendered those subjects to be "suspected" Covid cases without any follow-up testing.

(4) was an unacceptable basis for a claim and conclusion of satisfactory efficacy by the Respondents because:

a) of the matters pleaded in the above sub-paragraphs herein;

b) it was the predominant basis for the:

i) Pfizer Approval;

ii) promotion of the Pfizer Vaccine's efficacy to the entire Australian population.

c) of the intended and consequent public promotion of the 95% efficacy figure;

d) the high potential for reporting bias in the Pfizer Clinical Trial evaluation of Pfizer Vaccine efficacy;

e) the profound disparity between the relative and absolute risk reduction measures of efficacy;

f) the non-disclosure publicly of the absolute-risk reduction rate evident in the Pfizer Clinical Trial in abrogation of TGA guidelines for communicating risks and benefits to the Australian public;

g) the propensity to mislead the Australian public when cited without reference to the way in which they were determined.

Particulars

The Known Misleading Pfizer Efficacy Conclusion was stated in the TGA evaluator's assessment of the Pfizer Clinical Data contained in the Pfizer Original AUSPAR.

The data informing the Respondents was provided to the Secretary on or before November, 2020 in the Pfizer Clinical Trial Data upon which the Known Misleading Pfizer Efficacy Conclusion was based.

KNOWN MISLEADING CONCLUSION OF PFIZER CHILD VACCINE EFFICACY

77. The Respondents knew prior to the Pfizer Child Approval that its conclusion in or about December, 2021 that, based upon the Pfizer Clinal Trial Data, the Pfizer Child Vaccine achieved a demonstrated vaccine efficacy of 90.7% against Covid in children 5 to 11 years of age injected with 2 doses of the Pfizer Child Vaccine **("the Known Misleading Pfizer Child Efficacy Conclusion")** was a misleading interpretation of the actual efficacy of the Pfizer Child Vaccine evident upon the Pfizer Child Clinal Trial Data because:

a) the conclusion was claimed to be based upon the Pfizer Clinical Trial having been conducted upon approximately 4,500 subjects wherein the Known Misleading Pfizer Child Efficacy Conclusion is in fact based upon outcomes reported in only 19 trial participants;

b) the 4,500 subjects were divided approximately into 3000 Pfizer Child Vaccine recipients and 1,500 placebo recipients;

c) of that number only 19 subjects tested positive for Covid and developed mild or greater Covid symptoms being the defined confirmed cases endpoint for the study determined by Pfizer and known to the Respondents;

1 of the “confirmed Covid cases”:

(1) 3 were reported in the Pfizer Vaccine group;

(2) 16 were reported in the placebo group;

2 clinical efficacy of 90.7% was erroneously concluded and determined by applying these two relative numbers to each other as follows:

(1) comparing 3/19 for the Pfizer Vaccine group and 16/19 in the placebo group;

(2) inferring from that the Pfizer Child Vaccine was shown to be 90.7% effective;

3 wherein in fact:

(1) 98.9% of the unvaccinated group in the Pfizer Child Clinical Trial did not develop symptomatic Covid infection;

(2) 99.9% of the Pfizer Child Vaccine group in the Pfizer Child Clinical Trial did not develop symptomatic Covid infection;

(3) there was demonstrated an absolute risk reduction of symptomatic Covid infection of only 1% in the Pfizer Vaccine group;

(4) the absolute risk reduction is the correct measure of protection from symptomatic Covid infection which may only present as

mild symptoms in an uninfected population over the trial surveillance period.

4 in the circumstances the Respondents must have known the Known Misleading Pfizer Child Efficacy Conclusion:

(1) was misleading and not an accurate representation of the actual efficacy of the Pfizer Child Vaccine against Covid;

(2) did not reflect what the Australian population's general understanding of what 90.7% efficacy for the Pfizer Child Vaccine was;

(3) was an unacceptable basis for a claim and conclusion of satisfactory efficacy by the Respondents because:

a) of the matters pleaded at sub-paragraphs a) to c)4(2) herein;

b) it was the predominant basis for the:

i) Pfizer Child Approval;

ii) promotion of the Pfizer Child Vaccine's efficacy the entire Australian population.

c) the intended and consequent public promotion of the 90.7% efficacy figure;

d) the high potential for reporting bias in the Pfizer Child Clinical Trial evaluation of Pfizer Child Vaccine efficacy;

e) the profound disparity between the known relative and absolute risk reduction measures of efficacy;

f) the non-disclosure publicly of the absolute-risk reduction rate evident in the Pfizer Child Clinical

Trial in abrogation of TGA guidelines for communicating risks and benefits to the Australian public;

g) the propensity to mislead the Australian public when cited without reference to the way in which they were determined.

Particulars

The Known Misleading Pfizer Child Efficacy Conclusion was stated in the TGA evaluator's assessment of the Pfizer Clinical Data contained in the Pfizer Child AUSPAR.

The data informing the Respondents was provided to the Secretary on or before December 2021 in the Pfizer Child Clinical Trial upon which the Known Misleading Pfizer Child Efficacy Conclusion was based.

KNOWN MISLEADING CONCLUSION OF MODERNA VACCINE EFFICACY

78. The Respondents knew prior to the Moderna Approval that its conclusion in or about August, 2021 that, based upon the Moderna Clinical Trial Data, the Moderna Vaccine achieved a demonstrated vaccine efficacy of "a robust and highly protective" 94.1% against Covid **("the Known Misleading Moderna Efficacy Conclusion")** was a misleading interpretation of the actual efficacy of the Moderna Vaccine evident upon the Moderna Clinal Trial Data because the Moderna Vaccine data disclosed:

1 there was demonstrated an absolute risk reduction of symptomatic Covid infection of only 1.1% in the Moderna Vaccine group;

2 the absolute risk reduction is the correct measure of protection from symptomatic Covid infection which may only present as mild symptoms in an uninfected population over the trial surveillance period;

3 in the circumstances the Respondents must have known the Known Misleading Moderna Efficacy Conclusion:

(1) was not a true or accurate representation of the actual efficacy of the Moderna Vaccine against Covid;

(2) did not reflect what the Australian population's general understanding of what 94.1% efficacy for the Pfizer Child Vaccine was;

(3) was an unacceptable basis for a claim and conclusion of satisfactory efficacy by the Respondents because:

a) of the matters pleaded at sub-paragraphs 1 to 3(2) herein;

b) it was the predominant basis for the:

i) Moderna Approval;

ii) promotion of the Moderna Vaccine's efficacy the entire Australian population.

c) the intended and consequent public promotion of the 94.1% efficacy figure;

d) the high potential for reporting bias in the Moderna Clinical Trial evaluation of the Moderna Vaccine efficacy;

e) the profound disparity between the known relative and absolute risk reduction measures of efficacy;

f) the non-disclosure publicly of the absolute-risk reduction rate evident in the Moderna Clinical Trial in abrogation of TGA guidelines for communicating risks and benefits to the Australian public;

g) the propensity to mislead the Australian public when cited without reference to the way in which they

were determined.

Particulars

The Known Misleading Moderna Efficacy Conclusion was stated in the TGA evaluator's assessment of the Moderna Clinical Data contained in the Moderna AUSPAR.

The data informing the Respondents was provided to the Secretary on or before August 2021 in the Moderna Clinical Trial Data upon which the Known Misleading Moderna Efficacy Conclusion was based.

KNOWN UNDETERMINED VACCINES RISK-BENEFIT

79. The Respondents knew prior to the Approvals that no proper or reasonable risk-benefit analysis had been undertaken in respect of the Vaccines and that no proper or reasonable conclusion as to a positive risk-benefit profile of the Vaccines had been determined by the Respondents before the Approvals because **("the Known Failure to Determine Vaccine Risk-Benefit")**:

    a) in the Pfizer Clinical Trials and the Moderna Clinical Trials the data demonstrated and the Respondents thereby knew that:

        1 reevaluation of the Pfizer and Moderna Clinical Trial data using "All Cause Severe Morbidity", being the proper scientific endpoint of a clinical trial, as the primary endpoint of the trials, produced a statistically significant increase in All Cause Severe Morbidity in the participants who were vaccinated by the Vaccines over those receiving the placebo;

        2 All Cause Severe Morbidity in both the Vaccine and placebo control groups was defined as all reports of :

            (1) severe infection with Covid; combined with

            (2) all Serious Adverse Events.

3 the scientific conclusion drawn from the direct comparison of All Cause Severe Morbidity between the Vaccine and Placebo group participants, is that the Vaccines:

(1) do more harm than good;

(2) do not provide a health benefit; and

(3) fail any reasonable risk-benefit analysis.

Particulars

The data informing the Respondents was provided to the TGA in November 2020 for the Pfizer Clinical Trial data and on or before August 2021 in the Moderna Clinical Trial Data upon which the Known Failure to Determine Vaccine Risk-Benefit was based.

KNOWN SERIOUS DEATHS EVENTS REPORTING IGNORED

80. In or about January, 2021, and prior to the Approvals, it was known to the Respondents in published data by the Government of Norway provided to the TGA that **("the Norway Data")**:

a) there were 30 fatalities causally related to the Pfizer Vaccine in 40,000 recipient elderly individuals in Norway;

b) the Norwegian Agency subsequently updated guidance for vaccination with Covid vaccines advising that caution and case-by-case judgement should be used when vaccinating frail elderly subjects.

81. In response to the Norway Data the Respondents subsequently determined and publicly stated:

a) that there were no specific risks of vaccination with the Pfizer Vaccine in elderly patients;

b) in the Pfizer Product Information for health care professionals, the following advice:

1 the data for use in the frail elderly greater than 85 years of age is limited;

2 the potential benefits of vaccination with the Pfizer Vaccine as compared to the potential risk and clinical impact of even relatively mild systemic adverse events in the frail elderly should be carefully assessed on a case-by-case basis.

3 in circumstances wherein:

(1) the Pfizer Product Information contains:

a) no comment on the Norway Data or any deaths in the PI summary (section 4.8 Adverse effects);

b) death or renal failure is not listed as adverse events;

c) the special warning suggests that there is lack of data in elderly:

i) but does not report the fact that there were reports of deaths; and

ii) for that reason caution in the elderly was needed, which is misleading to a prescriber reading the statements.

Particulars

"Investigation reveals no specific risk of COVID-19 vaccinations in elderly patients". 2 February, 2021. https://www.tga.gov.au/news/media-releases/investigation-reveals-no-specific-risk-covid-19-vaccinations-elderly-patients#:~:text=The%20TGA%20has%20concluded%20that,19%20vaccine%20in%20elderly%20patients.&text=On%2014%20January%202021%20the,with%20the%20Pfizer%20BioNTech%20vaccine.

"Australian Product Information – Comirnaty Covid-19 Vaccine". https://www.tga.gov.au/sites/default/files/auspar-bnt162b2-mrna-210125-pi.pdf

KNOWN PFIZER CLINICAL DATA DANGERS, LACK OF EFFICACY AND BENEFIT – FDA COMMENTARY

82. Prior to the Approvals, the Respondents knew of the following matters evidencing significant safety and efficacy issues with the Pfizer Vaccine revealed in the Pfizer Clinical Data and provided to the Respondents in a review of the safety data and conclusions authored by the FDA in respect of the Pfizer Vaccine, contained in a briefing document dated December, 2020 **("the FDA Briefing Document")**, relied upon by the Respondents in granting the Pfizer Approval **("the Known Pfizer Vaccine Efficacy and Safety Issues – FDA Analysis")**:

a) 2 Pfizer Vaccine participants died during the Pfizer Clinical Trial reporting period from April 29, 2020 (first participant, first visit) to November 14, 2020 (cut-off date) wherein it was reported that:

1 one experienced a cardiac arrest 62 days after vaccination #2 and died 3 days later;

2 one died from arteriosclerosis 3 days after vaccination #1;

3 wherein:

(1) the FDA erroneously concluded the deaths to be of no concern because those deaths represent events that occur in the general population of the age groups where they occurred, at a similar rate;

(2) these events occurred after the vaccination, therefore by definition, when there was no more likely explanation (and noting that exclusion criteria for the trial included severe or uncontrolled chronic disease):

a) the events are at least possibly causal;

b) no further details on these events has been provided;

c) each is dismissed merely on the basis that the rate is in accordance with background death rates which in isolation is no basis to dismiss causality.

b) among 3410 total cases of suspected but unconfirmed Covid in the overall study population:

1 1594 occurred in the Pfizer Vaccine group of which 409 occurred within 7 days of vaccination;

2 1816 in the placebo group of which 209 occurred within 7 days of vaccination;

3 evidencing negligible efficacy in the Pfizer Vaccine;

4 wherein:

(1) the FDA erroneously concluded that in respect of the data relating to the occurrence of suspected unconfirmed Covid cases in the study population, the CDC determined that:

a) it was possible that the imbalance as between the Pfizer Vaccine group and the placebo group in suspected COVID-19 cases occurring in the 7 days postvaccination represents:

i) vaccine reactogenicity;

ii) symptoms that overlap with those of COVID-19;

b) the data imbalance did not raise a concern that the reporting of those suspected but unconfirmed Covid cases could have masked clinically significant adverse events that would not have otherwise been

detected.

(2) the data in truth presented clinical evidence of at least possible Vaccine-Associated Enhanced Respiratory Disease (VAERD);

(3) the FDA's conclusions had no logical, reasonable or scientific basis in the data;

(4) a reasonable analysis would determine that the imbalance of post vaccination reactogenic symptoms separated by definition as 'likely but not PCR confirmed COVID-19 cases' must raise a concern.

c) in respect of the safety of the Pfizer Vaccine it was reported that severe adverse reactions:

1 occurred in up to 4.6% of participants;

2 a Serious Adverse Event being and event that **("Serious Adverse Events")**:

(1) results in death;

(2) is life-threatening;

(3) requires inpatient hospitalisation;

(4) prolongs existing hospitalisation;

(5) results in persistent or significant disability or incapacity, including permanent impairment of a body function or permanent damage to a body structure;

(6) necessitates medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure;

(7) is a congenital anomaly or birth defect;

(8) makes one of the above more likely, or that requires intervention to prevent one of these outcomes.

3 were more frequent after Dose 2 than after Dose 1;

4 by age of the patient, occurred in:

(1) adults 55 years of age or older at a frequency of up to 2.8%;

(2) those under 55 years of age at a frequency of up to 4.6%.

5 wherein:

(1) events occurring more frequently after dose 2 (which could be considered a 'rechallenge' by causality assessment criteria) is indicative of likely causality;

(2) the rate of Serious Adverse Events is very high, up to 4.6%;

(3) there was a tendency for higher rates in younger persons;

(4) the clear risk of a Serious Adverse Event from the Pfizer Vaccine is significantly higher than the risk of a Serious Adverse Event from Covid infection thereby presenting a negative risk-benefit analysis at least in those aged under 55 years.

d) adverse events of special interest which occurred and determined to be possibly related to the Pfizer Vaccine were:

1 lymphadenopathy which was reported in:

(1) 0.3% of total recipients of the Pfizer Vaccine;

(2) 0.5% in the younger 16 to 55 years age group recipients of the Pfizer Vaccine;

(3) 0.1% in the older over 55 years age group recipients of the

Pfizer Vaccine; and

(4) 0.037% in the total placebo group.

2 Bell's Palsy which was reported:

(1) in four of the Pfizer Vaccine group;

(2) from Dose 1 through 1 month after Dose 2, there were three reports of Bell's palsy in the Pfizer Vaccine group;

(3) in none in the placebo group;

3 erroneously determined by the FDA to:

(1) have occurred at a frequency consistent with the expected background rate in the general population; and

a) thereby:

i) possessing a less certain causal relationship because:

1. the number of cases was small; and

2. not more frequent than expected in the general population.

ii) of no concern;

iii) not a bar to approval without further inquiry.

4 wherein:

(1) the FDA reference to a background rate of a condition is

reported as evidence against causality is false;

(2) no proper assessment of causality is provided;

(3) no further data on the background rate is provided;

(4) in truth in any case the reported rate of Bell's Palsy exponentially exceeds the true background rate because:

a) given that the events occurred in a one month period, the background rate for this number of events would not be expected to be this high based on true background population rates which are generally known to be 15-30 incidences per 100,000 per year;

b) in the Pfizer Clinical Study Bell's Palsy occurred at a rate of 4 per 43,448 in one month which equates to:

i) 110 cases per 100,000 persons per year;

ii) 3.7 times to 7.4 times the background rate in general population.

e) adverse reactions in the Pfizer Vaccine group occurred as follows with the following extremely high frequency:

1 injection site reactions (84.1%);

2 fatigue (62.9%);

3 headache (55.1%);

4 muscle pain (38.3%);

5 chills (31.9%);

6 joint pain (23.6%);

7 fever (14.2%);

f) in respect of the Pfizer Study resultant unknown risks and data gaps in certain subpopulations it was concluded by the FDA that:

1 there was insufficient data to make conclusions about the safety of the vaccine in subpopulations including:

(1) children less than 16 years of age;

(2) pregnant and lactating women; and

(3) immunocompromised individuals.

g) a numerically greater number of appendicitis cases occurred in the Pfizer Vaccine group but:

1 occurred no more frequently than expected background rate in the given age groups;

2 it was determined for that reason by the FDA similarly and erroneously:

(1) not to establish a causal relationship;

(2) not to raise a clear concern.

h) the FDA concluded that the risk of vaccine-enhanced disease over time:

1 remained unknown at that time;

2 was potentially associated with waning immunity;

3 needed to be evaluated further in:

(1) ongoing clinical trials; and

(2) observational studies conducted following authorization and/or licensure;

i) the conclusions evident in the FDA Briefing Document relied upon by the Respondents in granting the Pfizer Approval:

1 erroneously relied consistently upon the use of background rates and small study sizes to:

(1) dismiss adverse event causality;

(2) reject the need for further consideration of causality of adverse events;

(3) dismiss concern as to those reported adverse events.

2 were based in part upon obviously false premises;

3 were obviously erroneous.

j) contained data in respect of the Pfizer Vaccine which brought into obvious doubt the Pfizer Vaccine's:

1 safety;

2 efficacy;

3 positive risk-benefit assessment.

k) was relied upon by the Respondents as a basis for the Pfizer Approval by:

1 relying upon and adopting the obviously erroneous assumptions contained therein;

2 failing to apply any proper critical or scientific analysis to the conclusions and data contained therein.

Particulars

The Known Pfizer Vaccine Dangers – FDA Analysis were published to the Respondents in the document being the FDA Briefing Document as follows: “Vaccines and Related Biological Products Advisory Committee Meeting. December 10, 2020. FDA Briefing Document” - Pfizer-BioNTech COVID-19 Vaccine. Sponsor: Pfizer and BioNTech. https://www.fda.gov/media/144245/download pg. 41 – 43 and pg. 48-49

The rate of Bell’s Palsy in the world population is evident in studies including for example:

1. “Bell's Palsy: A Prospective Study”. Mustafa A, Suleiman A. 2020. Int J Dent. 2160256. https://pubmed.ncbi.nlm.nih.gov/32256592/

2. "Familial idiopathic facial palsy". Döner F, Kutluhan S 2000. European Archives of Oto-Rhino-Laryngology. 257 (3): 117–19.

3. "Annualized incidence and spectrum of illness from an outbreak investigation of Bell's palsy".Morris, AM et al. 2002. Neuroepidemiology. 21 (5): 255–61.

KNOWN SAFETY AND RISK-BENEFIT ISSUES – PFIZER CLINICAL TRIAL DATA

83. From prior to, on or about 25 January, 2021, and prior to the Pfizer Approval, the Respondents knew of the following matters evidencing significant safety and risk-benefit issues in respect of the Pfizer Vaccine arising in the Pfizer Clinical Trial disclosed in the totality of data relied upon by the Respondents in granting the AstraZeneca Approval:

a) Lymphadenopathy was reported as an adverse event:

1 in 64 participants or 0.3% of the Pfizer Vaccine group:

(1) comprised of:

a) 54 participants in the younger age group; and

b) 10 in the older age group;

(2) at a rate of more than 10 times more than the placebo group having 6 reports;

(3) 73% of which were determined by the Respondents' investigator to be causally related to the Pfizer Vaccine;

(4) with a mean duration of 10 days;

(5) 12 of which were ongoing at the time of the data cut-off date;

(6) reported in most instances within 2 to 4 days after vaccination;

b) Hypersensitivity was reported as an adverse event in:

1 two cases in the Pfizer Vaccine Group; and

2 one case in the placebo group.

c) Drug Hypersensitivity was reported as an adverse event:

1 in six cases in the Pfizer Vaccine Group;

2 in one case in the placebo group;

3 causing the Respondents to determine and assert that post-market monitoring for hypersensitivity events should be conducted.

d) Bell's Palsy was reported as an adverse event in:

1 four cases in the Pfizer Vaccine Group; and

2 none in the placebo group.

e) Serious Adverse Events were reported and found by the Respondents to be causally related to the Pfizer Vaccine in:

1 3 of the Pfizer Vaccine group to the Pfizer Vaccine, which involved:

(1) shoulder injury related to vaccine administration;

(2) ventricular arrhythmia; and

(3) lymphadenopathy;

(4) none of the placebo group.

f) 12 cases of appendicitis were reported comprised of:

1 8 in the Pfizer Vaccine Group; and

2 4 in the placebo group;

3 all of which were assessed by Pfizer and accepted and adopted by the Respondents as unrelated to the Pfizer Vaccine:

(1) based upon the sole fact that the number of events were purportedly not greater than expected based on estimated background rates;

(2) contrary to the Respondents' adopted and established methodologies of causality assessment being the:

a) Naranjo Scale; and

b) WHO Causality Assessment for Adverse Events.

g) 1 other event of lower back pain and bilateral lower extremity pain with radicular paraesthesia:

1 in the Pfizer Vaccine group;

2 in the younger age subgroup (18 to 55 years of age); and

3 assessed by the Respondents investigator as related to the Pfizer Vaccine.

h) withdrawals from the study of trial participants due to Severe Adverse Events, Serious Adverse Events or Adverse Events were characterised as "few" and reported as:

1 <1.2% for Severe Adverse Events;

(1) or <521 persons;

2 <0.5% for Serious Adverse Events;

(1) or <217 persons;

3 <0.2% for Adverse Events;

(1) or <86 persons;

a) the adverse events were so significant as to in every instance lead to withdrawal of the participant from the study;

b) no detail is provided for whether these participants belonged to the Pfizer Vaccine or Placebo groups;

i) despite the Respondents knowing that such information would be critical to forming an accurate risk-benefit assessment of the Pfizer Vaccine.

c) the characterisation of the data is misleading as to the known and true incidence of Adverse Events in the Pfizer Vaccine group compared to the placebo group such that:

i) it coalesces the incidence of Adverse Events in the Pfizer Vaccine group with the Placebo group;

ii) the true distribution of the Adverse Events between study groups has been obfuscated;

iii) it is possible that the occurrence of Adverse Events reported may have been entirely in the Pfizer Vaccine group;

iv) the characterisation of those events as "few" is obviously false.

d) the data disclosed clearly indicates a high incidence of Adverse Events leading to withdrawal of participants from the study.

Particulars

The Pfizer Original AUSPAR. Pages 28, 29.

KNOWN SAFETY AND RISK-BENEFIT ISSUES – MODERNA CLINICAL TRIAL DATA

84. By on or about August, 2021 and prior to the Moderna Approval, the Respondents knew of the following matters evidencing significant safety and risk-benefit matters in respect of the Moderna Vaccine disclosed in the Moderna Clinical Data relied upon by the Respondents in granting the Moderna Approval **("the Known Moderna Clinical Studies Issues")**:

a) the data from the Moderna Clinical Trial disclosed to the Respondents prior to the Moderna Approval that those in the Australian population receiving the Moderna Vaccine, including the risk of a Serious Adverse Event arising from Covid infection:

1 were at a significantly higher risk of a Serious Adverse Event:

(1) than those whom did not receive the Moderna Vaccine;

(2) being an excess risk of 15.1 per 10,000 vaccinated;

2 were at a risk of Serious Adverse Event of at least 1 in 662.

Particulars

The Moderna Clinical Data from the Moderna Clinical Trial upon which the Respondents relied upon in granting the Moderna Approval provided to the Respondents from prior to August, 2021 and prior to the Moderna Approval.

The knowledge of the Moderna Clinical Data and the conclusions of the Respondents pleaded are evident in the Moderna Clinical Data having been provided to the Respondents in connection with the Moderna Approval application and further references to that data in the Moderna AUSPAR.

KNOWN SAFETY AND RISK-BENEFIT ISSUES – ASTRAZENECA CLINICAL TRIAL DATA

85. By on or about 28 January, 2021 and prior to the AstraZeneca Approval, the Respondents knew of the following matters evidencing significant safety, efficacy and risk-benefit matters in respect of the AstraZeneca Approval Vaccine disclosed in the AstraZeneca Clinical Data relied upon by the Respondents in granting the AstraZeneca Approval **("the Known AstraZeneca Clinical Studies Issues")**:

a) the AstraZeneca Trial Data disclosed that sudden adverse events arising in the AstraZeneca Vaccine group were:

1 one case of Multiple Sclerosis;

2 one case of transverse myelitis;

3 each of which was highly likely to have been related to the AstraZeneca Vaccine;

4 following which the Respondents and prior to the AstraZeneca Approval:

(1) determined that each was unlikely to be related to AstraZeneca Vaccine:

a) based entirely upon a bare assertion of AstraZeneca to that effect;

b) without the benefit of patient level data;

c) without further request for information or investigation of causality by the Respondents;

(2) should have cautiously examined each event before the AstraZeneca Approval;

(3) failed to truly determine the causality or significance of those adverse events.

Particulars

The AstraZeneca Clinical Data from the AstraZeneca Clinical Trial upon which the Respondents relied upon in granting the AstraZeneca Approval provided to the Respondents from prior to January, 2021 and prior to the AstraZeneca Approval.

The knowledge of the AstraZeneca Clinical Data and the conclusions of the Respondents pleaded are evident in the AstraZeneca Clinical Data having been provided to the Respondents in connection with the AstraZeneca Approval application and further references to that data in the following TGA Respondent produced documents:

1. the AstraZeneca Original AUSPAR;

2. the AstraZeneca Clinical Evaluation Report;

3. the ACV AstraZeneca Minutes;

4. the AstraZeneca Delegate's Overview.

KNOWN DEFECTIVE DATA IN APPROVING THE PFIZER BIVALENT VACCINE

86. Before 27 October, 2022 and prior to the Pfizer Bivalent Approval, the Respondents knew of the following matters relating to the Pfizer Bivalent Vaccine **("the Known Defective Pfizer Bivalent Data")**:

a) on or about 27 October 2022, the TGA provisionally approved the Pfizer (Comirnaty) Bivalent Original/Omicron BA.1 vaccine **("the Pfizer Bivalent Vaccine")** for use as a booster COVID-19 vaccine in people aged 18 years and older;

b) ATAGI conducted an evaluation of the immunogenicity, efficacy, and safety data on this Pfizer Bivalent Vaccine;

c) the Pfizer Bivalent Vaccine was known by the Respondents from before 27 October, 2022 and prior to the Pfizer Bivalent Approval:

1 to be 30% effective in preventing Covid infection during the time when the virus strains dominant in the community were represented in the vaccine;

2 to contain antigens represented in the original vaccine as well as antigens representing the BA.4/BA.5 lineages of the Omicron variant;

3 to have been determined for approval by the Respondents without any demonstration of effectiveness in clinical studies;

4 to have no data on the immunogenicity or safety of the Pfizer bivalent vaccine in people under 55 years of age;

5 to have evidence supporting its use limited to:

(1) immunogenicity and safety data from the C4591031 trial (substudy E) at 4 weeks after a second booster dose (fourth dose);

(2) participants aged >55 years received Pfizer bivalent vaccine as their second booster dose, 5 to 12 months following a Pfizer original primary course and Pfizer original first booster dose against the Omicron BA.1 variant;

6 was tested only in people without prior infection even though:

(1) a CDC study had estimated at that time that 64% of 18-64 year old persons and 75% of all adults as at February 2022 had antibodies indicating prior infection with Covid;

(2) people without prior infection were a minority;

(3) inclusion of those individuals with prior infection would likely produce different results to those reported.

7 wherein the Pfizer Bivalent Vaccine was approved by the Respondents for use as a booster in everyone aged 18 years and over despite:

(1) the only clinical trial the Respondents based their approval on was 4 weeks of data of participants aged 55 years and older who received their 4th dose of Pfizer vaccine;

(2) trial participants being already vaccinated with the Pfizer Vaccine 3 times wherein the trial:

a) compared the fourth dose of the bivalent Pfizer Vaccine to a fourth dose with the original Pfizer Vaccine;

b) had no unvaccinated control group;

(3) ATAGI having determined that it was inappropriate to approve this vaccine as a booster in people less than 55 years of age where no data for this age group existed.

Particulars

The basis for knowledge contained in the Known Defective Pfizer Bivalent Data arises by the ATAGI Statement - ATAGI recommendations on use of the Pfizer bivalent (Original/Omicron BA.1) COVID-19 vaccine Recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) the Pfizer bivalent (Original/Omicron BA.1) COVID-19 vaccine. Dated 14 Nov 2022 regarding Pfizer bivalent vaccine. https://www.health.gov.au/news/atagi-recommendations-on-use-of-the-pfizer-bivalent-originalomicron-ba1-covid-19-vaccine. https://www.cdc.gov/mmwr/volumes/71/wr/mm7117e3.htm

KNOWN DEFECTIVE PFIZER STUDY PROTOCOL

87. Before the Pfizer Approval, the Respondents knew of the following deficiencies relating to the trial protocols adopted and utilised by Pfizer in undertaking the Clinical Pfizer Study **("the Pfizer Clinical Trial Protocol")** upon which the Respondents relied in granting the Pfizer Approval **("the Known Pfizer Study Protocol Deficiencies")**:

    a) the Pfizer Study Protocol accepted by the TGA prior to the Pfizer Approval stated in respect of the stopping rule criteria for participants in the studies as **("the Pfizer Study Stopping Rules")**:

        1 the participation of the person in question in the study would be ended if:

            (1) any participant vaccinated with the Pfizer Vaccine, at any dose level, develops a Serious Adverse Event which is assessed by the investigator as:

                a) possibly related to the Pfizer Vaccine; or

                b) there is no alternative, plausible, attributable cause other than such event being related to the Pfizer Vaccine.

(2) any participant vaccinated with the Pfizer Vaccine, at any dose level, develops a Grade 4 local reaction or systemic event after vaccination which is assessed by the investigator as:

a) possibly related to the Pfizer Vaccine; or

b) there is no alternative, plausible, attributable cause other than such event being related to the Pfizer Vaccine.

(3) any participant vaccinated with the Pfizer Vaccine, at any dose level, develops a fever greater than 40.0°C (104.0°F) for at least 1 daily measurement after vaccination which is assessed by the investigator as:

a) possibly related to the Pfizer Vaccine; or

b) there is no alternative, plausible, attributable cause other than such event being related to the Pfizer Vaccine.

(4) any 2 participants vaccinated with the Pfizer Vaccine, at any dose level, report the same or similar severe (Grade 3) Adverse Events (including laboratory abnormalities) after vaccination which is assessed by the investigator as:

a) possibly related to the Pfizer Vaccine; or

b) there is no alternative, plausible, attributable cause other than such event being related to the Pfizer Vaccine.

(5) any participant dies or requires ICU admission due to SARS-CoV-2 infection;

b) the Pfizer Study Stopping Rules were defective and known by the Respondents to be defective because they prevented conclusions or data substantiating the Pfizer Vaccine's:

1 efficacy in preventing death in Covid infected patients;

2 efficacy in preventing serious disease in Covid infected patients;

3 efficacy in preventing Covid infection;

4 efficacy in preventing transmission of the Virus.

Particulars

The Pfizer Clinical Trial Protocol. Pg. 63-65 and s. 8.2.2.

KNOWN WHO DECLARED NATURAL IMMUNITY FROM COVID IN THE AUSTRALIAN POPULATION

88. The Respondents knew of the following factual matters declared by the World Health Organisation in relation to the natural immunity to Covid in the Australian population prior to the Approvals **("the Known Pre-Approval Natural Immunity from Covid")**:

a) as to natural immunity from Covid in humans:

1 numerous studies demonstrate that a proportion of the population have some level of cross-reactive immunity to Covid without ever having been infected by the virus seen in 40-60% of the population;

2 neutralizing antibodies to Covid are stably produced in the naturally immune person after infection for 6-7 months after infection, even in patients who had mild symptoms.

3 most individuals develop strong protective immune responses following natural infection with the Virus;

4 natural infection provides similar protection against symptomatic disease as vaccination, at least for the available follow up period;

b) and in fact had not, given any reasonable consideration at all to the Known Pre-Approval Natural Immunity from Covid in:

1 any risk-benefit analysis of the Vaccines;

2 any analysis or determination as to the need or benefit of the Vaccines in the Australian Population;

3 any risk determination in relation to Covid as compared to the Vaccines;

4 granting the Approvals.

Particulars

The following paper containing the factual matters relating to natural immunity were published to and known to the Respondents prior to the Approvals as follows: World Health Organisation - SAGE Working Group on COVID-19 Vaccines – dated 22 December 2020. Background paper on Covid-19 disease and vaccines. Prepared by the Strategic Advisory Group of Experts (SAGE) on Immunization Working Group on COVID-19 vaccines **("the WHO Background Paper")**. Pg. 8.

KNOWN WHO POTENTIAL EFFECTIVENESS OF COVID VACCINES

89. The Respondents knew of the following factual matters declared by the World Health Organisation in relation to the potential effectiveness of Covid vaccines including the Vaccines **("the Known WHO Potential Effectiveness of Covid Vaccines")**:

a) as to the potential effectiveness of Covid vaccines including the Vaccines:

1 the potential for vaccination to eliminate Covid from any population depends upon a vaccine's effectiveness against infection and virus shedding;

2 at that time, effectiveness against infection and virus shedding were unknown;

b) the Respondents at the time of the Approvals:

1 knew that:

(1) no data provided by the Sponsors allowed any determination as to whether the Vaccines could or would:

a) prevent infection with Covid;

b) prevent shedding of the Virus;

(2) the ability of the Vaccines to prevent infection with Covid or shedding of the Virus was unknown;

2 had not, given any reasonable consideration at all to the Known WHO Potential Effectiveness of Covid Vaccines in:

(1) any risk-benefit analysis of the Vaccines;

(2) any analysis or determination as to the need or benefit of the Vaccines in the Australian Population;

(3) any risk determination in relation to Covid as compared to the Vaccines;

3 granting the Approvals.

Particulars

The WHO Background Paper, Page 15

KNOWN WHO PANDEMIC CONTROL PRINCIPLE

90. TGA Respondents knew of the following factual matters declared by the World Health Organisation in relation to the mechanism by which a vaccine, including the Vaccines, would control Covid and end the Covid Pandemic **("the Known WHO Means to Control Covid")**:

a) as to the mechanism by which a vaccine, including the Vaccines, would

control Covid and end the Covid Pandemic, the World Health Organisation's overarching goal in addressing the Covid Pandemic was to control Covid by:

1 slowing down transmission of the Virus; and

2 preventing associated illness and death.

b) the Respondents at the time of the Approvals:

1 knew that:

(1) no data provided by the Sponsors allowed any determination as to whether the Vaccines could or would:

a) prevent infection with Covid;

b) prevent transmission of the Virus;

c) prevent serious illness from Covid infection;

d) prevent death from Covid.

(2) the ability of the Vaccines to prevent infection with Covid, transmission of the Virus, serious illness from Covid infection or death from Covid, at the time of the Approvals, was unknown;

2 had not given any reasonable consideration at all to the Known WHO Means to Control Covid in:

(1) any risk-benefit analysis of the Vaccines;

(2) any analysis or determination as to the need or benefit of the Vaccines in the Australian Population;

(3) any risk determination in relation to Covid as compared to the Vaccines;

(4) granting the Approvals.

Particulars

The WHO Background Paper - Page 7.

KNOWN RISK-BENEFIT RISKS

91. The Respondents knew at all material times prior to the Approvals that the Vaccines have the following unique features which require vaccines to have a highly favourable risk-benefit profile **("the Vaccines Risk-Benefit Profile")**:

a) the Vaccines engaged novel therapies and ingredients:

1 never before tested for use or used:

(1) in humans;

(2) in a mass vaccination program.

2 possessing of unknown effects in the human body.

b) the Vaccines were intended to be and were in fact administered to large populations of healthy subjects, including children;

c) the Vaccines were liable to be and in fact were introduced by health authorities as mandatory in certain settings including workplaces;

d) there was a known significant excess risk of Serious Adverse Events arising in the use of the mRNA Vaccines being the Known Vaccines Excess Risk Data;

e) there was no release of participant - level datasets by the Vaccine Sponsors to the Respondents prior to the Approvals;

f) there was a statutory, policy, and scientific requirement for the Respondents to:

1 perform an appropriate risk-benefit analysis of the Vaccines prior to the Approvals;

2 identify that the Vaccines' benefits needed to substantially exceed its risks before the Approvals;

3 obtain an appropriately high positive risk-benefit profile for each of the Vaccines:

(1) before granting the Approvals;

(2) stratified according to the actual risk of serious Covid outcomes for each of those classes of persons.

Particulars

The Respondents were aware of these matters by reason of having obtained the data and concomitant conclusions pleaded and particularly in the Known Vaccines Excess Risk Data and the Respondents having received the entirety of the data upon which the Sponsors relied in seeking and the Respondents in granting the Approvals.

KNOWN EXCESS RISK – PFIZER AND MODERNA CLINICAL TRIALS

92. The following factual matters disclosing the material excess risks of taking the Pfizer and Moderna Vaccines were known to the Respondents prior to the Approvals arising from the Clinical Trials conducted in respect of the Pfizer Vaccine and the Moderna Vaccines **("the Known Vaccines Excess Risk Data")**:

a) as to the mRNA Phase 3 Vaccine Trials:

1 Pfizer and Moderna each undertook prior to the Approvals a single phase III randomized trial to accumulate data and advance conclusions;

2 submitted the data and conclusion results of these single phase III randomized trials to the TGA in support of the Approvals;

3 the trials were expected to monitor participants for two years;

4 reported data to the TGA at the time of the declared cut-off date being:

(1) 14 November 2020 for the Pfizer Phase 3 Trial;

(2) 25 November 2020 for Moderna Phase 3 Trial.

b) Serious Adverse Events were evident in the placebo-controlled, phase III randomized clinical trials and consequent data provided to the TGA of the Vaccines utilising mRNA mechanism, being the Pfizer Vaccine and the Moderna Vaccine **("the mRNA Vaccines")**:

1 being the Phase 3 Trial for **("the mRNA Vaccine Trials")**:

(1) the Pfizer Vaccine, being study C451001 **("the Pfizer Phase 3 Trial")**;

(2) the Moderna Vaccine, being study mRNA-1273-P301 **("the Moderna Phase 3 Trial")**.

2 made evident by application of the internationally accepted standard of Brighton Collaboration adverse events of special interest;

c) the data contained within the mRNA Vaccine Trials disclosed to the Respondents the following conclusive facts based upon that data ("**the mRNA Vaccine Trial Data")**:

1 Serious Adverse Events of special interest in:

(1) the Pfizer Phase 3 Trial disclosing an excess risk of 10.1 per 10,000 Pfizer Vaccine recipients over placebo baselines of 17.6;

(2) the Moderna Phase 3 Trial disclosing an excess risk of 15.1 per 10,000 Moderna Vaccine recipients over placebo baselines of 42.2;

2 the mRNA Vaccines were associated with an excess risk of Serious Adverse Events of special interest of:

(1) 12.5 per 10,000 mRNA Vaccines recipients; and

(2) a risk ratio of 1.43.

d) the Pfizer Phase 3 Trial data disclosed to the Respondents that for those taking the Pfizer Vaccine:

1 as to Serious Adverse Events:

(1) a 36% higher risk of Serious Adverse Events than the unvaccinated group, wherein a Serious Adverse Event **("Serious Adverse Event")**:

a) relates to an event or occurrence that led to a death or serious deterioration in the state of health of the person;

b) is an adverse event for which one or more of the following is true for the person:

i) results in death;

ii) is life-threatening;

iii) requires inpatient hospitalisation;

iv) prolongs existing hospitalisation;

v) results in persistent or significant disability or incapacity, including permanent impairment of a body function

or permanent damage to a body structure;

vi) necessitates medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure;

vii) is a congenital anomaly or birth defect;

viii) is a medically important event:

1. that make one of the outcomes above more likely, or that require intervention to prevent one of these outcomes; or

2. that require intensive treatment in an emergency department or at home but do not result in hospitalisation, such as allergic bronchospasm, a blood disorder or convulsions.

(2) a risk excess of a Serious Adverse Event of 18 per 10,000 in those receiving the Pfizer Vaccine; and

(3) a risk ratio of 1.36 of a Serious Adverse Event in those receiving the Pfizer Vaccine;

2 in respect of the occurrence of multiple Serious Adverse Events in recipients of the Pfizer Vaccine:

(1) a 84.6% higher number than the placebo group;

(2) 24 multiple cases as compared to 13 in the placebo group.

3 a statistically significant greater number of cardiovascular Adverse Events of Special Interest occurring in those receiving the Pfizer Vaccine than in the placebo group;

4 as to related Serious Adverse Events of Special Interest **("Serious AESI")**:

(1) a 57% higher risk of Serious AESI wherein a Serious AESI is a Serious Adverse Event that:

a) is a pre-defined medically-significant event that may be causally connected to the vaccine; and

b) must be carefully monitored.

(2) an incidence of 27.7 Serious AESI per 10,000 reported in the Pfizer Vaccine recipients as against 17.6 per 10,000 in the placebo group; and

(3) a risk difference of 10.1 Serious AESI per 10,000 Pfizer Vaccine recipients.

e) the Moderna Phase 3 Trial data disclosed to the Respondents that for those taking the Moderna Vaccine:

1 as to Serious Adverse Events there was:

(1) a 6% higher risk of a Serious Adverse Event in the Moderna Vaccine recipients than the unvaccinated group;

(2) a risk excess of a Serious Adverse Event of 7.1 per 10,000 in the Moderna Vaccine recipients; and

(3) a risk ratio of 1.06 of a Serious Adverse Event in the vaccinated.

2 as to Adverse Events of Special Interest:

(1) a 36% higher risk of Serious AESI in Moderna Vaccine recipients over the placebo group;

(2) an incidence of 57.3 AESI per 10,000 reported in the Moderna Vaccine recipients as against 42.2 per 10,000 in the placebo group; and

(3) a risk difference of 15.1 of Serious AESI per 10,000 Moderna Vaccine recipients.

f) the combined mRNA Vaccine Trials disclosed to the Respondents that for those taking either of the mRNA Vaccines:

1 as to Serious Adverse Events:

(1) there was a 16% higher risk of a Serious Adverse Event in mRNA Vaccines recipients than the placebo group;

(2) a risk excess of a Serious Adverse Event of 13.2 per 10,000 mRNA Vaccine recipients; and

(3) a risk ratio of 1.16 of a Serious Adverse Event in the mRNA Vaccine recipients.

2 as to Serious AESI's:

(1) a 43% higher risk of Serious AESI in the mRNA Vaccine recipients;

(2) a risk difference of 12.5 AESI per 10,000 mRNA Vaccine recipients;

(3) of the 236 Serious AESIs occurring across the combined mRNA Vaccine Trials:

a) 230 out of 236 (97%) were adverse event types included as AESIs because they are seen in Covid infected persons;

b) the largest excess risk occurred amongst the AESI Category of coagulation or clotting disorders.

Particulars

The TGA was provided and considered and thereby the Respondents had reasonable access to and knew of the contents of the following study documents in the course of and prior to the Approvals:

1. The Pfizer Clinical Trial; and
2. The Moderna Clinical Trial.

The above clinical trials are referenced by the TGA as the source of the data relied upon in The Pfizer Original AUSPAR and
The Moderna Original AUSPAR.

The Commonwealth, the Secretary, the TGA and Skerritt advanced upon such data in providing the Approvals to the mRNA Vaccines.

The Brighton Collaboration is known and accepted internationally as a standard for the classification of AESI's.
https://brightoncollaboration.us/

KNOWN FALSE RISK-BENEFIT PRESUMPTIONS – PFIZER VACCINE

86. From prior to or about 21 January, 2021 and prior to the Pfizer Approval, the Respondents proceeded to undertake the following in respect of assumptions in the risk-benefit analysis of the Pfizer Vaccine purportedly disclosed in the Pfizer Nonclinical Trials and the Pfizer Clinical Trial data relied upon by the Respondents in granting the Pfizer Approval **("the Known Pfizer Clinical & Nonclinical Trial Data Issues")**:

a) in undertaking a purported risk-benefit analysis in respect of the Pfizer Vaccines, the Respondents assert that at that time the following matters considered to be indicative of a proper risk-benefit analysis having been undertaken by the Respondents in arriving at a favourable risk-benefit

determination in respect of the Pfizer Vaccine **("the TGA Asserted Risk Benefit Considerations")**:

1 that there was an unmet public health need in respect of Covid, being:

(1) a safe and effective Covid vaccine;

2 that the incidence rate of Covid in Australia was better than other countries;

3 that life for Australians was far from the normal life Australians led pre-Covid including travel restrictions and border closures and that these have been having a negative impact on the daily life of Australians;

4 Covid outbreaks had been occurring frequently;

5 a safe and effective vaccine is one of the important tools in the fight against the Covid pandemic;

6 no Covid vaccine was currently registered in Australia.

b) the TGA Asserted Risk Benefit Considerations and TGA Respondents determination of a favourable risk benefit profile for the Pfizer Vaccine were made by the Respondents in circumstances of the following false assumptions, wherein the Respondents either knew or were recklessly indifferent as to their falsity **("the TGA Known False Risk Benefit Assumptions")**:

1 the Pfizer Vaccine was proven to be safe and effective;

2 that a vaccine was the only known available means by which Covid could and must be addressed;

3 that there were no known alternatives to vaccination in the treatment and mitigation of Covid infection;

4 that the Pfizer Vaccine had established in the Pfizer Trial data that it would prevent Covid:

(1) infection;

(2) severe symptoms; and

(3) death.

5 that the loss of "normal life" and negative effects associated with the Covid pandemic was:

(1) a function of direct effect of Covid; and

(2) not solely a function of the implementation of mitigation measures made without scientific basis or positive effect.

6 that Covid infection would be so obviously injurious to the Australian population that the mass injection of the Australian population with a never-before-used therapy of unknown long term effects was an obvious benefit and necessity.

Particulars

The full extent on the data relied upon by the Respondents in granting the Pfizer Approval will be particularised upon further discovery.

The Pfizer AUSPAR. Pg. 33-35.

KNOWN RISK-BENEFIT ANALYSIS FAILURE AND EVIDENT VACCINES RISK-BENEFIT NEGATIVE PROFILE

87. Prior to the Approvals, the Respondents at all material times knew of the following factual matters in respect of the obligations to conduct risk-benefit analysis in respect of the Vaccines before the Approvals and the actual risk benefit profile of the Vaccines evident in the known Covid Data and Vaccines Trial Data:

a) risk - benefit analysis is the essential means by which any of the Vaccines should be considered for approval;

b) policy formation should consider potential harms alongside potential benefits;

c) accepted scientific protocol dictates that in respect of the harm-benefit analysis in the use of medicines including the Vaccines **("Correct Risk-Benefit Analysis")**:

1 risk is primarily ascertained as to the frequency of Serious Adverse Events;

2 Serious Adverse Event frequencies are weighed against the nature of the Vaccines being use in otherwise healthy subjects to prevent disease which weighs relatively less heavily against risk;

3 in the case of preventative medicines in healthy subjects including the Vaccines, this is weighed against the comparative risk that the disease being purportedly prevented, being symptomatic Covid disease:

(1) would ever occur; and

(2) would, if occurring, progress to a disease with a risk of harm approaching or exceeding the risk of receiving the Vaccines;

4 determination and consideration comparatively of the extent of doses of the Vaccines to be administered wherein the risk of Serious Adverse Events increase proportionally to the volume of doses administered;

5 is appropriately applied further in a stratified manner accounting for the differing levels of risk and benefit in each group by, inter alia, age, physical condition, and pregnancy status;

d) Correct Risk-Benefit Analysis:

1 is the appropriate methodology by which the TGA was required to determine whether or not to grant the Approvals for any or all of the Vaccines for use by the Australian public;

2 was at no stage prior to the Approvals:

(1) undertaken by any of the Vaccine Sponsors;

(2) undertaken by any of the Respondents upon the data available to or provided to them prior to or subsequent to the Approvals;

(3) applied to the data provided to the Respondents by the Sponsors, available to the Respondents, or within the Respondents possession **("the Available Risk-Benefit Data")**;

(4) sought by the Respondents from the Sponsors;

(5) sought to be facilitated by the Respondents by obtaining a reasonably sufficient degree of data to effect Correct Risk-Benefit Analysis.

e) by reason of c), the Respondents failed to fulfil its obligations to **("the Failure to Undertake Required Risk Benefit Analysis")**:

1 undertake Correct Risk-Benefit Analysis or any reasonable risk-benefit analysis in respect of the Vaccines;

2 only register the Vaccines for use in Australia where it had properly determined that the benefits of the Vaccines are much greater than its risks;

3 rigorously assess the Vaccines for safety, quality and efficacy before they can be used in Australia;

4 use the best available scientific evidence to assess the risks and benefits of each Vaccine before approval;

5 carefully assess the results of the Vaccines' clinical trials;

6 only grant the Approvals where the Vaccines trials demonstrated that the benefits of the Vaccines greatly outweighed the risks.

f) the TGA, prior to the Approvals, knew or ought to have known and was recklessly indifferent to the fact that the Available Risk-Benefit Data disclosed the following to the Respondents **("the Failure to Consider the Serious Vaccines Risks")**:

1 obligatory risk benefit analysis in respect of the Vaccines required of the Respondents:

(1) a comparison between:

a) the Known Vaccines Excess Risk Data and documented counts of Serious Adverse Events in the Vaccines prior to the Approvals known to the TGA; and

b) severe-critical Covid cases in of each the Vaccines and comparison control group in each of the respective Vaccines Clinical Trial; and

(2) examination of the comparable data extending from 14 days after the full vaccination of the subjects with the Vaccines or placebo until the end of the study data.

2 it was evident to the Respondents prior to the Approvals upon the Available Risk-Benefit Data that the short-term risk-benefit performance of:

(1) the Pfizer Vaccine was demonstrated to be:

a) harmful;

b) entirely unbalanced in favour of harm;

c) possessing of a harm-benefit ratio of 25, wherein:

i) a harm-benefit ratio of 0.1 or less is acceptable for approval;

ii) a harm-benefit ratio of 1 indicates literally more harm than good with every dose.

(2) the Moderna Vaccine was demonstrated to be:

a) harmful;

b) entirely unbalanced in favour of harm;

c) possessing of a harm-benefit ratio of 1.1, wherein:

i) a harm-benefit ratio of 0.1 or less is acceptable for approval;

ii) a harm-benefit ratio of 1 indicates literally more harm than good with every dose.

(3) the AstraZeneca Vaccine was unknown and unable to be demonstrated due to the absence of sufficient data made available to the Respondents at the time of the AstraZeneca Approvals.

Particulars

The requirement of the Respondents to establish safety, efficacy and positive risk-benefit of any medicine prior to approval is contained within:

The TGA Policies;
The Adopted EMA Policies; and
The Statutory Obligations.

KNOWN ISSUES OF PFIZER NONCLINICAL TRIALS

86. By on or about 15 January, 2021 and prior to the Pfizer Approval, the Respondents knew of the following matters evidencing significant safety, efficacy and risk-benefit matters in respect of the Pfizer Vaccine disclosed in the Pfizer Nonclinical Trial data relied upon by the Respondents in granting the Pfizer Approval **("the Known Pfizer Nonclinical Studies Issues")**:

a) almost the same lung inflammation was found in monkeys in control and Pfizer Vaccine groups, demonstrating minimal benefit of the Pfizer Vaccine;

b) Pfizer did not in the Pfizer Nonclinical Trial or at all compare the antibody response between Pfizer Vaccine group and the control group;

c) Pfizer did not study any autoimmune diseases that may have been induced by the Pfizer Vaccine, nor was any data of that nature provided to the Respondents;

d) Pfizer did not study pharmacokinetic data in relation to the Pfizer Vaccine nor was any data of that nature provided to the Respondents;

e) Pfizer claimed that those studies were not necessary:

1 upon the erroneous basis that the Pfizer Vaccines was purportedly a "vaccine";

2 the Respondents inappropriately accepting Pfizer's excuse for those failures to study;

3 in circumstances where in truth the Pfizer Vaccine was a never-before used gene therapy.

f) no material distribution data of the Pfizer mRNA or s-protein in the human body was conducted in circumstances where in truth the trial:

1 was stopped by Pfizer after 2 days;

2 at the 2 day mark showed lipids, mRNA and protein of the Pfizer Vaccine in that group:

(1) present in multiple organs; and

(2) still increasing in certain organs in the body at that point;

g) no data as to the degradation of the protein was provided or obtained by Pfizer or the TGA;

h) the antibody and T-cell response which was present initially:

1 decreased significantly over 5 weeks;

2 made apparent the fact that any response elicited by the Pfizer Vaccine was short-lived;

i) long-term immunity of the Pfizer Vaccine was not studied nor was any data of that nature provided to the Respondents;

j) Vaccine-induced autoimmune diseases were not studied nor was any data of that nature provided to the Respondents;

k) Pfizer had not performed any study nor provided to the Respondents any safety data in respect of the following:

1 toxicity studies on lipid nanoparticle formulation;

2 secondary species toxicology;

3 genotoxicity studies;

4 carcinogenicity studies;

5 immunotoxicology studies;

6 juvenile animal studies;

7 studies conducted on the novel excipients used in the Pfizer Vaccine.

l) no study of mucosal immunity was undertaken nor data provided to the Respondents in relation to mucosal immunity in Pfizer Vaccine recipients in circumstances where in truth:

1 Covid is an infection of the mucosal space and the airway;

2 mucosal infections are typified by Ig-A in secretions which is where the immune response:

(1) is required and should occur;

(2) should be examined to prove efficacy of the Pfizer Vaccine or any Covid Vaccine.

3 the failure to undertake such a study and accept the absence of such data indicates an obvious neglect of the biology of the condition of Covid infection by Pfizer and the Respondents;

m) the data from the Pfizer Nonclinical Trial unquestionably disclosed to the Respondents that:

1 the mRNA codon in the Pfizer Vaccine had been optimised to make more spike protein;

2 the spike protein and the LNP encasing the spike protein has been contrived by Pfizer is to facilitate its entry into the cells of the recipient to produce the antigen;

3 the resultant effect of the Pfizer Vaccine in recipients is that cells in recipients can and do produce antigens in:

(1) an indiscriminate manner;

(2) a completely unknown amount;

(3) a completely unknown distribution.

4 the Pfizer Vaccine Lipid Nanoparticle would go into:

(1) all body cells;

(2) significantly more cells than the Virus itself could go into physiologically because the Virus did not possess the receptors to do so;

5 the Pfizer Vaccine produces more protein than the actual virus would, which:

(1) is unprecedented in any previously produced vaccine;

(2) is the precise opposite of typical vaccines which are normally attenuated and weaker than the actual virus being immunised against.

6 one of the four lipids in the Pfizer Vaccine lipid nanoparticles slightly ionised, which:

(1) allows the Pfizer Vaccine to enter any cell;

(2) renders the lipid to be more infectious than the Virus;

7 the poly-A tail of the Pfizer Vaccine's mRNA:

(1) was modified to be about 3 times the length of the virus' mRNA poly-A tail;

(2) degrades significantly more slowly than the Virus' mRNA;

n) the mice and monkeys used in the Pfizer Nonclinical Study (and other studies) were not appropriate animal models for a Pfizer Vaccine because:

1 those animals are known not to be affected by the Virus in the same way as humans;

2 serious disease from Covid infection does not occur in monkeys.

o) the Respondents' conclusion, and further acceptance of Pfizer's assertion that large amounts of the Pfizer Nonclinical Trial data are not required because the Pfizer Vaccine is "a vaccine" like any other were obviously false in the case of the Pfizer Vaccine because:

1 the Pfizer Vaccine is not a vaccine like any other that has successfully been used before;

2 traditionally a vaccine is an antigen or deactivated virus that is no longer able to infect the recipient but can trigger an immune response;

3 the Pfizer Vaccine instead carries and injects genetic information designed to instruct the body's cells to create the antigen;

4 as a result of the Pfizer Vaccine's mechanism of effect, every cell throughout the body may make the antigen;

5 the prolific production of antigen in the body of the recipient caused by the Pfizer Vaccine is profoundly different to a traditional vaccine wherein the antigen stays in the injection site;

6 mRNA would as a result of the Pfizer Vaccine be produced potentially in every cell in the body;

7 the intentionally and excessively limited distribution data showed the nanolipid Vaccine adjuvant present in numerous organs in the body.

p) the reproductive/fertility study undertaken by Pfizer known to the Respondents prior to the Pfizer Approval undertaken as part of the Pfizer Nonclinical Trial referred to and known by the Respondents:

1 was of obvious profound importance in respect of the safety of the Pfizer Vaccine because of the known distribution of the Pfizer mRNA to the ovaries of recipients;

2 showed implantation loss in the mice:

(1) at a rate of:

a) 4.1% in the control group;

b) 9.8% or 139% higher in Pfizer Vaccine group;

(2) justified and excused as of no significance and accepted by TGA Respondents as the same:

a) on the basis that historical controls have shown similar rates of miscarriage;

b) a basis which is obviously and profoundly inappropriate and wrong because:

i) historical studies cannot be compared to contemporary data due to the variance to an unknowable degree as between historical and current control groups;

ii) a contemporaneous prospective study control group is in every case required as a true measure of baseline as they possess precisely the same characteristics as the Pfizer Vaccine group.

q) the fetal abnormalities study undertaken by Pfizer known to the Respondents prior to the Pfizer Approval undertaken as part of the Pfizer Nonclinical Trial referred to and known by the Respondents:

1 was of obvious profound importance because a vaccine of the kind which the Pfizer Vaccine is was never before used as a vaccine;

2 revealed 9 occurrences of fetal abnormalities in the Pfizer Vaccine Group being significantly higher than in the control group;

3 produced results of significantly higher abnormalities in the Pfizer Vaccine group than the control group which:

(1) were asserted by both Pfizer and the Respondents to be of no consequence, concern or bar to approval;

(2) were never sought to be further understood or clarified by the Respondents as further studies of that nature were:

a) not conducted by Pfizer; or

b) not requested by the Respondents;

c) asserted by Pfizer to not be required;

d) found to be acceptable by TGA Respondents by accepting and justifying Pfizer's assertions without any sound or scientific basis.

r) T-cell studies undertaken by Pfizer and associated data known to the Respondents as part of the Pfizer Nonclinical Trial, which examined cytokine production in Pfizer Vaccine recipients, showed significant variation in immune response, and demonstrated an obvious:

1 unpredictable and different response in individual Pfizer Vaccine recipients depending on many factors which determine how much any individual will produce the antigen;

2 amount of antigen production in Pfizer Vaccine recipients which is uncontrolled because it is dependent upon the individual's own immune response and will differ from person to person.

s) cytokine studies undertaken by Pfizer and associated data known to the Respondents as part of the Pfizer Nonclinical Trials, which examined cytokine production in Pfizer Vaccine recipients obviously demonstrated:

1 the dominant cytokine produced in Pfizer Vaccine recipients was IL-10 which is the main cytokine produced by the T-suppressor cells which turn off the immune response in the human body;

2 a short-acting duration of antibody response to the Pfizer Vaccine in the body;

3 the downregulation of immune response occurred such that:

(1) with a small antigen load, the IL-10 cytokine was produced in relatively small amounts; and

(2) with increased antigen load, the IL-10 cytokine production increased significantly;

4 a red flag as to safety and efficacy ignored by the Respondents.

t) the Pfizer Nonclinical Trial undertaken by Pfizer and associated data in confluence known to the Respondents made obviously known to TGA at that time and prior to the Pfizer Approval that the Pfizer Vaccine:

1 possesses the propensity to have effects on future generations;

2 disclosed no evidence of better efficacy or speed of production over traditional vaccines;

3 disclosed no evident basis to have been used over traditional vaccines;

4 disclosed a significantly higher risk than traditional vaccines;

5 displayed an unpredictable and different response depending on many factors which determine how much any individual will produce the antigen;

6 displayed an amount of antigen production which is uncontrolled because it is dependent upon the individual's own immune response

will differ from person to person.

u) the limited studies showed that the ALC-0315 novel excipient used in the Pfizer Vaccine was:

1 only slowly eliminated; and

2 retained in the liver.

v) that the Respondents had determined that:

1 there were shortcomings in the repeat dose toxicity study design implemented by Pfizer in respect of the Pfizer Vaccine for the Pfizer Approval;

2 those shortcomings should not preclude approval of the Pfizer Vaccine.

(1) such determinations made by the Respondents in circumstances where in truth the Respondents ought to have insisted upon a proper and complete repeat dose toxicity study from Pfizer prior to the Pfizer Approval;

w) the novel excipients in the Pfizer Vaccine were subject to:

1 no repeat dose studies;

2 no reproductive toxicity studies

x) the Respondents determined that findings in the studies with the Pfizer lipid nanoparticle formulation were due to the lipid excipients in the case of hepatocyte vacuolation, which was probably a manifestation of hepatocyte uptake of lipids;

y) the potential of the Pfizer LNP or the vaccine formulation for complement activation or stimulation of cytokine release was not adequately assessed in nonclinical studies;

z) there was no data provided to the TGA or at all relating to the kinetics of Pfizer mRNA degradation;

aa) there was unknown metabolism of the lipid nanoparticle adjuvants in the liver and that the metabolic studies in vitro:

1 were stopped at between 2 hours and 4 hours at which time:

2 almost none of the lipids had been metabolised from the liver at all;

3 levels in many cases were still increasing in the liver;

4 the half-life of the lipid nanoparticle in the liver, was determined to be:

(1) somewhere between 4 hours and forever;

(2) unknown.

bb) how long these products stay in the body or their metabolic pathway is entirely unknown;

cc) the Pfizer Vaccine was evidently highly inflammatory, crossed the blood-brain barrier and into the neuro tissues, into the spinal cord and into the ovaries and testes;

dd) a single-dose intravenous study in rats demonstrated that both novel lipid excipients - ALC-0159 and ALC-0315 - in the Pfizer LNP formulation rapidly distributed from plasma to the liver being the only organ collected for analysis;

ee) the elimination of both lipids from the recipients were slow;

ff) that the study cited in the Pfizer Vaccine Approval Application:

1 indicated lipid nanoparticles in:

(1) the injection site;

(2) liver;

(3) spleen;

(4) adrenal glands; and

(5) ovaries;

2 did not investigate draining lymph nodes;

3 did not involve any analysis of:

(1) faeces;

(2) urine;

(3) carcass; and

(4) cage-wash samples.

4 was explained by Pfizer to the Respondents which was similarly accepted by the Respondents, as collecting a standard panel of tissues which did not include the draining lymph nodes;

5 such explanations accepted by the Respondents occurring in circumstances of:

(1) metabolic studies having not been adequately performed to determine how either the mRNA, the produced spike protein or lipids were metabolised or excreted

(2) the possibility of toxic metabolites having not been adequately assessed.

gg) that in assessing toxicity of the Pfizer Vaccine in the Pfizer Nonclinical Trial Data provided by Pfizer:

1 the Respondents determined that the dosing interval utilised by Pfizer in the study was not optimal; and

2 repeat dose toxicity studies with a dosing interval of 2 or 3 weeks not utilised by Pfizer would be more appropriate for investigating the potential toxicity of the vaccine.

hh) the Respondents determined that:

1 another repeat dose study in animals is not considered necessary because of "the availability of clinical data"; and

2 the deficiencies in the provided repeat dose toxicity study design should not preclude approval of the Pfizer Vaccine;

ii) the Respondents accepting and determining that "given the availability of clinical data" being cited by the TGA as justification for why another repeat dose study is not necessary meant that:

1 the Respondents had in fact determined that the Australian public were the suitable test subjects for this novel vaccine in the absence of a proper study on repeat doses being available by Pfizer at the time of the Pfizer Approval.

jj) as to major toxicities identified in the Pfizer Nonclinical Trial Data**:**

1 treatment related findings in the repeat dose study in rats with the Pfizer Vaccine (V9) were:

(1) increased body temperature;

(2) acute inflammation at the injected site with oedema and erythema,

(3) increased WBC;

(4) neutrophils;

(5) large unstained cells (LUC);

(6) eosinophils;

(7) basophils; and

(8) fibrinogen;

2 the albumin to globulin ratio was decreased;

3 acute phase proteins, α2-macroglobulin and α1-acid glycoprotein increased;

4 transient lower reticulocytes;

5 lower red cell mass;

6 spleen weights increased, associated with enlarged spleen and lymph nodes.

kk) treatment related microscopic findings were seen at:

1 the injection sites and surrounding tissues (mixed cell inflammation, mostly neutrophils);

2 draining lymph nodes (hypercellularity of germinal centre and increased plasma cells, mostly plasmablasts);

3 bone marrow (hypercellularity of hematopoietic cells, primarily myeloid cells);

4 spleen (increased hematopoiesis and germinal centre); and

5 liver (vacuolation of hepatocytes in the portal region).

ll) the findings were determined by the Respondents of no concern and to be consistent with:

1 immune stimulation and responses; and

2 inflammatory reactions and responses;

3 except for hepatocyte vacuolation deemed to probably be lipid vacuoles;

4 the Respondents' determinations being made in circumstances where in truth:

(1) it was scientifically established and known to the Respondents since at least 2019 in respect of the meaning of these Adverse Events in the Pfizer Nonclinical Trial data that:

a) in the context of a preclinical toxicity study:

i) an adverse effect is:

1. a test item-related change in the morphology, physiology, growth, development, reproduction or life span of the animal model;

2. likely to result in an impairment of functional capacity to maintain:

a. homeostasis; and

b. an impairment of the capacity to respond to an additional challenge;

b) as the most abundant plasma protein, albumin is largely responsible for producing the oncotic pressure that keeps fluid within the vascular system:

i) severe hypoalbuminemia results in loss of oncotic pressure causing edema and ascites due to accumulation of fluid in interstitial spaces;

ii) marked or severe decreases in albumin are associated with clinical edema are Adverse Events;

c) hypoalbuminemia:

i) results from and reflects the inflammatory state;

ii) interferes with adequate responses to events like surgery or chemotherapy;

iii) is associated with:

1. poor quality of life;

2. reduced longevity;

3. liver failure;

iv) is an adequate indicator of deterioration of the clinical state of a patient.

d) the lowered albumin outcome:

i) was excused by Pfizer as an expected inflammatory response;

ii) was accepted by the Respondents and adopted as an acceptable inflammatory response of no consequence to the Pfizer Approval;

iii) was in fact, as in the Pfizer Nonclinical Trial, when coupled with oedema or swelling, which was present in the toxicology animal studies is:

1. an adverse finding;

2. associated with liver failure; or

3. indicative of clinical deterioration; and

4. a serious safety finding which:

a. required further investigation;

b. is not appropriately dismissed as an inconsequential observation;

c. is indicative of a safety issue in the Pfizer Vaccine.

mm) the Respondents in accepting and relying upon the Pfizer Nonclinical Trial data as a basis for establishing safety and efficacy in the Pfizer Vaccine and thereby as a basis for granting the Approval of the Pfizer Vaccine, obviously and knowingly:

1 failed to obtain data essential to establishing the safety or efficacy of the Pfizer Vaccine;

2 failed to identify and make public the obvious safety and efficacy issues made evident by the data and lack of data contained in the Pfizer Nonclinical Trial;

3 accepted excuses for the non-production of essential data from Pfizer in the Pfizer Nonclinical Trial without any proper or scientific basis for doing so;

4 could not have in the circumstances and in fact did not establish the safety or efficacy of the Pfizer Vaccine prior to the Pfizer Approval or at all;

5 acted with willful or reckless disregard for their obligation:

(1) to obtain data from Pfizer to establish safety or efficacy of the Pfizer Vaccine before the Pfizer Approval;

(2) arising under statute and policy, both express and implied.

Particulars

The Respondents' knowledge of the above matters is evident in the document produced by and for the Respondents or their agent dated 8 January, 2021 (revised 15 January, 2021) – the Pfizer Nonclinical Evaluation Report. Pages: 4, 5, 6, 10, 11, 12-14, 18-19, 47, 55; and the Pfizer Original AUSPAR.

The requirement of the Respondents to establish safety, efficacy and positive risk-benefit of any medicine prior to approval is contained within:

1.The TGA Policies;
2. The Adopted EMA Policies; and
3. The Statutory Obligations.

The Respondents knowledge as to the scientifically known approach to the observed adverse events in the trial is exemplified for example in:

"Principles for Assessing Adversity in Toxicologic Clinical Pathology" - Lila Ramaiah. Toxicologic Pathology 2017, Vol. 45(2) 260-266. 2017, pg. 261.

Hypoalbuminemia: Pathogenesis and Clinical Significance. Soeters, P.B., Wolfe, R.R. and Shenkin, A. (2019). Journal of Parenteral and Enteral Nutrition, 43: 181-193. Pg. 181.

KNOWN EVIDENCE OF PFIZER ADJUVANT DISTRIBUTION THROUGHOUT THE BODY

87. The Respondents knew from at least 9 November, 2020 and prior to the Approvals that the Lipid Nanoparticles used as the delivery vehicle for the synthetic mRNA in the Pfizer Vaccine **("the Early Known Pfizer Biodistribution Danger Data")**:

a) extensively bio-distributes throughout the human body;

b) accumulates in various organs including:

1 kidney;

2 spleen;

3 adrenal glands;

4 testes; and

5 ovaries;

c) the distribution testing was assessed for only 48 hours before stopping, at which time:

1 the adrenal glands and ovaries:

(1) displayed their highest mean concentrations;

(2) the concentration of LNP's was still increasing;

d) was known by the Respondents at that time to have effects from the delivered synthetic mRNA upon the various organs studied which are unknown;

e) were known at that time and prior to the Approvals by the Respondents to have toxicity to humans;

f) there was thereby direct evidence of a significant and unquantified danger and effects in human recipients of the Pfizer Vaccine.

Particulars

The Early Known Pfizer Biodistribution Danger Data was contained in, provided to and known to the Respondents:

1. the biodistribution of Lipid Nanoparticle-mRNA was also evident to the Respondents as from 9 November, 2020 in the paper published on or about that date and available to the Respondents - FDA released document: Acuitas Therapeutics Inc / Pfizer "A Tissue Distribution Study of a [3 H]-Labelled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rats" at pg. 21. https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf.

2. as at on or about 28 February, 2021 the data contained in the Pfizer Post-Marketing Data pg. 9 and 12 known to the Respondents;

The toxicity of lipid nanoparticles in humans including those used in the Vaccines and known to the Respondents was well documented and accepted scientifically including for example, the following studies:

1. "Oxygen Radical-Mediated Pulmonary Toxicity Induced by Some Cationic Liposomes". Dokka, S et al. 2000. Pharm Res 17, 521–525 https://doi.org/10.1023/A:1007504613351;

2. "Toxicity of cationic lipids and cationic polymers in gene delivery". Hongtao, LV et al. 2006. Journal of Controlled Release, Volume 114, Issue 1, Pages 100-109. https://doi.org/10.1016/j.jconrel.2006.04.014;

4. "The systemic toxicity of positively charged lipid nanoparticles and the role of Toll-like receptor 4 in immune activation". Ranit, K et al. 2010. Biomaterials, Volume 31, Issue 26, Pages 6867-6875. https://doi.org/10.1016/j.biomaterials.2010.05.027;

5. "Toxicity and immunomodulatory activity of liposomal vectors formulated with cationic lipids toward immune effector cells". Filion, M., Phillips, N. 1997. Biochemical et Biophysica Acta (BBA) – Biomembranes, Volume 1329, Issue 2, Pages 345-356. https://doi.org/10.1016/S0005-2736(97)00126-0.

KNOWN PFIZER CLINICAL TRIAL ISSUES – TGA EVALUATION

88. From prior to, on or about 8 January, 2021 and prior to the Pfizer Approval, the Respondents knew of the following matters evidencing significant safety, efficacy and risk-benefit issues in respect of the Pfizer Vaccine disclosed in the Pfizer Clinical Trial data relied upon by the Respondents in granting the Pfizer Approval **("the Known Pfizer Clinical Data Issues")**:

a) the Respondents at no time prior to the Pfizer Approval were provided or aware of any immunogenicity data in respect of the Pfizer Vaccine in the Pfizer Clinical Trial **("the Known Pfizer Immune Response Failures")**;

b) the Respondents were not aware prior to the Pfizer Approval which variant of the Pfizer Vaccine is referred to in the data, variant V8 or V9, and therefore **("the Known Pfizer Unknown Variants Approved")**:

1 which medicine was intended by Pfizer to be mass-produced and distributed to the Australian public pursuant to the Pfizer Approval;

2 whether Pfizer variant V8 or V9 or both:

(1) were subject to the Phase 1, 2, and 3 Pfizer Clinical Trial evaluation;

(2) if either were subject to Phase 1, 2, or 3 evaluation, whether such data was ever provided to the Respondents for the Pfizer Approvals;

(3) were approved by the Respondents by the Pfizer Approval;

(4) in fact were manufactured for mass use;

(5) were the product being used and currently in use by the Australian population;

3 that each variant is in fact so distinctly different in composition that separate approvals were required in respect of each by the Respondents which have not occurred.

c) the entirety of the Pfizer Clinical Trial data received from Pfizer in respect of the Pfizer Vaccine at that time and prior to the Approvals and provided to the TGA and relied upon in the Approvals **("the Known Pfizer Clinical Data Efficacy Failures")**:

1 failed to demonstrate the pre-specified success criterion for true efficacy in the Pfizer Vaccine;

2 the Pfizer Clinical Trial did not test for or provide data and thereby no conclusions could be or were drawn or demonstrated as to:

(1) Pfizer Vaccine efficacy in prevention of severe illness from Covid infection;

(2) Pfizer Vaccine efficacy in prevention of transmission of the Virus between persons;

(3) Pfizer Vaccine efficacy in prevention of death from Covid infection;

(4) Pfizer Vaccine efficacy in prevention of Covid infection at all.

d) that **("the Known Declining Pfizer Efficacy")**:

1 changes in Covid pandemic characteristics would change the efficacy of the Pfizer Vaccine over time;

2 sustained protective efficacy for Pfizer Vaccine could not be concluded;

e) that in defining the Virus, Pfizer states scientific literature **("the Known Failure to Examine Identified Effective Alternatives")**:

1 which holds that:

(1) the serine protease inhibitor blocks the Virus from entering and infecting lung cells;

(2) full inhibition of the Virus was attained when camostat mesylate and E-64d, and inhibitor of CatB/l, were added.

2 the Respondents became aware of the efficacy of those compounds:

(1) but did not consider or explore those therapies;

(2) which were known by the Respondents to be:

a) already in use and production for clinical use;

b) able to block the Virus entry into cells.

PARTICULARS

The Respondents' knowledge of the above matters is evident in the Pfizer Clinical Evaluation Report. Pages 8, 24, 27, 39, 41, 42.

The study cited by the Respondents in defining the Virus is: "SARS-CoV-2 Cell Entry Depends on ACE2 and TMPRSS2 and Is Blocked by a Clinically Proven Protease Inhibitor", Hoffmann M et al, Cell. 2020; 181(2):271-280.e278 at section entitled "The Cellular Serine Protease TMPRSS2 Primes SARS-2 for Entry, and Serine Protease Inhibitor Blocks SARS-CoV-2 Infection of Lung Cells"

KNOWN PFIZER CLINICAL TRIAL ISSUES – TGA AUSPAR

89. From prior to, on or about 21 January, 2021 and prior to the Pfizer Approval, the Respondents knew of the following matters evidencing significant safety, efficacy and risk-benefit issues in respect of the Pfizer Vaccine disclosed in the Pfizer Nonclinical Trial and the Pfizer Clinical Trial data relied upon by the Respondents in granting the Pfizer Approval **("the Known Pfizer Vaccine Trial Data Issues")**:

a) long term effect of the Pfizer Vaccine was not evident as:

1 antibodies and T-Cells produced as a consequence of the Pfizer Vaccine declined quickly over 5 weeks;

2 the Respondents doubted and were concerned as to any long-term immunity which may be afforded by the Pfizer Vaccine;

b) the totality of data provided by Pfizer for assessment by the TGA in respect of the Pfizer Approval disclosed objectively and in the expressed determination of the Respondents:

1 only short term evaluation of protection by the Pfizer Vaccine;

2 a lack of any pharmacokinetic data for the S antigen-encoding in the mRNA of the Pfizer Vaccine (v.9);

3 suboptimal dosing intervals undertaken in the repeat dose study;

4 a lack of any repeat dose toxicity studies in a second species;

5 a lack of any genotoxicity studies with the novel excipients in the Pfizer Vaccine being used which had never before been tested or approved by the TGA;

6 a lack of any studies investigating potential for autoimmune diseases from the Pfizer Vaccine;

7 a lack of any studies of long-term immunity in the Pfizer Nonclinical Trial;

8 a lack of any studies of vaccine induced autoimmune diseases in the Pfizer Nonclinical Trial;

9 a lack of complement activation in the Pfizer Nonclinical Trial;

10 a lack of stimulation of cytokine release studies in the Pfizer Nonclinical Trial;

11 numerous adverse events of special interest (AESI's) and AE in the vaccine group that were absent in the placebo group assessed by the investigator as "unrelated to study intervention" and "none were assessed as related to study intervention by the investigators" which was accepted by the TGA suggesting:

(1) a disregard for the purpose and function required of the regulator; and

(2) a tendency to simply accept any justifications or explanations of the sponsor despite the clear risk to the public that such an approach may create;

(3) failure or refusal by the Respondents to:

a) review individual case data for any of the adverse events reported in the study; or

b) enquire further when no further information on individual cases was provided.

12 multiple cases of Serious Adverse Events were reported in the Pfizer Trials in the Pfizer Vaccine group only which:

(1) should have triggered the stopping rules for the trial;

(2) represented a safety signal;

(3) were assessed and accepted by the Respondents as not related to the Pfizer Vaccine;

(4) should have:

a) prompted a review of the investigators assessments of the adverse events but were not;

b) alerted the Respondents to independently review the investigators assessments against Brighton Collaboration case definitions, but were not.

c) that from a clinical point of view:

1 the entire data set upon which the Respondents relied was a single clinical trial (Study C4591001) for which interim findings for a median follow up period of around 2 months only are available;

2 short follow-up duration limits in the Pfizer Trials limited any possible conclusions in respect of:

(1) persistence of efficacy of the Pfizer Vaccine;

(2) late onset adverse events;

(3) rare adverse events.

d) that the Respondents had determined at that time that the obvious defects in data received by the Respondents from Pfizer in the Pfizer Approval indicated that provisional registration was the most appropriate regulatory pathway in circumstances where in truth conclusion indicated that the Respondents possessed and advanced upon **("the Abrogation of Provisional Approval Obligations")**:

1 a subjective understanding that the data received was utterly deficient for the purposes of determining the actual safety and efficacy of the Pfizer Vaccine;

2 an utter abrogation of the policy, statutory and implied requirements of assessment of the Pfizer Vaccine in granting the Pfizer Approval which were upon the Respondents at that time;

3 an utter misconstruction of the role, requirements and purpose of the Provisional Approval Pathway as constituting a pathway to approval of medicines without having established:

(1) safety;

(2) efficacy; or

(3) a positive risk-benefit profile.

4 a subjective willingness to approve for consumption by the entire adult Australian population a medicine without having established subjectively or objectively or in fact the Pfizer Vaccine's:

(1) safety;

(2) efficacy; or

(3) a positive risk-benefit profile.

Particulars

The Respondents' knowledge of the above matters is evident in the Pfizer Original AUSPAR - Pages 14, 15, 30.

The stopping criteria for the Pfizer Clinical Trial are found in the Pfizer Clinical Trial Protocol. Page 63-64.

In proceeding under the Abrogation of Provisional Approval Obligations, the Respondents have knowingly breached the following in the Pfizer Approval:

The requirement of the Respondents to establish safety, efficacy and positive risk-benefit of any medicine prior to approval is contained within:

1. The TGA Policies;
2. The Adopted EMA Policies; and
3. The Statutory Obligations.

KNOWN CONFLICTS OF INTEREST – PFIZER ANALYSIS STUDY

90. Prior to the Approvals, the Respondents knew that analysis of the Pfizer Clinical Trial Data in respect of the efficacy and safety of the Pfizer Vaccine produced in December, 2020 **("the Pfizer Vaccine Analysis Study")** upon which the Respondents relied in granting the Approvals **("the Known Conflicts of Interest")**:

a) was known by the Respondents to have been conducted by 29 authors, of which:

1 21 had direct conflicts of interest;

2 19 were employees of Pfizer;

3 18 held stock in Pfizer;

4 2 had received research grants for their institutions or sites from

Pfizer;

5 1 was a grant recipient from Pfizer and retained personal fees from Pfizer; and

6 1 obtained fees for their involvement in the Pfizer Clinical Study.

b) the Pfizer Vaccine Analysis Study:

1 was relied upon by the TGA including its conclusions in relation to the Pfizer Approval;

2 was funded by BioNTech and Pfizer.

KNOWN PFIZER CLINICAL TRIAL FRAUD EVIDENCE

91. By 10 November, 2021 it was known to the Respondents that:

a) a senior executive at a Pfizer Testing Site had made allegations relating to the Pfizer Clinical trial of the Pfizer Vaccine that **("the Reported Pfizer Trial Fraud")**:

1 data was falsified;

2 integrity of the data was corrupted;

3 patients were unblinded in the midst of the trial;

4 the vaccination staff were inadequately trained;

5 protocol deviations were not reported;

6 trial specimens were mis-labelled.

b) the circumstances of the Reported Pfizer Trial Fraud are relevantly that **("the Reported Pfizer Trial Fraud Circumstances")**:

1 the Reported Pfizer Trial Fraud from were reported to have been supported by produced:

(1) internal company documents;

(2) photos;

(3) audio recordings;

(4) emails; and

(5) the corroborating oral evidence of:

i. a high-level executive at the relevant facility;

ii. another two employees at the facility.

c) the regulatory body the FDA had not at the time of the TGA's statements (or any time since) inspected the site notwithstanding a complaint having been made in respect of the Data Fraud Allegations over 1 year earlier on 25 September, 2020;

d) the subsequent trial data including data to which the Data Fraud Allegations related were accepted by the TGA in approving the Pfizer Vaccine.

e) in response to the Reported Pfizer Trial Fraud, the Respondents claimed **("the TGA Pfizer Fraud Response")**:

1 that TGA was seeking additional information from Pfizer in relation to the Reported Pfizer Trial Fraud;

2 notwithstanding the Reported Pfizer Trial Fraud that:

(1) the Pfizer Vaccine is highly safe and effective; and

(2) Australians should not be concerned about the allegations of fraud and other matters raised in the Reported Pfizer Trial Fraud;

(3) the benefits of the Vaccines are:

i. clear; and

ii. not in dispute;

(4) all eligible Australians who are not yet vaccinated should be vaccinated with one of the Vaccines as soon as possible;

(5) given that the Reported Pfizer Trial Fraud only pertain to 2 per cent of the trial population, the overall results are not expected to be impacted;

3 the TGA Pfizer Fraud Response occurred in circumstances where in truth:

(1) the Respondents had not received at the time any information as to the Reported Pfizer Trial Fraud from Pfizer or the FDA;

(2) the Respondents have not at that time nor at any time since:

i. properly investigated the Reported Pfizer Trial Fraud;

ii. finally determined the veracity of the Reported Pfizer Trial Fraud;

iii. inspected the facility in question or the operations of that facility;

Particulars

"BMJ Investigation - Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial". BMJ 2021; 375 (Published 02 November 2021) https://www.bmj.com/content/375/bmj.n2635

News.Com.Au Article – 10 November, 2021 - "TGA

requests information from Pfizer after medical journal alleges contractor 'falsified' safety data" https://www.news.com.au/technology/science/human-body/tga-requests-information-from-pfizer-after-medical-journal-alleges-contractor-falsified-safety-data/news-story/342806323e802035bb1d810e561977f4.

KNOWN ASTRAZENECA NONCLINICAL TRIAL ISSUES

92. From prior to, on or about 15 February, 2021, and prior to the AstraZeneca Approval, the Respondents knew of the following matters evidencing significant safety, efficacy and risk-benefit issues in respect of the AstraZeneca Vaccine disclosed in the AstraZeneca Nonclinical Trial data relied upon by the Respondents in granting the AstraZeneca Approval **("the Known AstraZeneca Nonclinical Trial Data Issues")**:

a) antibodies decrease rapidly within 2 weeks after the 2nd dose of the AstraZeneca Vaccine;

b) no long-term immunity in respect of the AstraZeneca Vaccine was assessed in nonclinical studies**;**

c) immunogenicity of the AstraZeneca Vaccine may decrease with repeated vaccination;

d) the AstraZeneca Nonclinical Trial data disclosed an obvious lack of immunity with the AstraZeneca Vaccine beyond 2 weeks affecting profoundly the risk-benefit analysis;

e) because a reproductive toxicity study of the AstraZeneca Vaccine was ongoing at that time by AstraZeneca, a Pregnancy Category B2 was considered acceptable;

f) the Respondents determined that without adequate assessment of the effects upon embryofetal development the AstraZeneca Vaccine was not recommended for use in pregnant women, in circumstances where in truth:

1 the AstraZeneca Vaccine claimed by the Respondents at the time of the Approvals to be safe for use in pregnant women;

2 a B2 Pregnancy Category is incorrect in the circumstances according to the AstraZeneca Protocol as there were neither nonclinical animal studies, nor human study results available to the Respondents or at all as the trials were ingoing;

3 subsequent data indicate high toxicity in pregnancy.

g) there were unexpected and unexplained findings of significantly higher viral RNA load in the intestinal tissues of animals vaccinated with a 2nd dose of the AstraZeneca Vaccine over the 1st dose at 7 days after the injection;

h) animals receiving the 2nd dose of the AstraZeneca Vaccine as compared to 1st dose only required further investigation;

i) the lack of boosting of antibody or protective responses following 2nd dose of the AstraZeneca Vaccine in animals tested required further investigation;

j) the Respondents adopted a conclusion that there was no evidence of vaccine associated enhanced disease despite subjective findings of the Respondents:

1 of a 'surprising' and 'unexplained' finding involving potential T cell exhaustion;

2 of evidence of a small set of cytokines not being elevated by the booster;

3 that identified phenomena occurring post-vaccination could not be excluded by:

(1) the absence of a single cytokine being elevated;

(2) the T cell exhaustion theory; and

(3) abnormal response to booster vaccination which required careful assessment and scrutiny.

k) the data from the AstraZeneca Nonclinical Trial disclosing an obvious failure to establish AstraZeneca Vaccine:

1 safety;

2 efficacy; or

3 positive risk-benefit profile.

Particulars

The Respondents' knowledge of the above matters is evident in the AstraZeneca Nonclinical Evaluation Report, pg. 5 and 8.

KNOWN ASTRAZENECA CLINICAL TRIAL ISSUES

93. From prior to, on or about 27 January, 2021, and prior to the AstraZeneca Approval, the Respondents knew of the following matters evidencing significant safety, efficacy and risk-benefit issues in respect of the AstraZeneca Vaccine disclosed in the AstraZeneca Clinical Trial data relied upon by the Respondents in granting the AstraZeneca Approval **("the Known AstraZeneca Clinical Trial Data Issues")**:

a) that the Respondents considered that:

1 for provisional registration of a medicine including the Vaccines the role of the TGA is to assess whether:

(1) quality of the Vaccine has been adequately established for the purpose for which the Vaccine is to be used;

(2) safety of the Vaccine has been adequately established for the purpose for which the Vaccine is to be used;

(3) efficacy has been adequately established for the purpose for which the Vaccine is to be used;

2 in approving a medicine including the Vaccines, for a vaccination to be rolled out with the aim of protecting the Australian population, the context of this use needs to be considered;

3 there needs to be consideration as to whether the efficacy demonstrated by the Vaccines is sufficient:

(1) for use in the Australian context where Covid was at that time less prevalent;

(2) that expert advice in this respect be sought.

b) AstraZeneca Clinical Trial data known to the Respondents disclosed that:

1 AstraZeneca reported neurological disorders:

(1) including headaches which occurred in:

a) 9.3% of subjects who received the AstraZeneca Vaccine; and

b) 6.1% of the control group;

c) the first 7 days after vaccination; and

d) which AstraZeneca purportedly considered, and the Respondents accepted as fact without any evident basis, to be due reactogenicity.

(2) including tremor which:

a) was more commonly seen in the AstraZeneca Vaccine group than the control group;

b) tended to be in the first 7 days after vaccination; and

c) which AstraZeneca purportedly considered, and the Respondents accepted as fact without any evident basis, to be due reactogenicity.

(3) in circumstances where in truth it was known to the Respondents that higher reactogenicity:

a) indicates an obvious risk of Vaccine-Associated Enhanced Respiratory Disease;

b) should properly have been have further investigated as an adverse finding by the Respondents but was not;

2 AstraZeneca reported that 2 participants in the AstraZeneca Vaccine group suffered Serious Adverse Events:

(1) being:

a) pyrexia; and

b) transverse myelitis.

(2) which the Respondents' investigator considered may have been causally associated with the AstraZeneca Vaccine;

3 AstraZeneca reported angina:

(1) in 3 cases in the AstraZeneca Vaccine group;

(2) as not occurring in the control group at all;

(3) as occurring between 16 and 17 days after the AstraZeneca vaccination;

(4) the causality of which was:

a) purportedly considered by AstraZeneca to be unlikely to be related to the AstraZeneca Vaccine;

b) accepted by the Respondents without proper basis to be unlikely to be related to the AstraZeneca Vaccine;

4 AstraZeneca reported death occurring in 2 of the AstraZeneca Vaccine group:

(1) 1 reportedly due to fungal pneumonia in a patient with HIV; and

(2) 1 reportedly due to malignant neoplasm;

(3) as to causality of the deaths, relevantly:

a) purportedly considered by AstraZeneca not to be causally related to the AstraZeneca Vaccine;

b) accepted by the Respondents without proper basis as not causally related to the AstraZeneca Vaccine;

c) using the causality assessment probability scales and WHO criteria, the deaths:

i) are at least possible;

ii) more likely probable or certain causal.

d) there were exclusion criteria known to the Respondents for anyone with serious medical conditions, or any chronic condition unless it was stable and well controlled;

i) wherein:

1. a stable HIV patient died of reported fungal pneumonia, and:

ii) for the event to have occurred after the product with a temporal relationship;

iii) the death is in fact obviously indicative of immune interference from the AstraZeneca Vaccine triggering disease progression and immunodeficiency.

e) the malignant neoplasia required closer and further evaluation by the Respondents as:

i) malignant neoplasms were also reported in the Pfizer Clinical Trial known to the Respondents;

ii) no mutagenicity studies were conducted; and

iii) the patient would have been excluded from the AstraZeneca Clinical Trial if they had malignant neoplasia prior to the study;

iv) to have developed neoplasia and succumbed to this during the study period is evidence obviously indicative of a highly concerning causality for aggressive malignancy.

5 AstraZeneca reported in 2 cases of sudden adverse events in the AstraZeneca group:

(1) transverse myelitis in a 37 year old subject wherein it was reportedly concluded by AstraZeneca and adopted by the Respondents that there was uncertainty as to whether the Serious Adverse Event was causally:

a) inflammatory (and drug related); or

b) vascular; or

c) multiple sclerosis; and

d) possibly and to an unknown degree attributable causally to the patient's family history of Charcot-Marie-Tooth Disease type 1a;

e) in circumstances where in truth in fact:

i) Charcot-Marie-Tooth type 1a family history is likely irrelevant and obviously not a better causal answer to AstraZeneca Vaccine causality;

ii) no details on the degree of relatedness of this family history were given to or by the Respondents in suggesting this alternative causality;

iii) no details of the gene mutation for the family member were given to or by the Respondents in suggesting this alternative causality;

iv) no details of any genetic testing on the patient were given to the Respondents in suggesting this alternative causality;

v) the rejection of AstraZeneca Vaccine causality by the Respondents in the circumstances is made without any evident basis.

(2) multiple sclerosis in a 37 year old subject wherein it was reportedly concluded by AstraZeneca and adopted by the

Respondents that:

a) the patient's brain had multiple lesions;

b) most of the patient's brain lesions were thought to pre-date the vaccination; and

c) the multiple sclerosis was considered not related to the AstraZeneca Vaccine;

d) in circumstances where in truth in fact:

i) the TGA asserts that the MRI results disclose that the brain lesions for MS mostly were thought to pre-date the vaccination;

ii) no details are provided and no evident basis as to how AstraZeneca or the Respondents came to this conclusion;

iii) it is impossible to 'date' MS lesions on an MRI unless a previous MRI has been reviewed for comparison;

iv) the rejection of AstraZeneca Vaccine causality by the Respondents in the circumstances is made without any evident basis.

6 the control group in the study improperly used either meningococcus vaccine or saline without any further detail as to the proportion of each or reason for using another vaccine as the control;

7 AstraZeneca concluded and the Respondents accepted the conclusion that there were was a clinically meaningful imbalance in the incidence of Adverse Events of Special Interest being Vaccine-Associated Enhanced Respiratory Disease;

8 AstraZeneca reported that there was a case of transverse myelitis and multiple sclerosis in the AstraZeneca Vaccine group;

9 there was an reported case of chronic inflammatory demyelinating polyneuropathy known to the Respondents at that time:

(1) in the ongoing US study of the AstraZeneca Vaccine;

(2) for which causality in respect the AstraZeneca Vaccine was determined to have remained uncertain;

10 the safety data in the elderly was determined by the Respondents to be:

(1) important as applying to at-risk individuals;

(2) relatively limited and small in sample size and quantity;

(3) derived from only 8.9% of participants who were over 65 years old; and

(4) derived from only 6.1% of all study participants were over 70 years old;

11 reactogenicity was reported as less severe in the elderly than in the younger population;

c) the AstraZeneca Clinical Trial data upon which the TGA relied in the AstraZeneca Approval was such that the TGA had determined at the time of the AstraZeneca Approval:

1 no conclusions could be drawn from the data in respect of the efficacy of the AstraZeneca Vaccine;

2 the results in respect of efficacy of the AstraZeneca Vaccine were uninterpretable;

3 the data was incapable of secondary analysis;

4 animal studies of the AstraZeneca Vaccine demonstrated persistent spreading of the Virus in the upper respiratory tract in the AstraZeneca Vaccine group;

5 efficacy of the AstraZeneca Vaccine in preventing asymptomatic disease was unknown;

6 efficacy of the AstraZeneca Vaccine in preventing transmission of the Virus was unknown;

d) that the Respondents considered at that time in respect of the AstraZeneca Vaccine that:

1 it is important that the Australian population understand the facts about:

(1) the efficacy of the AstraZeneca Vaccine;

(2) the limitations of the AstraZeneca Vaccine efficacy data; and

(3) the need to continue other public health measures to prevent the spread of disease until more information about vaccine efficacy is available;

2 the duration of follow up, and reasons for missing data in follow up, are important in determining efficacy;

3 lower duration of follow up may be from drop outs or the censoring of cases by the applicant;

4 longer duration of follow up increases the time of exposure and increases the opportunity for true effectiveness (or non-effectiveness) to be demonstrated;

5 one of the major limitations of the AstraZeneca Clinical Study in respect of efficacy is the short and variable duration of follow up.

e) that in the AstraZeneca Clinical Trials those at high risk of Covid were excluded or insufficiently represented to conclude safety or efficacy in those groups including:

1 the elderly;

2 pregnant women; and

3 those with significant co-morbidities.

f) in the Respondents' opinion:

1 the standard for approval for registration is a different assessment to a risk/benefit analysis as the potential risks of vaccination are small, and the potential benefits in this population large;

2 identified high risk populations should not be excluded from the indication:

(1) because:

a) it is reasonable to extrapolate efficacy in those groups; and

b) the risks of Covid outweigh potential risks of the vaccine.

(2) notwithstanding:

a) the entire absence of evidence indicating efficacy in those groups;

b) the TGA Respondent's complete absence of assessment or quantification of the actual risks of Covid; and

c) the obvious failure to establish safety and thereby risk in respect of the AstraZeneca Vaccine.

3 the Respondents must ensure:

(1) adequate warning about the limitations of the data in the AstraZeneca Product Information; and

(2) a recommendation to prescribers that the potential risks and benefits to an individual are be considered prior to proceeding to vaccinate with the AstraZeneca Vaccine.

4 in respect of the High Risk Groups, the totality of data submitted to the Respondents by AstraZeneca for the AstraZeneca Approval contained:

(1) insufficient patients in the study; and

(2) incomplete pre-clinical studies.

g) the Respondents determined the following in respect of the AstraZeneca Vaccine and recommended that for potential users of the AstraZeneca Vaccine, the following warnings were appropriate:

1 vaccination with the AstraZeneca Vaccine or any other vaccine may not protect all recipients of that vaccine;

2 the AstraZeneca Vaccine or any other vaccine should be used along with other infection control measures to prevent acquiring Covid;

3 immunisation with AstraZeneca Vaccine reduces the risk of symptomatic disease but does not eliminate the risk of acquiring Covid;

4 individuals who test positive for Covid on PCR swab may still be infectious and require isolation even though vaccinated with the AstraZeneca Vaccine;

h) the totality of data submitted to the Respondents by AstraZeneca for the AstraZeneca Approval in fact disclosed to the Respondents:

1 no real understanding as to the actual risks to AstraZeneca Vaccine recipients;

2 no real understanding as to the actual efficacy or benefit of the AstraZeneca Vaccine to recipients;

3 no possible conclusion as to the AstraZeneca Vaccine:

(1) safety;

(2) efficacy;

(3) risk-benefit profile.

i) the conclusions by the Respondents drawn from that totality of data submitted to the Respondents by AstraZeneca for the AstraZeneca Approval involved:

1 assumptions by the Respondents as to efficacy and safety of the AstraZeneca Vaccine without any scientific basis;

2 no application of risk-benefit analysis by the Respondents by comparing actual threat of Covid to risks associated with AstraZeneca Vaccine;

3 an obvious and complete misunderstanding by the Respondents of an appropriate risk-benefit evaluation;

4 an abrogation of the statutory, policy and implied standard of assessment required before granting the AstraZeneca Approval.

Particulars

The Respondents' knowledge of the above matters is evident in the document produced by and for the

Respondents or their agent dated 28 January, 2021 as follows:

The AstraZeneca Delegate Report, pg. 6, 21, 22, 24.

The AstraZeneca Clinical Evaluation Report, pg. 5, 8, 20, 44, 47, 48, 49, 51, 54, 58, 59.

GENOTOXICITY/CARCINOGENICTY - KNOWN EXTREME RISK OF PFIZER MRNA VACCINE

94. Prior to the mRNA Vaccine Approvals, the Respondents knew of the following matters evidencing significant safety issues in respect of the Pfizer Vaccine in their known configuration upon humans disclosed in the totality of data relied upon by the Respondents and scientific knowledge known at that time:

a) that the active ingredient in the Pfizer Vaccine is a single-stranded, 5'-capped messenger RNA (mRNA) **("the Pfizer Vaccine mRNA")**:

1 produced using a cell-free in vitro transcription from the corresponding DNA templates;

2 encoding the viral spike (S) protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2);

b) the Pfizer 3' Untranslated Region (UTR) provides a coding sequence:

1 homologous for mitochondrial human RNA for the mitochondrial 12S protein;

2 which is a nucleoside modified sequence wherein each uridine is replaced with pseudouridine.

c) the full sequence of the Messenger RNA encoding the full-length SARS-CoV-2 spike glycoprotein of the Pfizer Vaccine **("the Pfizer Vaccine mRNA") ("the Known Untranslated mRNA")**:

1 the 3´UTR region of the Pfizer mRNA comprises two sequence elements derived from the amino-terminal enhancer of split (AES)

mRNA and the mitochondrial encoded 12S ribosomal RNA to confer RNA stability and high total protein expression;

2 the untranslated regions thereby contain mitochondrial RNA;

3 the coding sequence for the Pfizer Vaccine contains several regions:

(1) in addition to the mRNA encoding the spike protein;

(2) includes the untranslated regions.

d) the Pfizer coded sequence for the Pfizer mRNA has a long polyA tail;

e) it was a scientifically established fact known to the Respondents from at least March 2020 in respect of considerations of gene therapy for mitochondrial diseases that **("the Known Mitochondrial RNA Risks")**:

1 the consequences of mutations in the mitochondrial genome (mtDNA) and mitochondria-related nuclear genes are:

(1) often severe;

(2) are attended by a poor prognosis;

2 the mtDNA encodes a small but critical subset of genes;

3 mitochondrial DNA is exclusively inherited from the mother;

4 therefore a woman with mutant mtDNA can:

(1) pass the disease directly through female offspring;

(2) transmit heritable genetic afflictions for multiple generations down the maternal line;

5 mtDNA variants can have devastating consequences for the health of the patient by disrupting mitochondrial function;

6 the overproduction of mitochondrial proteins (whether encoded by mtDNA or nDNA) may, in and of itself, cause severe defects in:

(1) mitochondrial function; and

(2) metabolism.

7 production of defective and/or misfolded mitochondrial proteins encoded from the nuclear genome can lead to:

(1) a toxic accumulation of mitochondrial protein precursors in the cytosol (mitochondrial precursor over-accumulation stress); and

(2) dysfunction within the mitochondria itself**;**

8 the overexpression of homologous repair and DNA repair enzymes can lead to:

(1) genome instability;

(2) significant harm to the patient.

f) the potential harm of arising from the use of mitochondrial RNA in sequence as used in the Pfizer mRNA contained in the Pfizer Vaccines is potentially:

1 intergenerational;

2 catastrophic;

3 causing transfection which is species significant;

g) the presence of non-coding sequences such as microRNA in the untranslated regions has potential clinical significance;

h) integrating vectors and mutagens containing polyA signals either engineered or endogenous as in the Pfizer mRNA may:

1 induce cancer by mutating host genes in a number of different ways;

2 elicit premature termination of gene transcription;

i) the risk of mutagenesis and oncogenic potential thereby arising in the Pfizer Vaccine;

j) despite these significant intergenerational known risks, the Respondents neither undertook nor sought studies to understand these risks in respect of the Pfizer Vaccine, being:

1 genotoxicity studies; and

2 carcinogenicity studies.

k) despite the Known Mitochondrial RNA Risks being published and known prior to the Pfizer Approval, the TGA has not prior to the Pfizer Approval or at any time:

1 conducted a detailed examination or consideration of the untranslated regions of the Pfizer mRNA, nor sought or been provided evidence of such examination or consideration by Pfizer;

2 evaluated or considered the risks associated with, nor sought or having been provided with such evaluation or consideration from Pfizer:

(1) the use of mitochondrial RNA in the Pfizer Vaccine;

(2) the presence of non-coding sequences such as microRNA in the Pfizer Vaccine.

3 evaluated or considered the impact of the replacement of every uridine with a pseudouridine, nor sought or having been provided with such evaluation or consideration by Pfizer;

4 evaluated or considered the impacts on stabilisation of function, translation of protein and splicing regulation in the Pfizer Vaccine,

nor sought or having been provided with such evaluation or consideration by Pfizer;

5 evaluated or considered the genetic sequence data in the Pfizer mRNA implications in respect of potential mutagenesis and oncogenic potential, nor sought or having been provided with such evaluation or consideration by Pfizer;

6 evaluated or considered the genetic sequence data in the Pfizer mRNA implications in respect of potential inflammatory or oncogenic risks, nor sought or having been provided with such evaluation or consideration by Pfizer;

7 evaluated or considered the potential for the long polyA tail in the Pfizer mRNA, nor sought or having been provided with such evaluation or consideration by Pfizer, to:

(1) induce cancer by mutating host genes;

(2) elicit premature termination of gene transcription.

8 evaluated or considered the untranslated regions of the Pfizer mRNA nor sought or having been provided with such evaluation or consideration by Pfizer;

9 at the time of the Pfizer Approval the TGA was entirely unaware, nor had it sought the answer to, the following matters in respect of the Pfizer mRNA of critical medical consequence for recipients of the Pfizer Vaccine:

(1) whether or not those non-coding regions enter the nucleus for translations as would usually occur with an RNA virus;

(2) by what process the mRNA segment is spliced or removed from the remaining RNA;

(3) by what process are the nucleotide sequences degraded;

(4) the potential for micro RNA inclusion in the UTR;

(5) the nucleotide sequence was NOT solely the mRNA coding for the spike protein:

a) despite the presumption and public pronouncements by the Respondents that that nucleotide sequence was only the mRNA encoding the spike protein.

Particulars

The Respondents above knowledge is based upon the following:

1. the knowledge and conclusions of the TGA Respondent in the following documents prepared by the Respondents prior to the MRNA Vaccine Approvals:

    1. the Pfizer Original AUSPAR
    2. the Pfizer Product Information, pg. 1.
    3. the Pfizer Nonclinical Evaluation Report

2. knowledge as to the Known Mitochondrial RNA Risks arises from the uncontroversial scientific literature published and known to the Respondents prior to the MRNA Vaccine Approvals, including for example:

    1. Slone, J., Huang, T. “The special considerations of gene therapy for mitochondrial diseases”. npj Genom. Med. 5, 7 (2020). https://doi.org/10.1038/s41525-020-0116-5

    2. “Cancer Gene Discovery: exploiting insertional mutagenesis”, Ranzani et all, Mol Cancer Res 2013 October; 11(10) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3836224/pdf/emss-54324.pdf

3. the Known Untranslated mRNA was known to the Respondents before the mRNA Vaccine Approvals by reason of the World Health

Organisation document published and known to them WHO International Nonproprietary Names Programme 11889 – Description Messenger RNA encoding the full-length SARS-CoV-2 spike glycoprotein. https://web.archive.org/web/20210105162941/https://mednet-communities.net/inn/db/media/docs/11889.doc published in or about September, 2020.

4. The relevant details of the Pfizer mRNA was contained in the Pfizer Product Information prepared by the Respondents on or about January, 2021 and before the Pfizer Approval.

5. The Respondents' failure to understand or seek to understand the risks pleaded herein is evident in the TGA FOI response to the following questions as "no such documents exist relating to the following" (refer FOI 3604):

    a. the risk of and/or presence of micro-RNA sequences (miRNA) comprised within the Comirnaty mRNA active ingredient (mRNA genomic sequence).

    b. the risk of and/or presence of Oncomirs (oncogenic miRNA - microRNA) comprised within the Comirnaty mRNA active ingredient (mRNA genomic sequence).

    c. the risk of and/or presence of Stop Codon read-through (suppression of stop codon activity) arising as a result of the use of pseudo uridine in the Comirnaty miRNA active ingredient (mRNA genomic sequence).

    d. the composition of the final protein product (molecular weight and amino acid sequence) produced following injection of the Comirnaty mRNA product in human subjects.

    e. the risk of the use of the AES-mtRNR1 3' untranslated region of the Comirnaty mRNA product in human subjects.

KNOWN FAILURE TO REFER PFIZER AND MODERNA VACCINE TO OFFICE OF THE GENE TECHNOLOGY REGULATOR

95. From prior to the Pfizer Approval and the Moderna Approval the Respondents knew of the following relevant to their obligation to refer the Pfizer Vaccine and the Moderna Vaccine to the Office of the Gene Technology Regulator **("the OTGR")** prior to granting the Approvals:

a) the binding obligations under the Act being the Requirement to Seek Gene Technology Regulator Advice and the Requirement to Consider Gene Technology Regulator Advice which require that the Respondents:

1 give written notice to the Gene Technology Regulator requesting the Gene Technology Regulator to give advice about the Pfizer Application and the Moderna Application;

2 ensure that the advice received by the Secretary pursuant to Requirement to Seek Gene Technology Regulator Advice is taken into account in making a decision on the application for Registration that the advice relates to, being the Pfizer Application and the Moderna Application;

b) the OTGR regulates therapies that involve in-vivo genetic manipulation of human cells as prescription medicines under s. 23 of the *Gene Technology Act 2000* (Cth), including:

1 small silencing RNAs;

2 CRISPR;

3 other gene editing technologies; and

4 gene therapies administered by vectors.

c) the Department-produced document for the Office of the Gene Technology Regulator published in October, 2021 stated that **("the OTGR GMO Definitions Document")**:

1 the document was prepared to assist regulated organisations to understand which new technologies, including gene editing techniques, result in genetically modified organisms **("GMOs")** that are regulated under the *Gene Technology Act 2000* (Cth);

2 exclusion of RNAi techniques from being properly regarded as gene technology can only occur if:

(1) the genomic DNA sequence cannot be changed by the technique; and

(2) if the introduced RNA cannot be translated into a protein or lead to production of infectious agents.

d) the Pfizer Vaccine and the Moderna Vaccine are GMO for the purposes of and therefore subject to **("the GMO Requirements")**:

1 the requirements of the *Gene Technology Act 2000* whereby the Gene Technology Regulator should have undertaken or commissioned research in relation to risk assessment and the biosafety of the GMOs in the Pfizer Vaccine and the Moderna Vaccine;

2 the Act provisions and particularly the:

(1) Requirement to Seek Gene Technology Regulator Advice; and

(2) the Requirement to Consider Gene Technology Regulator Advice.

e) the Respondents knowingly failed or refused to comply with the provisions of the GMO Requirements prior to the Approvals or at all thereby:

1 failing to obtain critical safety advice from the OTGA in respect of the mRNA Vaccines prior to approval;

2 approving the mRNA Vaccines which are in substance gene therapies in the absence of any knowledge or understanding as to

the effects of the active mRNA ingredients of each.

Particulars

OTGR GMO Definitions Document - Aust Gov, Dept of Health, Office of Gene Technology Regulator produced in Oct 2021 document entitled "Overview - status of organisms modified using gene editing and other new technologies". https://www.ogtr.gov.au/sites/default/files/2021-11/overview_-_status_of_gene_editing_and_other_new_technologies.pdf.

The Requirement to Seek Gene Technology Regulator Advice and the Requirement to Consider Gene Technology Regulator Advice are contained in s. 30C(2)(b) and s. 30E of the Act.

KNOWN GENOTOXICITY OF THE VACCINES

96. Prior to the mRNA Approvals the Respondents knew of the following matters relevant to the known genotoxicity and mutagenicity of the mRNA Vaccines and a relevant consideration for the Respondents in respect of the safety of the mRNA Vaccines in granting the mRNA Approvals **("the Known mRNA Vaccine Risks and Failures")**:

a) genotoxicity and mutagenicity are a material and serious risk in those receiving the mRNA Vaccines by reason of:

1 the presence of in each of the mRNA Vaccines:

(1) novel nano-lipid compounds;

(2) micronuclei in genotoxicity studies described for the lipids in the Moderna mRNA Vaccines;

2 the presence of micronuclei in genotoxicity studies being causally connected with in humans:

(1) chromosomal aberrations;

(2) highly inflammatory reaction;

(3) genotoxicity; and

(4) mutagenicity.

3 the novel excipient used in the mRNA Vaccines.

b) related risk and prevalence data was at no time before or after the mRNA Approvals:

1 obtained or produced by Pfizer or Moderna;

2 provided to or considered by the Respondents.

c) the novel excipients in the mRNA Vaccines:

1 have not been assessed for safety by the Respondents; and

2 are not approved for use by registration in the Register.

d) analysis of potential for both genotoxicity (damage to genes) and mutagenicity (potential to cause cancer) are:

1 among the highest priorities from a regulatory perspective;

2 particularly warranted in the mRNA Vaccines wherein:

(1) the mRNA Vaccines are genetic therapeutics;

(2) it was always contemplated that the mRNA Vaccines would be approved and promoted for use:

a) in healthy individuals of all ages;

b) for the entire adult population of Australia.

e) in approving the mRNA Vaccines, the Respondents:

1 approved product information statements in respect of those mRNA Vaccines which acknowledge the omission of this important pre-clinical (in-vitro and/or animal) genotoxicity and mutagenicity safety data;

2 granted the Approvals in respect of the mRNA Vaccines wherein it was known that there is a possibility that:

(1) the mRNA contained in the mRNA Vaccines may be reverse transcribed or incorporated into the recipient's DNA around the body including a wide variety of tissues and organs including eggs in the ovary;

(2) the mRNA Vaccines may induce cancers;

(3) that these adverse effects may be inherited into future generations;

(4) which in total were, prior to the mRNA Vaccine Approvals:

a) contrary to the assumptions and statements made by the Respondents;

b) indicative of an extreme need for further investigation of the mRNA Vaccines by the Respondents;

c) of such extreme importance and concern so as to obviously:

i) preclude the mRNA Vaccines from being considered safe for use in humans; and

ii) indicate immediate withdrawal of the mRNA Vaccines from authorised use in

humans from and at the time of the mRNA Vaccine Approvals granted by the Respondents.

Particulars

The absence of genotoxicity and carcinogenicity studies is acknowledged by the Respondents in:

1. The Pfizer Clinical Evaluation Report;
2. The Pfizer Original AUSPAR;
3. The Moderna Original AUSPAR.

The requirement of the Respondents to consider genotoxicity and mutagenicity in respect of the safety of the mRNA Vaccines in granting the mRNA Approvals, arises from:

1. The TGA Policies;
2. The Statutory Obligations;
3. The Adopted EMA Policies.

KNOWN GENOTOXICITY AND CARCINOGENICITY ISSUES – PFIZER VACCINE

97. From prior to, on or about 25 January, 2021, and prior to the Pfizer Approval the Respondents knew of the following matters evidencing significant genotoxicity and carcinogenicity risks in respect of the Pfizer Vaccine disclosed in the totality of data relied upon by the Respondents in granting the Pfizer Approval **("the Known Pfizer Genotoxicity Issues")**:

a) in respect of potential genotoxicity of the Pfizer Vaccine:

1 no genotoxicity studies were conducted for the Pfizer Vaccine;

2 no genotoxicity studies were undertaken on the novel excipients contained in the Pfizer Vaccine;

b) Pfizer asserted, and the Respondents accepted without further consideration or evidence that **("the Pfizer Genotoxicity Assertions")**:

1 the novel lipid excipients were not expected to be genotoxic based on in silico analysis of the novel lipids and their primary metabolites for which reports were not provided;

2 the absence of genotoxicity studies with the novel lipid exposures were justified on the basis that:

(1) the threshold of toxicological concern (TTC) concept was satisfied; and

(2) the lipid excipients in the Pfizer Vaccine - ALC-0159 and ALC-0315 **("the Pfizer Excipients")** - were structurally and functionally similar to the two lipid excipients - PEG-2000-C-DMG and DLin-MC3-DMA - used in the drug Patisiran **("the Patisiran Excipients")**;

(3) both of the Patisiran Excipients were found to be safe in a full genotoxicity test battery of Patisiran.

c) that based solely upon the Pfizer Genotoxicity Assertions, the Respondents were thereby satisfied that **("the TGA Pfizer Genotoxicity Conclusions")**:

1 genotoxicity studies in respect of the Pfizer Vaccine were not required;

2 genotoxicity studies in respect of the Pfizer Excipients were not required;

3 the Pfizer Excipients were not expected to pose a genotoxic risk;

4 neither the mRNA nor the lipid excipients of the LNP formulation are expected to have genotoxic potential;

5 wherein in fact it was known to the Respondents that:

(1) in animal studies intravenous administration of Patisiran lipid complex resulted in:

a) developmental toxicity including:

i) embryofetal mortality; and

ii) reduced fetal body weight;

b) maternal toxicity.

(2) it is not scientifically acceptable and obviously erroneous to compare and rely upon a non-clinical genotoxicity test for structurally dissimilar lipids in Patisiran:

a) as it was known to be utilised solely for a terminal condition in humans not healthy subjects as in the Pfizer Vaccine;

b) it was known and proven to be teratogenic in animal studies;

i) whilst Pfizer would not provide to the Respondents the reports of the in-silico analysis;

ii) when those presumptions were based on having two vaccines per year, and now up to 5 doses are being used in many patients without any re-evaluation of the safety data.

c) the justification in respect of the satisfaction by the Pfizer Vaccine as satisfying the threshold of toxicological concern was known and obviously false because:

i) Pfizer justified and the Respondents accepted and similarly asserted without proper basis the absence of genotoxicity studies with the novel lipid exposures based on the threshold of toxicological concern (TTC) concept;

ii) Pfizer falsely claimed and the Respondents accepted and similarly asserted that the Toxicological Threshold of Concern (TTC) concept was much higher than someone having twice yearly vaccines for 70 years would be exposed to;

iii) the claim was and is obviously false because their calculations of TTC were invalid as:

iv) Pfizer calculated the exposure of the two novel excipients as follows:

1. per dose per day being **("the Pfizer Novel Excipient Levels")**:

    a. ALC-0159 – 53.4 mcg; and

    b. ALC-0315 – 430 mcg;

2. calculated a less than lifetime total exposure of threshold of toxicological concern to be 19.16 mg per day by:

    a. multiplying the TTC of a mutagenic substance of 1.5 mcg per day

projected over 70 years at 365 days per year divided by 2 days;

b. allowing then that the acceptable threshold per year to compare to the Pfizer Vaccine is 19.16 mg per day;

3. then comparing the per injection day rate of the excipients in the Pfizer Vaccine with the calculated less than lifetime total exposure of threshold of toxicological concern to be 19.16 mg per day **("the Concern Threshold Day Rate")** as follows:

a. the volume of ALC-0159 at 53.4 mcg per injection day received is 360 fold lower than the Concern Threshold Day Rate;

b. the volume of ALC-0315 at 430 mcg per injection day received is 45 fold lower than the Concern Threshold Day Rate.

v) the European Medicines Agency's Scientific guideline published at the time of the Pfizer Approval requires that when calculating the threshold:

1. the number of days is taken to be the number of **dosing** days;

2. not the time interval over which the doses were administered.

vi) as Pfizer used the interval time (so the number of days over 70 years of exposure = 25,550 days) in their calculation of TTC, it calculated the TTC level as over 19,000 mcg which is 45-360 times the exposure that someone would have from twice yearly vaccines for 70 years;

vii) however using the above EMA guideline, the TTC is in fact 20mcg calculated at 140 days for the 70 years at twice yearly dosing;

viii) at dose levels of 53.5mcg and 430 mcg, the Pfizer Novel Excipient Levels far exceed the true Toxicological Threshold of Concern in a single dose;

d) accordingly there was known to the Respondents at that time:

i) a known but unstated genotoxic risk in the Pfizer Vaccine;

ii) a failure to require genotoxicity testing predicated upon false reasoning and false assumptions.

d) the distribution of LNP-BNT162b2 (V9) mRNA or expressed S protein was not studied nor such data provided to or sought by the Respondents;

e) the distribution of lipid nanoparticles in the Pfizer Vaccine was investigated by monitoring of a radio-labelled lipid-marker after intramuscular administration in rats, wherein it was known to the Respondents by that data that:

1 the mean concentration of radioactivity in sexes combined in tissue and blood following single intramuscular dose of 50mcg RNA in a rat in the same report showed:

(1) in the ovaries of females:

a) a total lipid concentration of 0.104 mcg/g or ml of the Pfizer Vaccine lipid within 25 minutes of vaccination;

b) an increase in concentration by 11,788% within 48 hours of vaccination at which point testing did, and was known by the TGA to be stopped by Pfizer;

(2) in the testes of males:

a) a total lipid concentration of 0.031 mcg/g or ml of the Pfizer Vaccine lipid within 25 minutes of vaccination;

b) an increase in concentration by 1,032% within 48 hours of vaccination at which point testing did, and was known by the TGA to be stopped by Pfizer;

(3) distribution studies for the mRNA nucleotide or spike antigen from the Pfizer Vaccine were not provided to the Respondents;

(4) the surrogate distribution marker of the Liquid Nanoparticle distribution from the Pfizer Vaccine demonstrated distribution to the gonads in males and females; and

(5) examination of the concentration of the distribution marker was stopped by Pfizer at the 48 hour post-vaccination mark at which point concentrations were rising exponentially.

f) it was thereby obvious to the Respondents that:

1 the TGA Pfizer Genotoxicity Conclusions were:

(1) made without basis in the evidence known to the Respondents;

(2) opposed to the evidence known to the Respondents.

2 the Pfizer Vaccine was demonstrably:

(1) not safe;

(2) subject to significant known genotoxicity and carcinogenicity risks.

Particulars

The Pfizer Nonclinical Evaluation Report - pg. 13, 40, 43, pg. 45 - Table 4.2

The Pfizer Original AUSPAR – pg. 14,15.

Publicly Available - Patisiran Product Information - https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210922s000lbl.pdf. pg. 6, 7.

"ICH M7 Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk - Scientific guideline" Pg. 12 – s. 7.3.
https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-m7r1-assessment-control-dna-reactive-mutagenic-impurities-pharmaceuticals-limit_en.pdf
Published since 3 February, 2018.

KNOWN GENOTOXICITY AND CARCINOGENICITY ISSUES – MODERNA VACCINE

98. From prior to, on or about 9 August 2021, and prior to the Moderna Approval the Respondents knew of the following matters evidencing significant genotoxicity and carcinogenicity risks in respect of the Moderna Vaccine disclosed in the totality of data relied upon by the Respondents in granting the Pfizer Approval **("the Known Moderna Genotoxicity Issues")**:

a) no genotoxicity studies were:

1 conducted for the Moderna Vaccine;

2 sought by the Respondents prior to the Moderna Approval or at all.

b) that Moderna has asserted that and the Respondents accepted that the Moderna Vaccine mRNA and lipid components were not expected to be genotoxic:

1 without any evidentiary or scientific basis;

2 as a basis for explanation of the absence of genotoxicity studies.

c) the Respondents had made the following determinations and determined that they were appropriate for publication in the Moderna Product Information **("the TGA Moderna Genotoxicity Determinations")**:

1 the novel lipid components of the Moderna Vaccine were negative in the bacterial reverse mutation Ames test and in vitro micronucleus test in human peripheral blood lymphocytes;

2 a luciferase mRNA in SM102-containing lipid nanoparticles was negative in a rat bone marrow micronucleus assay (IV dose of SM-102 28.5 mg/kg, PEG-2000-DMG 2.8 mg/kg);

3 a surrogate ZIKA mRNA-based vaccine formulated in SM-102-containing lipid nanoparticles induced micronuclei in male rats but not in females (IV dose of SM-102 60 mg/kg, PEG-2000-DMG 6 mg/kg;

4 the weight of evidence suggests the genotoxicity potential of the novel lipid components SM-102 and PEG-2000-DMG is very low;

5 the other components of Moderna Vaccine (other lipids and mRNA) are not expected to be genotoxic.

d) the TGA Moderna Genotoxicity Determinations were made in circumstances where in truth:

1 the genotoxicity study result for the Moderna Vaccine published in the Moderna Product Information but is not reported or considered in the Moderna Original AUSPAR;

2 studies performed on the Moderna lipid nanoparticles showed a marker for genotoxic potential in the micronuclei in male rats indicating positive genotoxicity potential in the Moderna Vaccine;

3 further information on the studies performed and further detail on genotoxicity nonclinical on data:

(1) was required to be requested and evaluated by the Respondents;

(2) was not sought by the Respondents before the Moderna Approval or at all.

Particulars

1. The Moderna Original AUSPAR - Pg. 15.
2. The Moderna Product Information - Pg. 24.

KNOWN GENOTOXICITY AND CARCINOGENICITY ISSUES – ASTRAZENECA VACCINE

99. From prior to, on or about 28 January, 2021, and prior to the AstraZeneca Approval the Respondents knew of the following matters evidencing significant genotoxicity and carcinogenicity risks in respect of the AstraZeneca Vaccine disclosed in the totality of

data relied upon by the Respondents in granting the AstraZeneca Approval **("the Known AstraZeneca Genotoxicity Issues")**:

a) three different animal studies using three different AstraZeneca Vaccine vectors examined the biodistribution in the bodies of the mice post-vaccination which found in one of the studies that the vector was found to have migrated to the subject's:

    1 heart;

    2 liver;

    3 ovaries;

    4 testes; and

    5 lymph nodes.

b) no genotoxicity studies were performed in respect of the AstraZeneca Vaccine;

c) no carcinogenicity studies were performed in respect of the AstraZeneca Vaccine;

d) that the absence of genotoxicity and carcinogenicity studies in the AstraZeneca Vaccine were determined by the Respondents to be justified on the erroneous bases that the AstraZeneca Vaccine was a vaccine in circumstances where in truth:

    1 it was concluded by the Respondents to be:

        (1) the first GMO vaccine in Australia ever;

        (2) the first vaccine of its kind in Australia;

    2 was acknowledged thereby to be completely novel in nature;

3 thereby incapable of being approached on the basis of being a known therapy.

e) the Respondents through the OTGR had determined by 8 February, 2021 and prior to the AstraZeneca Approvals that:

1 adenoviruses as used in the AstraZeneca Vaccine have led to random integration of the virus DNA into the host genome;

2 experimental studies in cell lines and mice have described possible integration of adenovirus vectors as used in the AstraZeneca Vaccine into host genomes at very low frequencies;

3 the GMO in the AstraZeneca Vaccine is expected to be confined to the intra-muscular injection site and the draining lymph nodes of the human host;

4 adenoviral vectors including the AstraZeneca Vaccine vector have been used extensively in clinical studies as a vaccine and gene therapy for almost 30 years and there is no evidence of integration of viral DNA into the host genome and so the consequences of integration of viral DNA into a host cell genome will not be further discussed;

5 such determinations being made by the Respondents:

(1) despite a risk of genome integration this was dismissed and not further evaluated;

(2) despite biodistribution studies demonstrating distribution to the ovaries and testes, thereby further genome integration, genotoxicity and germ cell integration studies should have been performed;

(3) known and published clinical evidence of:

a) integration of foreign DNA into the host human genome;

b) the use of Adenoviral Vector DNA such as is used in the AstraZeneca Vaccine can possibly lead to

i) integration of foreign DNA into host genomes;

ii) the disruption of genes in the host chromosome;

iii) mutations of the host chromosome.

c) foreign DNA integration can alter cellular DNA epigenetic signals immediately at the site of insertion;

d) extreme caution being required when injecting adenoviral vectors into humans;

e) modern adenovirus vectors as used in the AstraZeneca Vaccine are not dissimilar from older vectors which caused catastrophic experiences;

f) that as opposed to the AstraZeneca Vaccine more careful consideration of conventional vaccines based on recombinant spike protein to have been a safer choice.

(4) biodistribution data referenced did not take into account the study where distribution to gonads was demonstrated.

f) the Respondents determined that the AstraZeneca vector had negligible risks of **("the TGA AstraZeneca Genotoxicity Conclusions")**:

1 integrating into the human genome; or

2 recombination with human adenovirus.

g) it was thereby obvious to the Respondents that:

1 the TGA AstraZeneca Genotoxicity Conclusions were:

(1) made without basis in the evidence known to the Respondents;

(2) opposed to the evidence known to the Respondents;

(3) made in circumstances where in truth the matters asserted could not be known to the Respondents.

2 the AstraZeneca Vaccine was:

(1) not demonstrably safe;

(2) subject to significant known genotoxicity risks.

Particulars

The AstraZeneca Delegate's Overview, pg. 8, 9
The AstraZeneca Auspar, pg. 10.
Risk Assessment And Management Plan – full version, Department of Health and Aged Care, Office of the Gene Regulator, Licence number DIR 180 https://www.ogtr.gov.au/sites/default/files/2021-06/dir180-full_risk_assessment_and_risk_management_plan.pdf - DIR 180. Pg. 2, 6, 9.
Commercial supply of a genetically modified COVID-19 vaccine, dated 8 February 2021, https://www.ogtr.gov.au/gmo-dealings/dealings-involving-intentional-release/dir-180.

Study of the known possibility of integration of foreign DNA into the host human genome citing scientific data and studies to this effect since 2000 and known to the Respondents at the time of the AstraZeneca Approval:
"Adenoviral Vector DNA- and SARS-CoV-2 mRNA-

Based Covid-19 Vaccines: Possible Integration into the Human Genome - Are Adenoviral Genes Expressed in Vector-based Vaccines?" Doerfler W. Virus Res. 2021 Sep;302:198466.

DETERMINING VACCINE GENOTOXICITY AND CARCINOGENICITY – INTERNATIONAL GUIDELINES AND TGA FAILURES

100. WHO Guidelines published in 2014 and known to the Respondents at the time of the Approvals **("the WHO Genotoxicity and Carcinogenicity Guidelines")** stated a standard battery of genotoxicity studies is generally recommended for most novel adjuvants that are (or contain) new chemical entities.

Particulars

"Guidelines on the nonclinical evaluation of vaccine adjuvants and adjuvanted vaccines" WHO Technical Report Series No. 987, 2014 – World Health Organisation - Annex 2 https://cdn.who.int/media/docs/default-source/biologicals/vaccine-standardization/trs_987_annex2.pdf?sfvrsn=ea91caca_3&download=true Page 85: D.2.5 Genotoxicity and carcinogenicity studies.

101. Despite the provisions of the WHO Genotoxicity and Carcinogenicity Guidelines and the presence of novel adjuvants in the Vaccines, the Respondents at no point obtained or sought genotoxicity and carcinogenicity studies from the Sponsors without:

a) explanation; or

b) evident basis.

102. The European Agency for the Evaluation of Medicinal Products note for guidance on carcinogenic potential in medicines seeking registration published on 25 July, 2002 and known to the Respondents prior to the Approvals **("the EMA Carcinogenicity Guidelines")** states that the objective of carcinogenicity studies

is to identify a tumorigenic potential in animals as part of the assessment of the relevant risk in humans.

Particulars

"Note for Guidance on Carcinogenic Potential" Committee for Proprietary Medicinal Products. The European Agency for the Evaluation of Medicinal Products – Evaluation of Medicines for Human Use. Dated 25 July, 2002 and commencing operation in January, 2003.

103. Despite the provisions of the EMA Carcinogenicity Guidelines and the presence of novel adjuvants in the Vaccines, the Respondents at no point obtained or sought genotoxicity and carcinogenicity studies from the Sponsors:

a) without:

1 explanation; or

2 evident basis.

b) contrary to the EMA Carcinogenicity Guidelines by:

1 not regarding or applying the true objective of carcinogenicity testing being to identify and determine the potential of carcinogenicity in the Vaccines;

2 abrogating the purpose of and requirement for the study on the basis of mere postulation without basis that the risk was unlikely.

TGA GENE THERAPY GUIDELINES

104. The following international guidelines were published, known, and applicable to the conduct of the Respondents in considering and granting the Approvals upon the data provided by the Sponsors and relied upon by the Respondents **("the TGA and International Gene Therapy Guidelines")**:

a) The TGA guideline in respect of medicines produced by genetic manipulation, applicable to the mRNA Vaccines and the Approvals relevantly states **("the TGA Genetically Manipulated Medicines Guidelines")**:

1 medicines produced by genetic manipulation consist of:

(1) medicines derived or produced from GMOs (biological medicines);

(2) GMOs that are intended for use as medicinal agents (GMO medicines);

(3) regulation of genetically modified organisms in Australia and dealings with GMOs, including their research, manufacture, propagation and importation, are prohibited:

a) unless explicitly authorised under the *Gene Technology Act 2000* (Cth); and

b) in order to protect human health and safety, and the environment;

c) including:

i) all dealings with live, viable GMOs;

ii) those GMOs intended for use as, or in the manufacturing or testing of medicines.

(4) the Office of the Gene Technology Regulator (OGTR):

a) administers the *Gene Technology Act 2000* (Cth);

b) maintains a publicly accessible record of all dealings in Australia that involve GMOs or GM products (the Record).

(5) the Record includes information on all GM products that are approved for supply in Australia under a number of Acts, including therapeutic goods containing GM products that are approved for supply under the *Therapeutic Goods Act 1989* (Cth);

(6) the Respondents are required to inform the Office of Gene Technology Regulator about applications for the supply of therapeutic goods that contain GMOs;

(7) guidance on quality issues for recombinant or biotechnological medicines is provided in European Union guidelines **("the European GMO Guidelines")**, which includes production and quality control of medicinal products derived by recombinant DNA technology, and states expressly that:

a) appropriate attention needs to be given to the quality of all reagents used in production, including components of fermentation media;

b) specifications for these are to be included in documentation and they must comply with any relevant European recommendations;

c) tests for potency, abnormal toxicity, pyrogenicity and sterility etc., which apply to products made by conventional methods, will also apply to products made by rDNA technology;

d) the purpose of molecular genetic studies is to establish that:

i) the correct sequence has been made and incorporated in the host cell; and

ii) that both the structure and the number of copies of the inserted sequence are

maintained within the cell during culture to the end of production.

e) products expressed in foreign hosts:

   i) may deviate structurally, biologically or immunologically from their natural counterparts;

   ii) may suffer alterations leading to undesirable clinical effects which can arise:

      1. at posttranslational level; or

      2. during production or purification.

   iii) presence must be justified and shown to be consistently controlled.

f) unintended variability in the culture during production may lead to changes:

   i) which favour the expression of other genes in the host/vector system; or

   ii) which cause alteration in the product, resulting in:

      1. differing yield;

      2. change to the product itself (e.g. in the nature and degree of glycosylation); and/or

3. quantitative and qualitative differences in the impurities present.

g) procedures to ensure consistency of production conditions as well as the final product are imperative;

h) full details of the nucleotide sequence of the gene of interest and of the flanking control regions of the expression vector should be provided to confirm that the construction is identical to that desired;

i) southern blot analysis should be used, in addition to sequence analysis of mRNA or cDNA molecules in order to provide convincing data on the integrity of the expressed gene(s);

j) sufficient sequence information to characterise the gene product adequately should be obtained by the regulator.

b) the EMA Guideline on non-clinical testing for inadvertent germline transmission of gene transfer vectors in effect from May, 2007 requires that:

1 no gene therapy trials may be carried out which result in modifications to the subject´s germline genetic identity;

2 it is important to appropriately assess if there is a risk of inadvertent germline transmission;

3 in vivo use of naked DNA, genetically modified viruses, viral or non-viral vectors may be associated with a risk of vertical germline transmission of vector DNA which should be assessed;

4 the relative risk for germline transmission of each vector should be based on its:

(1) biodistribution profile;

(2) vector replication; and

(3) integration ability.

5 the route of administration is an important parameter as parenteral administration of vector could potentially lead to the presence of vector DNA within the gonads;

6 if a vector is detected in gonads, more detailed information will be needed;

7 a positive signal in the germline cells will require elucidation of whether stem cells are transduced;

8 if a positive signal is observed in gonadal tissues, additional testing will be needed;

9 the next consideration should be what type of population will be treated;

10 in the case of definitely sterile patients there is no need to perform germline transmission studies before the first use in man - in all other cases germline transmission studies should be performed;

11 prior to marketing authorisation application biodistribution studies should be performed:

(1) using the final vector construct with the gene of interest;

(2) with two dose levels at minimum;

(3) in at least two species, one of which should be a non-rodent species;

(4) using both sexes.

12 any deviation from this principle needs to be justified;

13 general principles for non-clinical germline transmission studies require:

(1) non clinical pharmacological studies, biodistribution studies in animals (2 different species and 2 sexes), one rodent and one non-rodent;

(2) no gene therapy trials may be carried out which result in modifications to the subject´s germline genetic identity where:

a) the vector is distributed to the gonads;

b) the population intended to be treated are not sterile;

c) the vector-derived DNA is detected within oocytes or sperm cells (cell fractionation studies).

c) the World Health Organisation in its COVID-19 Vaccines: Safety Surveillance Manual published on 22 December, 2020 stated that:

1 in developing a potential mRNA vaccine in respect of Covid including the mRNA Vaccines, developers were seeking to use genetic instructions in the form of DNA or RNA:

(1) wherein nucleic acid is inserted into human cells;

(2) which produces copies of the virus protein;

(3) in vaccines:

a) which will encode the virus's spike protein;

b) the production of which involves making genetic material only, not the virus;

c) which are unproven;

d) using technology which no other licensed vaccine uses.

2 the proposed mRNA Vaccines for Covid being developed at that time including the mRNA Vaccines:

(1) carried theoretical risks relating to:

a) immune-mediated events;

b) local and systemic reactions due to pro-inflammatory properties of the plasmids carrying the DNA sequence or the mRNA segment.

(2) are based on mRNA coding for an antigenic protein that poses the risk of integration into host cell DNA;

(3) introduce into the recipient residual molecules, originating from raw materials, which could induce unexpected immune responses.

d) the European Medicines Agency ICH Guideline on Non-Clinical Safety Studies For The Conduct Of Human Clinical Trials and Marketing Authorisation For Pharmaceuticals published in December, 2009 required that:

1 a complete battery of tests for genotoxicity should be completed before initiation of Phase II trials;

2 if a positive finding occurs, an assessment, and then possibly additional testing, should be conducted to determine if further administration to humans is still appropriate;

3 before the inclusion of pregnant women in clinical trials, all female reproduction toxicity studies and the standard battery of genotoxicity tests should be conducted;

4 safety data from previous human exposure should be evaluated.

Particulars

TGA Guidance 21: Medicines produced by genetic manipulation Previously ARGPM Appendix 21: Medicines produced by genetic manipulation, Version 1.0, July 2013. pg. 5 - 6. https://www.tga.gov.au/sites/default/files/pm-argpm-guidance-21.pdf.

European Medicines Agency - Pre-authorisation Evaluation of Medicines for Human Use - Committee For Medicinal Products For Human Use. "Guideline On Non-Clinical Testing For Inadvertent Germline Transmission Of Gene Transfer Vectors". https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-non-clinical-testing-inadvertent-germline-transmission-gene-transfer-vectors_en.pdf. Annexed as Appendix 13. dated 16 November 2006 and coming into operation on May 2007. Pg. 3, 4, 5, 6, 8

World Health Organisation – "Covid-19 vaccines: safety surveillance manual" 22 December 2020. https://www.who.int/publications/i/item/9789240032781. Pg. 5, 8,

The European Medicines Agency "ICH Guideline on non-clinical safety studies for the conduct of human clinical trials and marketing authorisation for pharmaceuticals" published in December, 2009. https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-m3r2-non-clinical-safety-studies-conduct-human-clinical-trials-marketing-authorisation_en.pdf. Pg. 18, 20

Production And Quality Control Of Medicinal Products Derived By Recombinant Dna Technology Guideline Title Production and Quality Control of Medicinal Products derived by recombinant DNA Technology Legislative basis Directive 75/318/EEC as amended Date of first adoption First adopted June 1987 This version adopted December 1994 Date of entry into force July 1995.

https://www.ema.europa.eu/en/documents/scientific-guideline/production-quality-control-medicinal-products-derived-recombinant-dna-technology_en.pdf.
Pg. 205–216 of Rules 1998 (3A)–3AB1a).

105. In granting the Approvals, the Respondents wholly, without proper basis and knowingly abrogated the TGA and International Gene Therapy Guidelines by granting the Approvals where:

a) there was a known risk of germline integration based on WHO guideline for nucleic acid COVID 19 vaccines, and with mRNA vaccines first in human use in this clinical trial the risk of germline integration was definitively unknown;

b) novel lipid adjuvants did not undergo genotoxicity studies, with justification referencing studies performed that were not made available to the Respondents, and that were performed on a dissimilar lipid compound which demonstrated teratogenicity in animal studies;

c) there was known evidence of distribution to gonads based on lipid distribution studies of the Vaccines;

d) studies on distribution or elimination of the nucleic acid or on the produced spike protein were not performed on the Vaccines nor sought by the Respondents;

e) no studies to assess for presence of nucleic acid in the oocytes/ sperm cells were performed nor sought by the Respondents;

f) no evaluation for chromosomal integration in oocytes and / or sperm cells were performed nor sought by the Respondents;

g) according to International Gene Therapy Guidelines the Vaccines in the known circumstances:

1 should never had even been approved for human trials;

2 should never have been granted the Approvals by the Respondents.

Particulars

The Pfizer Original AUSPAR;
The Moderna Original AUSPAR;
The AstraZeneca Original AUSPAR.

KNOWN NOVEL EXCIPIENT GUIDELINES

106. From prior to the Approvals, the Respondents knew of the provisions and the requirements to abide by the following guidelines relevant to the approval of vaccines containing novel excipients as in the case of the Vaccines approved under the Approvals **("the Novel Excipient Guideline Requirements")**:

a) the EU guideline adopted by the TGA in respect of repeated dose toxicity published on 18 March, 2010 states that:

1 the toxicology and pharmacokinetics of an excipient used for the first time in the pharmaceutical field must be investigated;

2 the same pivotal studies as for a new active substance should be performed;

3 studies with the active substance together with the excipients used in the final product may be needed.

b) the TGA guideline published in February, 2018 in respect of administrative information and prescribing information in Australia applicable to applications received by the TGA from 9 February 2018 states that:

1 nonclinical overview is required when the product includes a novel excipient or involves the novel use of an excipient;

2 where the applicant claims essentially similarity to a registered product the nonclinical overview should focus on:

(1) the grounds for claiming essential similarity; and, if applicable;

(2) the additional data to demonstrate evidence of the equivalence of safety and efficacy properties.

c) the European Agency for the Evaluation of Medicinal Products stated in a technical document in respect of the registration of pharmaceuticals for human use on 20 February, 2003 that in respect of non-clinical overview of a vaccine that where a drug product includes a novel excipient an assessment of the information regarding the safety of that novel excipient should be provided.

1 The Respondents failed to abide by these known guidelines in their acceptance of the Sponsors' justifications for why studies were not performed on the adjuvants contained in the Vaccines.

Particulars

Committee for Human Medicinal Products (CHMP) Guideline on repeated dose toxicity. 18 March 2010. https://web.archive.org.au/awa/20220816022836mp_/https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-repeated-dose-toxicity-revision-1_en.pdf. Page 4 s. 5.2.

CTD Module 1.4.2 Administrative information and prescribing information for Australia Applicable to applications received by the TGA from 9 February 2018 Version 4.0, February 2018. Therapeutic Goods Administration. https://www.tga.gov.au/sites/default/files/ctd-module-1-180219.pdf. Page 31 Module 2.4.

The European Agency for Evaluation of Medicinal Products. 20 February, 2003. ICH M4S Common Technical Document for the Registration of Pharmaceuticals for Human Use – Safety. Non-Clinical Overview and Nonclinical Summaries of Module 2 – Organisation of Module 4. Pg. 5.

KNOWN FAILURE TO EXAMINE PFIZER mRNA SEQUENCING – UNKNOWN mRNA

107. The Respondents knew prior to and at the time of the mRNA Vaccine Approvals and relevantly to the safety of the Pfizer Vaccine the following which was relied upon in the Pfizer Approval by the Respondents **("the Known Failure to Examine Pfizer MRNA Sequencing")**:

a) that an oncomir is a microRNA that is known and established scientifically to be associated with cancer;

b) the coding sequence for the Pfizer Vaccine contains several regions:

1 in addition to the mRNA encoding spike protein;

2 being 3'-UTR and 5'-UTR **("the Unknown Pfizer mRNA Regions")**;

c) the Unknown Pfizer mRNA Regions:

1 were never examined in detail by the Respondents prior to the Pfizer Approval or at all;

2 were unknown to the Respondents in their contents and untranslated at the time of the Pfizer Approval and since that time;

3 may contain oncomirs, the answer to which:

(1) was unknown to the Respondents at the time of the Pfizer Approval and presently;

(2) ought to have been sought and understood by the Respondents prior to the Pfizer Approval:

(3) must be known in order to declare the Pfizer Vaccine safe;

(4) remains unknown to the Respondents.

Particulars

The knowledge of the Respondents alleged in the Known Failure to Examine Pfizer MRNA Sequencing arises from the Respondents response to FOI3604 request which sought “all documents related to the TGA’s assessment of the risk and/or presence of oncomirs (oncogenic miRNA-microRNA) comprised within the Comirnaty mRNA active ingredient (mRNA genomic sequence)”, the response of the Respondents being that documents requested do not exist.

KNOWN PFIZER NOVEL EXCIPIENT SAFETY RISK

108. The Respondents knew prior to 15 January, 2021 and prior to and at the time of the Pfizer Approval and relevantly to the novel excipient safety of the Pfizer Vaccine the following which was relied upon in the Pfizer Approval by the Respondents **(“the Known Pfizer Novel Excipient Safety Risk”)**:

a) Pfizer did not study, nor did the Respondents receive, seek or require data upon, prior to the Pfizer Approval in respect of:

1 the toxicity of:

(1) the Pfizer Lipid Nanoparticle Formulation;

(2) the Pfizer Novel Excipients;

(3) the safety of the Pfizer Novel Excipients in a second species;

b) that the Respondents determined and accepted that prior to the Pfizer Approval in the Pfizer Nonclinical Trial or at all that there was no adequate assessment of the potential of the Pfizer Lipid Nanoparticle or the Pfizer Vaccine to produce:

1 complement activation; or

2 stimulation of cytokine release.

c) the statement and actual fact that Pfizer would provide no further data in addition to that provided in the Pfizer Nonclinical Study would be provided to the Respondents or at all in relation to the safety of the Pfizer Novel Excipients:

1 was stated by Pfizer prior to the Pfizer Approval;

2 was considered acceptable to the TGA Respondents and accepted by the TGA in proceeding with the Pfizer Approval.

d) in response to an enquiry by the TGA regarding the toxicity assessment of the novel excipients in the Pfizer Liquid Nanoparticle Formulation, Pfizer stated that **("the Pfizer Novel Excipient Justification")**:

1 the product Patisiran is:

(1) administered as a lipid nanoparticle formulation;

(2) approved in the US, Europe and Canada;

(3) the subject of approvals which were not reviewed by the Respondents;

(4) contains lipids DLin-MC3-DMA and PEG2000-C DMG **("the Patisiran Lipids")**;

2 that the Pfizer Novel Excipients (ALC-0315 and ALC-0159) respectively:

(1) have a similar toxicity profile to the Patisiran Lipids;

(2) are structurally and functionally similar to the Patisiran Lipids.

3 the Respondents determined:

(1) that there was structural similarity between:

a) the Pfizer Novel Excipient ALC-0159; and

b) the Patisiran Lipid PEG2000-C DMG.

4 there was in fact no similarity between the structures of **("the Novel Excipient Dissimilarity")**:

(1) the Pfizer Novel Excipient ALC-0315; and

(2) the Patisiran Lipid DLin-MC3-DMA.

5 despite the evident Novel Excipient Dissimilarity, the TGA accepted the Pfizer Novel Excipients Justification:

(1) as a basis for the determination that it was acceptable that:

a) Pfizer did not conduct repeat dose toxicity studies in a second animal species with the Pfizer Novel Excipients; and

b) the Pfizer Vaccine Approval Proceed;

(2) because the TGA had determined that:

a) the Pfizer Novel Excipients and the Patisiran Lipids are all amino or amino/PEG lipids; and

b) the potential lifetime exposure of a recipient to the Pfizer Novel Excipients is expected to be low.

6 the Pfizer Novel Excipient Justification undertaken by the Respondents occurred in the known circumstances of:

(1) the TGA's knowledge of dissimilarity between the Pfizer Novel Excipients and the Patisiran Lipids;

(2) Patisiran being a drug known by the Respondents to be used in terminal patients and not healthy patients as in the proposed recipients of the Pfizer Vaccine;

(3) Patisiran Lipids were found and publicly known to be toxic specifically:

a) in animal studies, intravenous administration of Patisiran Lipids to pregnant rabbits resulted in:

i) developmental toxicity;

ii) embryofetal mortality; and

iii) reduced fetal body weight;

iv) maternal toxicity.

b) in a separate study Patisiran administered to pregnant rabbits resulted in:

i) embryofetal mortality;

ii) reduced fetal body weight; and

iii) maternal toxicity.

(4) the acceptance of the Pfizer Novel Excipient Justification is unacceptable because:

a) spleen and lymph node histological changes did not normalise at the recovery phase;

b) the temperature change did not recover by the 3-week recovery phase;

c) liver vacuolation:

i) was not further investigated by the Respondents or Pfizer; and

ii) was simply reported as 'recovered' without an adequate evaluation of the underlying pathophysiology of this finding and the potential risks for use in humans.

d) the dose interval was known to be inadequate:

i) given the very long, and entirely unknown half-life of the lipid nanoparticles;

ii) not appropriate given that with short duration of immunity and unknown long-term protection that repeat doses were likely required; and

iii) the interval for booster doses was required to be formally examined on both efficacy and toxicity evaluations.

Particulars

The Pfizer Nonclinical Evaluation Report – Pg. 5, 12.
Patisiran Product / Prescribing Information - Pg. 6 -7.

KNOWN PFIZER NONCLINICAL IMMUNUE RESPONSE ISSUES

109. The Respondents knew prior to 15 January, 2021 and prior to and at the time of the Pfizer Approval and relevantly to the safety of and immune responses resulting from the Pfizer Vaccine the following which was relied upon in the Pfizer Approval by the Respondents **("the Known Pfizer Immune Response Risks")**:

a) Pfizer had determined that the findings in the Pfizer Nonclinical Trial Data presented to and then accepted and adopted by the Respondents of large unstained cells in the Pfizer Vaccine rat recipients were **("the False Pixatimod Justification")**:

1 consistent with:

(1) immune stimulation; and

(2) inflammatory responses.

2 determined by the Respondents to be of no consequence or bar to the Pfizer Approval based upon the erroneous assertion that increased large unstained cells has been reported for Pixatimod:

(1) being an immune stimulating agent;

(2) citing as a basis for the assertion, the study "Hammond et al. 2018" **("the Hammond Study")**; or

(3) acute viral infections;

(4) in circumstances where in truth the Hammond Study disclosed, as was known to the Respondents, that:

a) the experiment that was the subject of the Hammond Study was terminated on day 18 post-treatment initiation or 25 days post-inoculation due to emerging toxicities in all treatment groups;

b) following exposure to Pixatimod there were striking and the significant increases in large unstained cells in recipients;

c) the authors of the Hammond Study concluded that:

i) given the potent immune stimulatory activity of Pixatimod:

1. it is important to characterize toxicologic responses that could be associated with excessive activation of the immune system; and

2. the elevations in body temperature and large unstained cells in recipients were particularly noteworthy.

b) the False Pixatimod Justification:

1 was accepted and advanced by the Respondents as:

(1) an adequate explanation for the adverse finding of Large Unstained Cells in the Pfizer Nonclinical Study; and

(2) as a basis to proceed to the Pfizer Approval.

2 occurred in circumstances where:

(1) the Hammond Study expressly described the importance of characterising the toxicological responses that could be associated with excessive activation of the immune system;

(2) immune toxicity studies were:

a) not performed by Pfizer; or

b) required to be performed or sought by the Respondents;

(3) the Phase I monotherapy clinical trial of Pixatimod:

a) was known by the Respondents to be for the treatment of advanced metastatic cancer:

i) that had relapsed; and

ii) for which there were no further treatment options;

b) for palliative patients with almost zero survival

prospect;

c) produced data which was from a Phase 1 trial;

(4) the Pfizer Vaccine was for use on a healthy population;

(5) accepting data from the trial of such a product in the Hammond Study as a basis for regulatory approval for a healthy population was completely unacceptable;

(6) it was and is a known scientifically established and accepted fact, including by the Respondents that increases in large unstained cell numbers are an indication typically only of either:

a) viral disease; or

b) leukemia.

(7) the finding of large unstained cell in the Pfizer Nonclinical Trial should have raised a signal to the TGA that:

a) there was a problem with the Pfizer Lipid Nanoparticle;

b) further investigation was warranted;

(8) acceptance of the False Pixatimod Justification by the Respondents without further investigation was unacceptable.

Particulars

The Pfizer Nonclinical Evaluation Report – pg. 11.

The Hammond Study - “Immunomodulatory activities of pixatimod: emerging nonclinical and clinical data, and its potential utility in combination with PD-1 inhibitors”. Hammond et al. J Immunother Cancer 2018 Jun 14;6(1):54. doi: 10.1186/s40425-018-0363-5. https://jitc.bmj.com/content/6/1/54.long.

The known pathology related to Large Unstained Cell numbers as in the Pfizer Nonclinical Study is exemplified in such studies as follows:

The Mouse Adult Gross Anatomy Ontology and Mammalian Phenotype Ontology rate genome browser (a clinical database and website describing rat models in clinical trials) - https://rgd.mcw.edu/rgdweb/ontology/annot.html?acc_id=MP:0012362 – wherein the indication applied to the term "increased large unstained cell (LUC) number" states: Aberrations in the count of large unstained cells may be indicative of viral disease or leukemia.

KNOWN VACCINES' NOVEL ADJUVANT OIL CARCINOGEN

110. The Respondents knew at all material times prior to the Approvals with respect to a safety issue relating to the Vaccines' adjuvants that **("the Known Oil Adjuvant Risk")**:

a) a mineral or synthetic oil adjuvant:

1 is used in each of the Vaccines **("the Vaccines Adjuvants")**;

2 is scientifically known and established, including known to the Respondents that is to have carcinogenic potential in the animal host due to minimal metabolism of the oils;

3 where used in the Vaccines is the first time a mineral or synthetic oil adjuvant has been utilised in vaccines for human use; and

4 the use of mineral or synthetic oil adjuvant in the Vaccines indicated that rigorous evaluation for the known risks was reasonably required before the Approvals.

b) no testing of the Vaccines Adjuvants has been :

1 undertaken by the Sponsors;

2 sought or obtained by the Respondents prior to the Approvals or at

all.

Particulars

See - US Patent 3149036, Patented Sept 15 1964, for a novel vaccine adjuvant. “The need therefore exists for an adjuvant which is relatively nontoxic to the host and which will potentiate the antibody response to all antigens and additionally will maintain the titer over a long period of time thus endowing the host with a long period of immunity. In an attempt to satisfy the current needs, it had been proposed to use a mineral oil emulsion in which the antigen was incorporated in the aqueous phase. While this seemed to present some promise of providing an adjuvant type composition, it was found that it was not in fact a suitable solution because the mineral oil was not metabolized by the animal host and therefore could be a carcinogen.”

The Respondents knew of the Vaccine Adjuvants by way of the data provided to the Respondents before and in support of the Approvals of the Vaccines.

KNOWN VACCINES’ POLYETHYLENE GLYCOL RISK

111. The Respondents knew at all material times prior to the Approvals in respect of the safety issue in respect of the use of polyethylene glycol in the mRNA Vaccines that **(“the Known PEG Risk”)**:

a) polyethylene glycol (“PEG”):

1 is a lipid shell and has a triple role in the mRNA Vaccines being:

(1) to protect the genetic material from degradation prior to cellular uptake;

(2) facilitate cellular uptake; and

(3) act as an adjuvant.

2 has been known since at least the time of the Approvals including by

the Respondents to have, a high prevalence in national populations:

(1) of up to 72% in populations with no prior exposure to PEG-based medical therapy; and

(2) which can have important consequences for any PEG-based therapeutics; and

(3) the existence of which is correlated with:

a) a prevalence in populations of anti-PEG antibodies;

b) consequently in PEGylated-based therapeutics such as the Vaccines:

i) an impairment of therapeutic efficacy;

ii) the development of severe adverse effects; and

iii) more common and more severe reactions upon re-exposure.

Particulars

The Known PEG Risk was well documented and accepted scientifically including in for example the following studies:

1. “Antibodies Against Polyethylene Glycol in Human Blood: A Literature Review”. Hong, L., Wang, Z., Wei, X., Shi, J. & Li, C. (2020). Journal of Pharmacological and Toxicological Methods 102: 106678. https://doi.org/10.1016/j.vascn.2020.106678

2. “PEGylation and Anti-PEG Antibodies. Engineering of Biomaterials for Drug Delivery Systems”. Lila, A. S., Shimizu, A. T. & Ishida, T. (2018). Woodhead Publishing 51-68. https://doi.org/10.1016/B978-0-08-101750-0.00003-9

3. “Pre-existing Anti–Polyethylene Glycol Antibody Linked to First-Exposure Allergic Reactions to Pegnivacogin, A PEGylated RNA Aptamer”. Ganson, N. J., Povsic, T. J., Sullenger, B. A., Alexander, J. H., Zelenkofske, S. L., ... Hershfield, M. S. (2016). Journal of Allergy and Clinical Immunology 137(5): 1610-1613. https://doi.org/10.1016/j.jaci.2015.10.034

KNOWN mRNA SPIKE PROTEIN RISKS

112. From prior to, on or about 15 January, 2021, and prior to the mRNA Vaccines Approvals, the Respondents knew of the following matters evidencing significant safety, efficacy and risk-benefit issues in respect of the mRNA spike proteins produced by the mRNA Vaccines **(“the mRNA Spike Proteins”)** and their effect disclosed in the totality of data relied upon by the Respondents in granting the mRNA Vaccines Approvals:

a) the immunofluorescence staining of cells transfected with the Pfizer Vaccine showed:

1 a reduction to the endoplasmic reticulum immunofluorescence staining;

2 some form of change to proteins;

3 in circumstances where in truth at that time it was a known scientific fact, including such fact being known to the Respondents that:

(1) the observed reduced fluorescence (red) on the endoplasmic reticulum:

a) obviously indicated less endoplasmic reticulum/ golgi protein; and

b) is a known response to cellular stress; and

c) is a sign of impending cell death;

d) would consequentially lead to ER/ cytoplasmic vacuolation, which was known by the Respondents to have been found in the histopathology in the liver cells in the Pfizer Vaccine animal studies;

(2) Pfizer's assertion accepted and adopted by the Respondents that this was likely due to lipid uptake within the cells:

a) insinuated that small globules of lipid were seen in the cells or similar:

i) despite the fact that the lipids encapsulating the product were nano lipids which would be impossible to see on plain microscopy;

ii) which if visible through coalescence, would suggest an unstable nano lipid structure;

b) could only have been accepted by the Respondents at its highest by indifference to its truth or falsity.

(3) the data obtained by the Respondents indicated an obvious and extreme safety issue in the use of the mRNA Vaccines with respect to the mRNA Spike Proteins.

b) there was no data or testing by Pfizer provided to or sought by the Respondents in respect of:

1 the distribution and degradation data on the S antigen encoding mRNA;

2 the mRNA Spike Protein at all.

c) it was known by the Respondents that:

1 the mRNA Vaccines would go into the cell;

2 then the protein that would be created can either:

(1) be put onto the surface of the cell (the membrane) which will induce an autoimmune response; or

(2) be secreted into the body.

d) the Respondents knew from at least 19 February, 2021 that the EMA had found “fragmented species” of RNA in the Pfizer Vaccine injection solution which:

1 resulted from early termination of the process of transcription from the DNA template;

2 if translated by the human cell following injection, would generate incomplete spike proteins, resulting in:

(1) an altered and unpredictable three-dimensional structure; and

(2) a physiological impact that is:

a) at best neutral; and

b) at worst detrimental to the recipient’s cellular functioning.

(3) has never been controverted in its concluded effect by any known data.

e) that the Respondents knew that the available data disclosed a significant and known safety risk in respect of the use of the mRNA Vaccines producing the mRNA Spike Protein.

Particulars

The Pfizer Nonclinical Evaluation Report. pg. 8, 20, 34-35.

EMA Public Assessment Report Comirnaty Common name: COVID-19 mRNA vaccine (nucleoside-modified) Procedure No. EMEA/H/C/005735/0000 dated 19 February, 2021, pg. 18. https://ia802202.us.archive.org/5/items/assessment-report-pfizer-july/Assessment-Report-Pfizer-February.pdf

KNOWN MRNA SPIKE PROTEIN RISKS

113. Prior to the mRNA Vaccine Approvals, it ought to have been known to the Respondents acting reasonably that the totality of data provided to them by the Sponsors in respect of the mRNA Vaccine Approvals and the scientific data reasonably available to the Respondents at that time that the spike proteins produced by the mRNA Vaccines **("the Reasonably Known mRNA Spike Protein Risks")**:

a) possessed the long-term potential to induce autoimmune diseases in indeterminate volume; and

b) carried the risk of causing blood clotting and mitochondrial damage;

c) had no long-term safety data available in existence in connection with their use in humans;

d) interfered with the body's natural immune system including Toll Like Receptors;

e) could by their nature provoke latent viral eruptions of Herpes Zoster and Epstein-Barr viruses;

f) were profoundly different from the spike protein produced by the Virus because:

1 the uracil nucleotide bases (there are 4 different nucleotide bases in RNA: uridine, cytosine, guanine and adenine) are replaced with pseudo uridine (a methylated derivative); and

2 remain in circulation for a longer and unknown period.

g) impart profound pharmacological characteristics to the mRNA molecule produced by the mRNA Vaccines including the ability to evade natural degradation as occurs in natural mRNA;

h) contribute to Antibody-Dependent Enhancement (ADE) provoked by prior:

1 Covid infection; or

2 vaccination with the mRNA Vaccines.

i) manifest as either acute or chronic autoimmune and inflammatory conditions, such that:

1 it is not possible to distinguish an ADE manifestation of disease from a non-ADE viral infection and consequently:

(1) when diseases and deaths occur shortly after vaccination with an mRNA vaccine, it can never be definitively determined, even with a full investigation, that the vaccine reaction was not a proximal cause.

j) have a high binding affinity with the following which typically take years to manifest symptomatically in:

1 tTG (associated with Celiac Disease);

2 TPO (Hashimoto’s thyroiditis);

3 myelin basic protein (multiple sclerosis); and

4 several endogenous proteins.

k) possess the long-term potential in both children and adults who received mRNA Vaccines:

1 to cause vascular endothelial damage; and

2 to trigger pro-inflammatory response in brain endothelial cells;

3 to behave as a prion and cause prion-like diseases by way of:

(1) its ability to bind to many known proteins; and

(2) induce their misfolding into potential prions;

(3) actions similar to neurodegenerative diseases, including Alzheimer's and Parkinson's disease.

Particulars

Scientific data and studies published and known to the Respondents before the mRNA Approvals include:

Classen JB. COVID-19 RNA Based Vaccines and the Risk of Prion Disease. Microbiol Infect Dis. 2021; 5(1): 1-3.

KNOWN PREGNANCY RISKS - PFIZER REPRODUCTIVE STUDY IN PFIZER NONCLINICAL EVALUATION REPORT

114. From prior to, on or about 15 January, 2021, and prior to the Pfizer Approval, the Respondents knew of the following matters evidencing significant safety and risk-benefit issues arising from reproductive and pregnancy risks in the Pfizer Vaccine recipients disclosed in the totality of data relied upon by the Respondents in granting the Pfizer Approval:

a) the Pfizer Reproductive study performed on rats was the only reproductive study performed by Pfizer in respect of the Pfizer Vaccine for which data was provided to the Respondents relating to the Pfizer Approval **("the Pfizer Reproductive Study")**;

b) the Pfizer Reproductive Study disclosed to the Respondents at that time and summarised by the Respondents in the Pfizer Nonclinical Evaluation Report that:

1 adverse findings included:

(1) swelling, which is a scientifically accepted indicator of possible:

a) liver pathology;

b) heart pathology; or

c) kidney pathology;

(2) more than double the control rate of pre-implantation loss / miscarriage in the Pfizer Vaccine recipients being:

a) 9.8% in the Pfizer Vaccine group; and

b) 4.1% in the control group.

2 the Pfizer Reproductive Study utilised historical data:

(1) to justify that increased rate of pre-implantation loss and miscarriage seen in the Pfizer Vaccine group as being “within historical range”;

(2) without providing detail of the historical data referred to;

(3) that was not subject to any quality assurance audit;

(4) with the Respondents’ acceptance of that historical data as a basis for the Pfizer Approval and pregnancy classification of B1;

a) in circumstances where in truth scientifically it had been established since prior to the Pfizer Approval that:

i) the use of historical controls is inappropriate in nearly all studies; and

ii) contemporary controls are essential; and

iii) historical data, particularly from another

laboratory should be treated with considerable caution.

3 in the Pfizer Vaccine group there was:

(1) a total of 28 anomalies or malformations in a litter size of only 21;

(2) one animal which developed a solid, dark heterogeneous mass adherent to its liver tissue that was described by the Respondents in the Pfizer Nonclinical Evaluation Report as “a liver hernia”;

(3) in circumstances where in truth in:

a) a ‘liver hernia’:

i) is not a recognised diagnostic term known to medicine; and

ii) required clarification.

b) a solid, dark heterogenous mass adherent to liver tissue is scientifically known to:

i) suggest cancer tumor growth;

ii) required further evaluation;

iii) is significant in evaluation of the need for carcinogenicity studies which were never performed on the Vaccines;

c) the following clinical observations were made in the Pfizer Reproductive Study but were not included, discussed or considered by the Respondents in the Pfizer Nonclinical Evaluation Report:

1 the occurrence of chromodacryorrhea (associated with nutritional deficiencies, chronic physiological stress, chronic light exposure, or

dacryoadenitis) was found in:

(1) 1 pup in the Pfizer Vaccine group;

(2) none in the control group.

2 that limping was found in:

(1) 26 pups in the Pfizer Vaccine group;

(2) none in control group.

3 that piloerection was found in:

(1) 2 of the pups in Pfizer Vaccine group;

(2) none in the control group.

4 that swelling was found in:

(1) 92 of the pups in Pfizer Vaccine group;

(2) none in the control group.

5 significantly higher rates in the Pfizer Vaccine Group over the control group of:

(1) hair loss;

(2) red stained fur;

(3) scabs;

(4) swelling.

6 one pup in the Pfizer Vaccine group:

(1) with symptoms being:

a) cold to touch;

b) weak;

c) thin;

d) pale;

e) cyanotic.

(2) reasonably presumed:

a) pre-terminal;

b) subsequently dying.

(3) culled from the study such that the Pfizer Reproductive Study reported no deaths.

7 a pregnancy rate of:

(1) in the Pfizer Vaccine group: 95%;

(2) in the control group: 98%

8 clinically significant differences in uterine weight:

(1) 5.55g in the Pfizer Vaccine group;

(2) 17.93g in the control group.

9 clinically significant differences in late reabsorptions:

(1) 0.2 in the Pfizer Vaccine group;

(2) 0.1 in the control group.

10 reduced causal vertebra at the rates:

(1) 2 in the Pfizer Vaccine group;

(2) none in the control group;

11 clinically significant 21% higher rate of pre-birth loss in the Pfizer Vaccine group of:

(1) 8.22% in the Pfizer Vaccine group;

(2) 6.8% in the control group.

12 the occurrence of *situs inversus totalis* in the Pfizer Vaccine pup 255 which is:

(1) a rare congenital abnormality characterized by a mirror-image transposition of both the abdominal and the thoracic organs;

(2) not reported in:

a) any of the summary tables of the Pfizer Reproductive Study; or

b) any part of the Pfizer Nonclinical Evaluation Report.

13 demonstrating a known failure by the Respondents to consider or report highly significant study findings in the Pfizer Reproductive Study:

(1) being the only study ever undertaken to examine reproductive and pregnancy risks in Pfizer Vaccine recipient;

(2) relevant to the reproductive and pregnancy risks to recipients of the Pfizer Vaccine;

(3) disclosing significant reproductive and pregnancy risks to recipients of the Pfizer Vaccine.

Particulars

The Pfizer Nonclinical Evaluation Report – pg. 55-56. Table 6.1.

The Pfizer Reproductive Study – pg. 62, 87, 88, 89, 97,100,1061.

Scientific understanding of the incorrect use of historical control data in the study is exemplified in the following scientific study:

Fest et al, "Guidelines for the Design and Statistical Analysis of Experiments Using Laboratory Animals" ILAR Journal, Vol 43, Issue 4, 2002, pages 244-258
https://doi.org/10.1093/ilar.43.4.244. 1.
pg. 256
https://academic.oup.com/ilarjournal/article/43/4/244/981872?login=false

KNOWN IMPROPER APPLICATION OF PREGNANCY SAFETY CATEGORY B1 IN PFIZER VACCINE

115. From prior to, on or about 19 January, 2021, and prior to the Pfizer Approval, the Respondents knew of the following matters and undertook the following actions relevant to the allocation of a Pregnancy Category B1 to the Pfizer Vaccine disclosed in the totality of data relied upon by the Respondents in granting the Pfizer **Approval ("the TGA Pregnancy Categorisation of the Pfizer Vaccine")** :

a) on or about 11 January, 2021, the Respondents had determined and asserted through its delegate that in respect of the Pfizer Vaccine:

1 a Pregnancy Category of B2 was appropriate;

2 the reason that Pregnancy Category of B2 was appropriate was because the Reproductive Study showed increased occurrence of supernumerary lumbar ribs in fetuses in treated female rats;

3 the following wording with respect to use in pregnancy in the Pfizer Product Information was appropriate:

There is limited experience with use of COMIRNATY in pregnant women. A combined fertility and developmental toxicity study in rats showed increased occurrence of supernumerary lumbar ribs in fetuses from COMIRNATY- treated female rats. Administration of COMIRNATY in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus.

b) by on or about 15 January, 2021, the Respondents determined and asserted that in respect of the Pfizer Vaccine:

1 Pregnancy Category of B1 was appropriate;

2 that Pregnancy Category of B1 was appropriate because **("the Basis for Pfizer Reproductive Category B1")**:

(1) because "no embryofetal effects have been noted in a combined reproductive and development study in rats";

(2) by reference to the Pfizer Reproductive Study.

3 the following wording with respect to use in pregnancy in the Pfizer Product Information was appropriate:

There is limited experience with use of COMIRNATY in pregnant women. see Effects on fertility. Administration of COMIRNATY in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus;

c) by on or about 25 January, 2021, the Respondents determined and asserted again that in respect of the Pfizer Vaccine:

1 Pregnancy Category of B1 was appropriate; and

2 combined reproductive and developmental study:

(1) showed no adverse effects on female fertility, embryofetal development and post-natal development (up to weaning) in rats;

(2) by reference to the Pfizer Reproductive Study

d) the TGA has defined the Pregnancy Category of B1 from May, 2011 as follows **("the TGA Defined B1 Pregnancy Category")**:

1 drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed;

2 studies in animals have not shown evidence of an increased occurrence of fetal damage;

3 the use of any medicine during pregnancy requires careful consideration of both risks and benefits by the treating health professional;

4 this must not be used as the sole basis of decision making in the use of medicines during pregnancy;

5 TGA does not provide advice on the use of medicines in pregnancy for specific cases.

e) the TGA Pregnancy Categorisation of the Pfizer Vaccine undertaken by the Respondents:

1 proceeded upon the known and obvious falsehood that the Pfizer Reproductivity Study showed no adverse effects on female fertility, embryofetal development and post-natal development in rats;

2 applied an obviously erroneous Pregnancy Category of B1 to the Pfizer Vaccine based upon false interpretation of the Pfizer Reproductivity Study data;

3 proceeded where based upon the actual data in the Respondents possession the most appropriate Pregnancy Category of B3 was evident;

4 resulted in:

(1) the known grant of the Pfizer Approval in circumstances of demonstrated risk to pregnant women whom received the Pfizer Vaccine;

(2) the marketing of the Pfizer Vaccine to the Australian public with Product Information which was patently false;

(3) a known and obvious breach of the TGA Pregnancy Categorisation Policy.

Particulars

The Pfizer Delegates Overview. pg. 26-27.
The Pfizer Nonclinical Evaluation Report, pg. 15.
The Pfizer AUSPAR. Pg. 8.

TGA Australian Categorisation System For Prescribing Medicines In Pregnancy – May, 2011 **("TGA Pregnancy Categorisation Policy")**
https://www.tga.gov.au/australian-categorisation-system-prescribing-medicines-pregnancy.

"Category B2. Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals are inadequate or may be lacking, but available data show no evidence of an

increased occurrence of fetal damage”

KNOWN IMPROPER APPLICATION OF PREGNANCY SAFETY CATEGORY IN ASTRAZENECA VACCINE

116. From prior to, on or about 28 January, 2021, and prior to the AstraZeneca Approval, the Respondents knew of the following matters and undertook the following actions relevant to the allocation of a Pregnancy Category B2 to the AstraZeneca Vaccine disclosed in the totality of data relied upon by the Respondents in granting the AstraZeneca Approval **(“the TGA Pregnancy Categorisation of the AstraZeneca Vaccine”)**:

a) a fertility and embryofetal development study in respect of the AstraZeneca Vaccine had at no stage been completed prior to the AstraZeneca Approval;

b) the AstraZeneca Vaccine was at that time not recommended by the Respondents for use in pregnant women as the first Vaccine choice;

c) AstraZeneca proposed to the Respondents a Pregnancy Category of B2;

d) a Pregnancy Category B2 was asserted to be and considered appropriate by the TGA on the basis that animal reproductive studies had not been completed;

e) the TGA has defined the Pregnancy Category of B2 from May, 2011 as follows **(“the TGA Defined B2 Pregnancy Category”)**:

1 a drug has been taken:

(1) by only a limited number of pregnant women and women of childbearing age;

(2) without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed.

2 studies in animals are inadequate or may be lacking, but available

data show no evidence of an increased occurrence of fetal damage.

f) the TGA Pregnancy Categorisation of the AstraZeneca Vaccine by the Respondents:

1 applied an obviously erroneous Pregnancy Category of B2 to the AstraZeneca Vaccine which was erroneous due to the absence of any nonclinical or clinical trial reproductive results having been concluded at the time of the AstraZeneca Approval;

2 proceeded where based upon the actual data in the Respondents possession the most appropriate Pregnancy Category of B3 was evident;

3 resulted in:

(1) the known grant of the AstraZeneca Approval in circumstances of obvious:

a) inappropriate assignment of Pregnancy Category of B2 was evident;

b) Pregnancy Category of B3 was obviously appropriate.

(2) the marketing of the Pfizer Vaccine to the Australian public with Product Information which was patently false;

(3) a known and obvious breach of the TGA Pregnancy Categorisation Policy.

Particulars

The AstraZeneca Nonclinical Evaluation Report. pg. 10.
The TGA Pregnancy Categorisation Policy.

KNOWN IMMUNOTOXITY RISK - PFIZER

117. From prior to, on or about 15 January, 2021, and prior to the Pfizer Approval, the Respondents knew of the following matters evidencing significant immunotoxicity safety, efficacy and risk-benefit issues in respect of the Pfizer Vaccine disclosed in the totality of data relied upon by the Respondents in granting the Pfizer Approval **("the Known Pfizer Immunotoxicity Risk")**:

a) no dedicated immunotoxicity study was conducted by Pfizer nor obtained or sought by the Respondents in respect of the Pfizer Vaccine;

b) in-vitro study on stimulation of cytokine release in human PBMC cells provided by Pfizer disclosed inconclusive results;

c) immune-stimulatory effects in the Pfizer Vaccine recipients were observed in pharmacology and repeat dose toxicity studies;

d) no vaccine-related systemic intolerance or mortality was observed in the studies;

e) The Respondents, contrary to the First In Human Medicine Policy **("the Known EMA Policy Breaches")**:

1 knew prior to the Approvals that:

(1) toxic effects were observed at just 3 x the proposed dose in the Pfizer Clinical Trials phase I/II;

(2) a narrow therapeutic window;

(3) 100mcg and 50mcg doses for Pfizer were abandoned by Pfizer in those trials due to reactogenicity and side effects, indicating:

a) high potential for toxicity especially where liver metabolism was being relied upon as the means by which the substance would be metabolised.

(4) the dose of 30mcg was subsequently chosen for the Pfizer

Vaccine;

2 approved the Pfizer Vaccine in the circumstances.

f) in a study for the release of cytokines in Pfizer Vaccine recipients:

1 the number of animals studied was:

(1) three animals;

(2) determined by the Respondents and were in fact, objectively "small";

2 there was high inter-animal variation.

g) The Pfizer Nonclinical Trial data disclosed to the Respondents that:

1 IFN-γ has been found to play a role in autoimmunity as disclosed in studies:

(1) Lees 2015;

(2) Pollard et al. 2013;

2 IFN-γ was increased in animals immunised with the Pfizer Vaccine; and

3 that autoimmune diseases are and were a potential risk from use of the Pfizer Vaccine.

h) the Respondents determined and asserted at that time that the known Pfizer Vaccine autoimmune disease risk "is addressable by the ongoing 2-year clinical studies";

i) the Known Pfizer Immunotoxicity Risk was known to the Respondents in circumstances where in truth:

1 the known lack of immunotoxicity study for the Pfizer Vaccine was in

direct breach of the European Medicines Agency ICH Guideline adopted by the TGA on non-clinical safety studies for new human pharmaceuticals which requires that:

(1) all new human pharmaceuticals should be evaluated for the potential to produce immunotoxicity using standard toxicity studies and additional immunotoxicity studies;

(2) such studies should be conducted as appropriate based on a weight-of-evidence review, including immune-related signals from standard toxicity studies;

(3) if additional immunotoxicity studies are indicated these should be completed before exposure of a large population of patients (e.g., Phase III).

2 the Respondents should not have accepted the absence of immunotoxicity study data and should have required that this be performed prior to the Approvals being granted;

3 the WHO Background document on Covid-19 disease and vaccine current at the time of the Pfizer Nonclinical Trials and the Pfizer Approval stated that:

(1) that there existed concerns of antibody-enhanced disease:

a) which could occur in individuals who have antibodies induced by immunisation;

b) which remained an important issue for:

i) vaccine development; and

ii) safety monitoring.

(2) Covid can have three stages:

a) early Covid infection is marked by viral response with

mild symptoms;

b) a pulmonary phase associated with shortness of breath with or without hypoxia; and

c) a hyper-inflammation phase marked by host inflammatory response associated with acute respiratory distress syndrome, shock, and cardiac failure.

4 the Respondents ought reasonably to have concluded from the WHO declarations as to Covid prior to the Approvals that:

(1) the mild nature of early Covid infections warranted only the consideration for effective immunisation to be prevention of serious illness and death, however;

(2) it was unacceptable that the Respondents:

a) accepted that those outcomes were never tested in the clinical trials for any of the Vaccines;

b) accepted the endpoint being set in the Vaccines clinical trials as symptomatic Covid infection, with no regard to severity of symptoms or outcomes.

5 the Respondents knew at that time that:

(1) the 'host inflammatory response", causing the hyper-inflammation stage is the very underlying pathophysiology of severe disease;

(2) the response required careful evaluation of clinical markers for inflammatory hyper response, such as injection site inflammation findings, lymph node finding, cytokines etc. after the Vaccines;

(3) several adverse findings in the Vaccines Nonclinical Trials were explained by the Sponsors and accepted and asserted by the

Respondents to be “due to inflammatory response” when:

a) this explanation should reasonably have immediately raised an signal with the Respondents:

i) for high risk of VAED based on the cytokine release pattern in the provided data;

ii) that immunotoxicity studies were required;

iii) that there was a potential for autoimmune disease.

Particulars

The Pfizer Nonclinical Evaluation Report – pg. 10, 14

The Respondents knew of the Known EMA Policy Breaches by reason of having adopted the EMA policies and further having in their possession the entirety of the Pfizer Clinical Trials data prior to the Approvals.
EMA ICH Note for Guidance on Immunity Toxicity Studies for Human Pharmaceuticals.
https://www.ema.europa.eu/en/documents/scientific-guideline/ich-s-8-immunotoxicity-studies-human-pharmaceuticals-step-5_en.pdf – pg. 4.

ICH - European Medicines Agency - December 2009 EMA/CPMP/ICH/286/1995 “ICH guideline M3(R2) on non-clinical safety studies for the conduct of human clinical trials and marketing authorisation for pharmaceuticals - Step 5” – pg. 21.

World Health Organisation. DRAFT Prepared by the SAGE Working Group on COVID-19 Vaccines 22 December 2020 Background paper on Covid-19 disease and vaccines.

Prepared by the Strategic Advisory Group of Experts (SAGE) on Immunization Working Group on COVID-19 vaccines 22 December 2020. – pg. 9.

KNOWN PFIZER ISSUES – REPORTING TO ACV AND ACV RESPONSES

118. The Advisory Committee on Vaccines **("the ACV")** provides independent medical and scientific advice:

a) to the Minister and the TGA;

b) on vaccine issues relating to:

1 the safety, quality and efficacy of vaccines supplied in Australia;

2 pre-market assessment;

3 post-market monitoring; and

4 safe use in national immunisation programs.

119. On or about 11 January, 2021 and prior to the Pfizer Approval, the Secretary through a delegate advised the following determinations made by the Respondents in respect of the safety, efficacy, risk-benefit profile of the Pfizer Vaccine and data obtained through Pfizer in the Pfizer approval application, to the ACV in the context of obtaining advice relevant to approval of the Pfizer Vaccine **("the TGA Determined Deficiencies in Pfizer Vaccine Approval Data")**:

a) known identified limitations of the data provided by Pfizer to the Respondents in respect of the Pfizer Vaccine included that:

1 safety follow-up for the Pfizer Vaccine was limited to median two months after the second dose;

2 the duration of immune response from the Pfizer Vaccine was not known;

3 the duration of Pfizer Vaccine protection was not known;

4 Pfizer Vaccine efficacy against asymptomatic infection was not known;

5 Pfizer Vaccine efficacy against viral transmission was not known;

6 Pfizer Vaccine data in immunocompromised individuals was very limited;

7 there was a lack of data in respect of safety and efficacy of the Pfizer Vaccine in:

(1) children;

(2) pregnant women; and

(3) lactating mothers.

8 pharmacovigilance activities and post-market studies had been proposed by Pfizer as a means to address the data deficiencies after release of the Pfizer Vaccine.

120. Despite the Accepted Deficiencies in Pfizer Vaccine Approval Data the Respondents had determined as at 11 January, 2021 that:

a) there was no reason known to them that the application for the Pfizer Vaccine should not be approved for provisional registration; and

b) that the final decision, including Conditions for Provisional Registration would be made following ACV discussion in respect of the First TGA ACV Advice Request.

121. The ACV determined and asserted to the Respondents on or about 19 January, 2021, inter alia, the following in response to the advice request based upon the data, documents and correspondences provided by the Respondents and data obtained from Pfizer in the Pfizer Approval application for provisional approval **("the ACV Advised Deficiencies in Pfizer Vaccine Approval Data")**:

a) in respect of the quality of the Pfizer Vaccine:

1 the EMA Report to which the ACV had access and both the Respondents and the ACV were aware:

(1) acknowledged the presence of truncated and/or modified forms mRNA in the Pfizer Vaccine at concentrations higher than the Pfizer Clinical Trial;

(2) acknowledged that such quality issue could impact the immune response to the Pfizer Vaccine.

2 that:

(1) residual DNA should be part of batch testing; and

(2) increased DNA contamination has potential to increase reactogenicity to the Pfizer Vaccine;

(3) thereby indicating the Respondents knowledge at that time of:

a) DNA contamination had been observed;

b) the obligation for Office of the Gene Technology Regulator advice to have been sought;

c) the elevated risk of genome integration.

3 that there was a remaining safety concern in respect of the Pfizer Vaccine:

(1) being vaccine-associated enhanced disease (VAED) including vaccine-associated enhanced respiratory disease (VAERD);

(2) to be addressed in ongoing and planned pharmacovigilance activities;

(3) in circumstances where in truth the Respondents:

a) at no time have referred to VAED or VAERD in the Pfizer Product Information approved by the Respondents;

b) accepted that the Pfizer Approval would proceed in the face of remaining safety concerns to be clarified by observing the effects of the Pfizer Vaccine on the Australian population.

4 that there was limited or no information regarding the efficacy and safety of the Pfizer Vaccine:

(1) in patients with:

a) autoimmune or inflammatory disorders;

b) immunocompromised individuals;

c) pregnant women; and

d) individuals with a history of anaphylaxis.

(2) to be remedied by the requirement for clinical guidance to assist the Respondents in making a determination as to the risks of taking the Pfizer Vaccine;

(3) in circumstances where in truth the Respondents accepted that the Pfizer Approval would proceed in the face of remaining safety concerns to be clarified by observing the effects of the Pfizer Vaccine on the Australian population, including those unknown-risk groups.

5 that relevant consumer information in respect of the Vaccines, including deficiencies in knowledge relating to the Vaccines' safety and efficacy, would be critical to the formation of informed consent:

(1) by users of the Vaccines in a campaign roll-out;

(2) in circumstances where in truth the Pfizer Vaccine Consumer Medicine Information (CMI) summary approved by the Respondents did not include:

a) any reference to the presence of truncated and/or modified forms mRNA in the Pfizer Vaccine;

b) any statement of knowledge as to the absence of certainty and data in respect of safety and efficacy by TGA;

c) any reference to the risk of VAED:

i) including that it was a known special risk of concern;

ii) not referred to in the Pfizer Product Information approved by the Respondents.

d) the exclusion of the above matters by the Respondents from the approved documents prepared for the purported purpose of fully informing the Australian Public was:

i) an abrogation of informed consent in those receiving the Pfizer Vaccine;

ii) a known refusal or failure to inform the Australian public as to safety matters to which recipients of the Pfizer Vaccine had a reasonable expectation.

Particulars

ACV Meeting Minutes - January 2021.
https://www.tga.gov.au/sites/default/files/2023-03/foi-4093-01.pdf.

Pg. 6,7,8,10,12. Advisory Committee on Vaccines Meeting 18 Minutes on Item 2.1 BNT162b2 [mRNA] COVID-19 vaccine Proprietary Product Name: Comirnaty Sponsor: Pfizer Australia Pty Ltd. January 2021.

Document: A1b EMA – Assessment Report Dated 21 December 2020.

Documents provided to the ACV by the TGA upon which the ACV solely relied in providing the First ACV Advice.

The ACV considered the following documentation, provided at various times between 10 December 2020 and 15 January 2021:

A1 Delegate - request for ACV advice and overview – 'Delegate's Overview'
A1a Sponsor – clinical overview dated 3 December 2020
A1b EMA – assessment report dated 21 December 2020
A2 Sponsor - application letter dated 23 October 2020
M3 TGA - Quality – product summary
M3a TGA – Quality – evaluation report – active ingredient Drug Substance
M3b TGA – Quality – evaluation report – vaccine Drug Product
M3c TGA – Quality – draft consent for labels that do not comply with Labelling Order
M3d Sponsor – Labels for vial and 195 vial carton - European
M3e Sponsor – Labels for vial and 195 vial carton – Australian – FDA Emergency Use
M4 TGA - Nonclinical – summary and evaluation report
M4a TGA – Nonclinical comment on Supernumerary lumbar ribs

TGA STATUTORY REQUIRED INCLUSIONS – PRODUCT INFORMATION

122. The Respondents stipulate a form for providing Product Information, including the Vaccines which **("the TGA Product Information Requirements")**:

a) was and remains in force at the time of the Approvals;

b) was approved by the Secretary pursuant to s. 7D(1) of the Act;

c) with respect to Adverse Effects in medicines including the Vaccines, requires the following to be expressed in the Vaccines' Product Information at s. 4.8:

1 the Vaccines' Adverse or Undesirable Effects':

(1) severity;

(2) clinical importance; and

(3) frequency.

2 expressed in the following format:

(1) table of adverse events:

a) at a cut-off of, for example, 1% comparing:

i) the frequency of adverse events (n(%) or (%)) on drug; with

ii) placebo/active comparator (if studies support this comparison) (usually very common and common);

b) a line listing of adverse reactions that fall below the cut-off:

i) by System Organ Classes (SOC);

ii) using CIOMS frequencies (usually uncommon, rare); and

c) a post-marketing section of adverse reactions by system organ class using CIOMS frequencies (usually rare or very rare).

Particulars

Australian Government, Department of Health and Aging, TGA - Form for providing product information. https://www.tga.gov.au/resources/resource/guidance/form-providing-product-information

KNOWN DEFICIENCIES – ASTRAZENECA PRODUCT INFORMATION

123. Prior to and at the time of the AstraZeneca Approval, the Respondents prepared and published the AstraZeneca Product Information excluding the following matters known to the Respondents at that time **("the Known AstraZeneca Product Information Exclusions")**:

a) AstraZeneca reported tremor which was more commonly seen in the AstraZeneca Vaccine group than the control group and which tended to be in the first 7 days;

b) AstraZeneca reported angina:

1 in 3 cases in the AstraZeneca Vaccine group;

2 as not occurring in the control group at all;

3 occurring between 16 and 17 days after the AstraZeneca vaccination;

c) AstraZeneca reported a sudden case of:

1 transverse myelitis in an AstraZeneca recipient;

2 multiple sclerosis in an AstraZeneca recipient

d) AstraZeneca reported death in 2 of the AstraZeneca Vaccine group

wherein:

1 1 reportedly due to fungal pneumonia; and

2 1 reportedly due to malignant neoplasm.

e) AstraZeneca reported clinically meaningful incidence of Vaccine-Associated Enhanced Respiratory Disease in AstraZeneca Vaccine recipients;

f) there was an unusual case of chronic inflammatory demyelinating polyneuropathy in the ongoing US study of the AstraZeneca Vaccine;

g) in disclosing the reporting of "very rare events of demyelinating disorders have been reported following vaccination with COVID-19 Vaccine AstraZeneca" the Respondents state that "a causal relationship has not been established" in circumstances where in truth:

1 the comparison with controls and information about rates of events such as myelitis excludes reference to the fact that the control used was a meningococcal vaccine which has myelitis as a known potential risk.

124. The Respondents engaged in the Known AstraZeneca Product Information Exclusions:

a) in obvious breach of the TGA Product Information Requirements;

b) withholding from the users of the AstraZeneca Vaccine information:

1 essential to informed consent;

2 reasonably expected to have been disclosed by the Respondents;

3 required by law.

c) where the Respondents knew that the AstraZeneca Product Information would not be in any case likely to be received by patients wherein the

AstraZeneca Vaccine vials were typically provided in lots of large numbers of 100, with hundreds of doses in each allotment with:

1 no box; and

2 no product information provided.

Particulars

The AstraZeneca Product Information

The AstraZeneca Clinical Evaluation Report – pg. 20, 44, 47, 48, 49, 51, 54.

KNOWN DEFICIENCIES – PFIZER PRODUCT INFORMATION

125. Prior to and at the time of the Pfizer Approval, the Respondents prepared and published the Pfizer Product Information excluding the following matters known to the Respondents at that time **("the Known Pfizer Product Information Exclusions")**:

a) Lymphadenopathy was reported as an adverse event:

1 in 64 participants or 0.3% of the Pfizer Vaccine group:

2 comprised of:

(1) 54 participants in the younger age group; and

(2) 10 in the older age group.

(3) at a rate of more than 10 times more than the placebo group having 6 reports;

(4) 73% of which were determined by the Respondents' investigator to be causally related to the Pfizer Vaccine;

(5) with a mean duration of 10 days;

(6) 12 of which were ongoing at the time of the data cut-off date;

(7) reported in most instances within 2 to 4 days after vaccination;

b) Hypersensitivity was reported as an adverse event in:

1 two cases in the Pfizer Vaccine Group; and

2 one case in the placebo group;

c) Drug Hypersensitivity was reported as an adverse event:

1 in six cases in the Pfizer Vaccine Group;

2 in one case in the placebo group;

3 causing the Respondents to determine and assert that post-market monitoring for hypersensitivity events should be conducted.

d) Bell's Palsy was reported as an adverse event in:

1 four cases in the Pfizer Vaccine Group; and

2 none in the placebo group.

e) Serious Adverse Events were reported and found by the Respondents to be causally related to the Pfizer Vaccine in 3 of the Pfizer Vaccine group to the Pfizer Vaccine, which involved:

1 shoulder injury related to vaccine administration;

2 ventricular arrhythmia; and

3 lymphadenopathy;

4 none of the placebo group to the study intervention;

f) Serious Adverse Events were reported in 12 cases of appendicitis comprised of:

1 8 in the Pfizer Vaccine Group; and

2 4 in the placebo group;

g) 1 other event of lower back pain and bilateral lower extremity pain with radicular paraesthesia was reported in the Pfizer Vaccine group assessed by the investigator as related to the Pfizer Vaccine.

126. The Respondents engaged in the Known Pfizer Product Information Exclusions:

a) in obvious breach of the TGA Product Information Requirements;

b) withholding from the users of the Pfizer Vaccine information:

1 essential to informed consent;

2 reasonably expected to have been disclosed by the Respondents;

3 required by law.

c) where the Respondents knew that the Pfizer Product Information would not be in any case likely to be received by patients wherein:

1 the Pfizer Vaccine vials were typically provided in lots of large numbers of 100, with hundreds of doses in each allotment with:

(1) no box; and

(2) no product information provided.

Particulars

The Pfizer Product Information
The Pfizer Original AUSPAR – pg. 28.

KNOWN CONSENT FORM DEFICIENCIES

127. The official consent form authored and published by the Respondents in or about August, 2022 for the purpose of properly informing the Australian population as to matters relevant to the safety, efficacy and risk-benefit of the Vaccines thereby signifying informed consent to receiving the Vaccines **("the Vaccines Consent Form")** stated that:

a) medical experts have studied the Vaccines to make sure they are safe;

b) most side effects of the Vaccines are mild;

c) side effects of the Vaccines may:

1 start on the day of vaccination; and

2 last for one or two days.

d) the Vaccines may carry rare or unknown side effects;

e) thrombosis with thrombocytopenia syndrome:

1 is a very rare side effect of the AstraZeneca Vaccine;

2 does not happen at all after the Pfizer Vaccine or Moderna Vaccine.

f) myocarditis and pericarditis (heart inflammation):

1 is a rare risk following vaccination with the Moderna Vaccine, Pfizer Vaccine and AstraZeneca Vaccine;

2 risk is ranked from highest to lowest as follows:

(1) Moderna Vaccine;

(2) Pfizer Vaccine;

(3) AstraZeneca Vaccine.

128. The Vaccines Consent Form:

a) was composed by the Respondents for the express purpose of informing the reader of the risks associated with the Vaccines to a degree such that consent to receiving the Vaccines would only occur in circumstances of informed consent;

b) excluded known significant adverse event and risk information;

c) in no way provided information to the reader sufficient for the reader to have been sufficiently informed of the risks of the Vaccines to receive the Vaccines under informed consent;

d) was grossly misleading as to the actual risks of the Vaccines in fact and known to the Respondents at the time of publication;

e) it was known to the Respondents at that time that it could be reasonably expected that:

1 the patient would rely upon the Vaccines Consent Form as a source of risk information;

2 would not visit the TGA website find the vaccination AusPAR and associated Product Information in order to review the information themselves to make an informed decision.

Particulars

Australian Government – "Consent form for COVID-19 vaccination" https://www.health.gov.au/sites/default/files/documents/2022/08/covid-19-vaccination-consent-form-for-covid-19-vaccination-covid-19-vaccination-consent-form.pdf . Pg. 1 - 2 - updated on 29 August, 2022.

KNOWN SAFETY RISKS - PFIZER APPROVAL FOR 12 YEARS AND OLDER

129. From prior to, on or about 22 July, 2021, and prior to the Pfizer Adolescent Approval, the Respondents knew of the following matters evidencing significant

safety, efficacy and risk-benefit issues and undertook the following actions relevant to and in respect of the Pfizer Adolescent Vaccine disclosed in the totality of data relied upon by the Respondents in granting the Pfizer Adolescent Approval:

a) the Respondents prior to, on or about 15 January, 2021, had determined and asserted that the Pfizer Vaccine was at that time:

    1 was not proposed for paediatric use; and

    2 no specific studies in juvenile animals were submitted or known to the Respondents.

b) the Respondents on or about 22 July, 2021, determined to extend the indication for the Pfizer Vaccine to use in children 12 years of age and older, being the Pfizer Adolescent Approval, in circumstances where in truth at that time:

    1 the guideline adopted by the TGA being the International Guideline, Juvenile Animals required that:

        (1) even if adverse reactions on developing organ(s) can be predicted from adult human or animal data:

            a) studies in juvenile animals might be warranted:

                i) if there is a need to further address a specific concern; or

                ii) to study reversibility or possible aggravation of the expected findings; and

                iii) establish safety factors.

            b) approval of medicinal products intended for paediatric patients requires a special risk/benefit assessment where the possible effects of the product on the ongoing developmental processes in the age group(s) to be treated are also taken into consideration.

(2) at a minimum, prior to the commencement of studies in a paediatric population results should be available from the:

a) core safety pharmacology package;

b) appropriate repeat dose toxicity studies;

c) the standard battery of genotoxicity tests; and

d) relevant parts of the reproductive toxicity test program.

(3) situations which would justify toxicity studies in juvenile animals include, but are not limited to:

a) findings in nonclinical studies that indicate target organ or systemic toxicity relevant for developing systems;

b) possible effects on growth and/or development in the intended age group; or

c) if a pharmacological effect of the test compound will affect developing organ(s).

2 from prior to, on or about 22 July, 2021 and before the Pfizer Adolescent Approval, the Respondents knew of the following data evidencing significant safety, efficacy and risk-benefit issues in respect of the Pfizer Adolescent Vaccine disclosed in the totality of data relied upon by the Respondents in granting the Pfizer Adolescent Approval:

(1) from the first dose to one month after the second dose of the Pfizer Vaccine Serious Adverse Events reported in adolescents and young adults in the study were:

a) in adolescents:

i) 0.6% in the vaccine group; and

ii) 0.2% in the placebo group;

b) in young adults:

i) 1.7% in the vaccine group;

ii) 0.5% in the placebo group

c) in one adolescent in the Pfizer Vaccine group reported as developing grade 4 pyrexia of 40.4°C:

i) two days after Dose 1;

ii) with temperature returning to normal on Day 4;

iii) causing the participant to withdraw from the study;

iv) determined by Pfizer to be related to the Pfizer Vaccine;

v) which is by definition serious; and

vi) met the stopping rules for the Pfizer Child Trial.

d) two participants in the adolescent group had life threatening Adverse Events that:

i) occurred following the Pfizer Vaccine;

ii) occurred after they turned 16 years of age;

iii) because they turned 16 years of age

during the study, they:

1. were unblinded by Pfizer;

2. were not included in analyses of blinded data;

3. were no longer reported upon or followed up by Pfizer;

4. were not the subject of further inquiry by the Respondents or the provision of any further data.

iv) were thereby evidence of two adolescent trial participants who suffered life threatening Adverse Events from the Pfizer Vaccine was never pursued or reported by the Respondents.

(2) it was reported that Pfizer's safety surveillance and risk management team:

a) conducted a review of spontaneous reports of myocarditis and pericarditis;

b) provided details of the review of spontaneous reports of myocarditis and pericarditis to the Respondents in the April monthly summary safety report;

c) reported an overall conclusion purportedly based on the totality of the available data that there was not enough evidence to currently support a causal association between the vaccine and myocarditis and pericarditis;

d) the Respondents accepted and adopted Pfizer's

assertions as to the spontaneous reports of myocarditis and pericarditis in adolescent subjects:

i) on the bases that:

1. while a plausible mechanism for a causal association of myocarditis and pericarditis is not yet clear;

2. it may be postulated that myocarditis and pericarditis could be a systemic inflammatory reaction due to an immune response to the Pfizer Vaccine.

ii) In circumstances where in truth in fact:

1. the Pfizer Vaccine in this age group should not have been approved when there was suspicion in the trials;

2. a clear sign of risk causal to the Pfizer Vaccine was dismissed;

3. risk of myocarditis to adolescents and young adults outweigh the known risk of Covid infection in that age group;

4. thereby, risk–benefit analysis was ignored entirely by the Respondents and was never conducted in any proper form prior to the Pfizer Adolescent

Approval.

(3) Pfizer Vaccine efficacy for adolescents:

a) was never a pre-specified endpoint;

b) was determined and adopted by the Respondents by improperly using a data cut-off date of 13 March 2021 which was:

i) based on the immunogenicity and safety assessment; and

ii) not based on the number of COVID-19 cases accrued for the adolescent group.

(4) the Respondents had determined that data submitted by Pfizer had the following limitations:

a) at that time of the Pfizer Adolescent Approval the following remained entirely unknown:

i) the long-term efficacy of the Pfizer Vaccine;

ii) the safety of the Pfizer Vaccine;

iii) the efficacy of the Pfizer Vaccine against asymptomatic infection;

iv) the efficacy of the Pfizer Vaccine against viral transmission.

b) the number of adolescents in the study was not sufficient to detect vary rare adverse events in recipients of the Pfizer Vaccine;

c) no data was available or made available in respect of

co-administration of the Pfizer Vaccine with quadrivalent seasonal influenza vaccine;

d) safety and efficacy of the Pfizer Vaccine for use in adolescents with immunodeficient status and high health risks were not assessed;

e) the efficacy of the Pfizer Vaccine against variants of concern was not assessed;

f) even apparently mild episodes of myocarditis may lead to long term sequelae such as arrhythmias.

3 it was obviously known to the Respondents that:

(1) the Pfizer Vaccine was demonstrably unsafe for use by Adolescents;

(2) that the Pfizer Vaccine was in no manner demonstrated to be, for use by Adolescents;

a) safe;

b) effective;

c) displaying a positive risk-benefit profile.

Particulars

The Pfizer Nonclinical Evaluation Report – pg. 14.

The Pfizer 12-15 Year Old Extension AUSPAR - Pg. 23, 26, 29, 32.

European Medicines Agency - 24 January 2008 Doc. Ref. EMEA/CHMP/SWP/169215/2005 Committee For Human Medicinal Products (CHMP) – “Guideline On The Need For Non-Clinical Testing In Juvenile Animals Of Pharmaceuticals For Paediatric Indications” Guideline. Pg. 3.

https://web.archive.org.au/awa/20220816022753mp_/https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-need-non-clinical-testing-juvenile-animals-pharmaceuticals-paediatric-indications_en.pdf.

KNOWN SAFETY RISKS - PFIZER APPROVAL FOR 5-11 YEAR OLD CHILDREN

130. From prior to, on or about 3 December, 2021, and prior to the Pfizer Child Approval, the Respondents knew of the following matters evidencing significant safety, efficacy and risk-benefit issues and undertook the following actions relevant to in respect of the Pfizer Child Vaccine disclosed in the totality of data relied upon by the Respondents in granting the Pfizer Child Approval:

a) the Respondents from prior to, on or about 7 December, 2021 and before the Pfizer Child Approval, knew of the following data evidencing significant safety, efficacy and risk-benefit issues in respect of the Pfizer Child Vaccine disclosed in the totality of data relied upon by the Respondents in granting the Pfizer Child Approval:

1 the Respondents had determined that children:

(1) were as likely to be infected with the Virus as adults;

(2) are in most cases asymptomatic when infected with the Virus;

(3) when symptomatically infected by the Virus, have symptoms which are usually mild;

2 at the time of approval of the Pfizer Child Approval, reported deaths per reported confirmed cases of Covid was:

(1) 0 out of 10,467 deaths (0.00%);

(2) zero.

3 transmission of the Virus was not tested in any clinical trial for the Pfizer Child Vaccine;

4 the Pfizer Child Trial data disclosed:

(1) a total of only 48 participants which:

a) were assigned to the Pfizer 5 Year Old Vaccine group;

b) were administered doses of 10 μg, 20 μg, and 30 μg of BNT162b2 in numbers of 16 each;

c) received 2 doses of Comirnaty vaccine; and

d) completed the 1-month follow up.

(2) due to observed reactogenicity in the initial 4 out of 16 participants of the assigned 30 μg dose level group after receiving both doses:

a) a decision was made by Pfizer for the remaining 12 participants in that dose level group:

i) that they would receive the same dose that was to be selected for Phase II/III (10 μg) at Dose 2; and

ii) the 30 μg dose level was discontinued completely in the study.

(3) phase I immunogenicity results in the clinical study report were not presented to the Respondents for the 30 μg dose level group;

(4) participants assigned to the 30 μg dose level are included in safety analyses, but safety results are reported separately for those who received different dose levels at Dose 2.

5 the Respondents knew and asserted matters confirming the absence of any logical or proper risk-benefit assessment the TGA Respondent in respect of the Pfizer Child or any positive risk-benefit profile wherein they stated and knew that:

(1) the Risk Management Plan report released by Pfizer in February 2022 reviewed all available US COVID-19 cases and deaths to 14 August 2021 showing incident of death in children who tested positive to COVID-19 in ages 0-4 and 5-11 years was listed as "<0.1%" for each group;

(2) the mortality rate in children hospitalised with COVID-19 of less than 0.18%, which is less than the mortality rate seen in children from seasonal influenza;

(3) 7% of children 0 to 18 years being asymptomatic upon infection;

(4) no children died and 4 aged 5-11 were admitted to Intensive Care Units (ICU);

(5) that there was a known inflation of Covid associated hospitalisations and death statistics which arise by reason of the recording of data of those being hospitalised or dying as including those both "with Covid" and "from Covid" as:

a) at least some of those cases are often admitted for serious co-morbidities but coincidentally tested positive for Covid;

b) thereby such information is rendered unreliable.

(6) the risk of COVID-19 death in an otherwise healthy 5-11 year-old is virtually or statistically nil;

(7) there was a mortality rate of zero from Covid among children without a pre-existing medical condition;

(8) thereby even a minute risk in the Pfizer Child Vaccine rendered the risk-benefit analysis of the Pfizer Child Vaccines as unbalanced negative.

6 the Respondents had determined and asserted that there were no:

(1) adverse events of special interest including:

a) thrombocytopenic events;

b) thromboembolic or intravascular coagulation events;

c) autoimmune or demyelination events;

d) meningitis;

e) encephalitis;

f) neuritis;

g) Kawasaki disease;

h) multisystem inflammatory syndrome in children; or

i) acute respiratory distress syndrome.

(2) severe Covid cases;

(3) potential vaccine-associated enhanced respiratory disease; or

(4) severe or serious related rash;

(5) in circumstances where in truth:

a) at the time of those determinations and assertions, being 7 December, 2021, there were reported on DAEN and known to the Respondents Adverse Events reported related to the Vaccines in DAEN, to which the Respondents were obliged to refer, disclosed in Australian young people age under 18 years the following:

i) 399 reports of the above Adverse Events

of Special Interest related to the Vaccines;

ii) 2 cases where death was a reported outcome;

iii) 152 cases of pericarditis;

iv) 142 cases of myocarditis, 1 case of which reported death as the outcome;

v) 56 cases of myopericarditis;

vi) 16 cases of anaphylactic reaction;

vii) 12 cases of appendicitis;

viii) 6 cases of thrombocytopenia;

ix) 5 cases of Bell's Palsy;

x) 3 cases of demyelination;

xi) 2 cases of immune thrombocytopenia;

xii) 2 cases of multisystem inflammatory syndrome in children;

xiii) 2 cases of Guillain-Barre syndrome;

xiv) 1 cases of multi-organ dysfunction syndrome.

b) had any such a risk-benefit assessment been conducted by the Respondents, the Pfizer Child Vaccine should never have been approved as:

i) even a slight risk of Severe Adverse

Events would unbalance the risk of the Pfizer Child Vaccine well above the benefit.

b) it was obviously known to the Respondents that:

(1) the clinical data received provided no basis for assessment as to safety, efficacy or risk-benefit of the Pfizer Child Vaccine;

(2) the Pfizer Child Vaccine was demonstrably unsafe for use by children;

(3) that the Pfizer Child Vaccine was in no manner demonstrated to be, for use by Adolescents;

a) safe;

b) effective;

c) displaying a positive risk-benefit profile.

(4) no risk-benefit analysis was undertaken by the Respondents;

(5) risk-benefit analysis in respect of the Pfizer Child Vaccine displayed a significantly higher risk than benefit to children from the Pfizer Child Vaccine.

Particulars

The Pfizer 5-11 Year Old Extension AUSPAR - Pg. 10, 11, 20, 53.

The Pfizer Risk Management Plan – dated February 2022 - US COVID-19 cases and deaths to 14 August 2021 - s. 6.6, 7.1, 7.2, 7.3.

The DAEN data obtained from:
https://daen.tga.gov.au/medicines-search

Applied filters:

Tradename and Active Ingredient contains 'covid' Date 1/08/2020 and is before 8/12/2021 Reaction Term is Immune thrombocytopenia, Anaphylactic reaction, Myopericarditis, Multisystem inflammatory syndrome in children, Multiple organ dysfunction syndrome, Bell's palsy, Appendicitis, Myocarditis, Pericarditis, Demyelination, Guillain-Barre syndrome, or Thrombocytopenia Age Category is 5 to 11, 12 to 17, or Less than 5.

PART J - RESPONDENTS POST-APPROVAL KNOWLEDGE OF VACCINES RISK AND CONDUCT

KNOWN RESTRICTION OF ADVICES REGARDING VACCINES - AHPRA

131. On or about 9 March, 2021, the Australian Health Practitioner Regulation Agency, with the knowledge of the Department, the TGA, the Minister and the State, produced and forwarded a statement to every or nearly every registered health practitioner in Australia, which contained, inter alia, the following assertions **("the AHPRA Covid Vaccine Statement of Prohibited Advices")**:

a) any promotion of anti-vaccination statements or health advice which contradicts the best available scientific evidence or seeks to actively undermine the national immunisation campaign (including via social media) is not supported by National Boards and may be in breach of the codes of conduct and subject to investigation and possible regulatory action;

b) concerns about the conduct or practice of a health practitioner can be reported to AHPRA via the AHPRA concerns submission portal. National Boards can consider whether the practitioner has breached their professional obligations and will treat these matters seriously and in accordance with established procedure.

1 in circumstances known to the Respondents where the AHPRA

Covid Vaccine Statement of Prohibited Advices:

(1) limited the independent advices of medical practitioners Australia wide in respect of the safety, efficacy and risk-benefit of injection with the Vaccines such that:

a) any independent advice must only have accorded with ongoing promotion and encouragement to all patients to take the Vaccines without further consideration as only accords with the Respondents' official position;

b) the medical practitioners independently formed views as a medical professional were excluded from disclosure to any patient where it conflicted with the Respondents' promotion of the Vaccines;

c) were an obvious abrogation of the independent doctor-patient relationship such that medical practitioners were bound to advise, where arising, in direct conflict with their own professional opinion;

d) the errors of the Respondents in regulating the Vaccines were unable to be rectified or controverted by the independent medical practitioners whom were required to adopt the Respondents' view solely.

Particulars

AHPRA Position Statement on Covid-19 Vaccination dated 9 March, 2021 and distributed to every Australian registered health practitioner and health student.

KNOWN RESTRICTION OF VACCINES ADVICES

132. In or about August, 2021, the Respondents (through the TGA) and AHPRA jointly declared in a public statement to the Australian public *inter alia* that **("the TGA Covid Vaccine Statement of Prohibited Advices")**:

a) for general information about COVID-19 and vaccines, the Commonwealth and state and territory Department of Health websites are the most accurate and up to date sources of information;

b) the public can talk to their GP about the COVID-19 vaccines and what would be best for them in their circumstances;

c) the public can be safe in the knowledge that registered health practitioners must meet national standards Registered health practitioners and thereby have a professional obligation when providing care in person or sharing information online to only share information that is:

1 evidence-based;

2 in line with the best available Government health advice; and

3 is consistent with public health campaigns such as the Australian COVID-19 Vaccination Policy;

d) action could be taken against a practitioner that doesn't meet those standards;

e) the public must not be swayed by other opinions;

f) by inference, doing so would put your health or your loved ones' health at risk;

g) reliable sources of information on COVID-19 and vaccines in Australia were solely the state and federal regulatory authorities, including the Department.

1 in circumstances known to the Respondents where the TGA Covid Vaccine Statement of Prohibited Advices:

(1) limited the independent advices of medical practitioners Australia wide in respect of the safety, efficacy and risk-benefit of injection with the Vaccines such that:

a) any independent advice must only have accorded with ongoing promotion and encouragement to all patients to take the Vaccines without further consideration as only accords with the Respondents' official position;

b) the medical practitioners independently formed views as a medical professional were excluded from disclosure to any patient where it conflicted with the Respondents' promotion of the Vaccines;

c) were an obvious abrogation of the independent doctor-patient relationship such that medical practitioners were bound to advise, where arising, in direct conflict with their own professional opinion;

d) the errors of the Respondents in regulating the Vaccines were unable to be rectified or controverted by the independent medical practitioners whom were required to adopt the Respondents' view solely.

Particulars

"Joint statement on COVID-19 and COVID-19 vaccines from nation's regulators". 30 August, 2021. https://www.tga.gov.au/news/media-releases/joint-statement-covid-19-and-covid-19-vaccines-nations-regulators

133. The Respondents:

a) knew that AHPRA at that time of publication of the TGA Covid Vaccine Statement of Prohibited Advices had already provided the AHPRA Covid Vaccine Statement of Prohibited Advices to all or almost all Australian Health Practitioners preventing them from conveying any information that would:

1 undermine the National Immunisation Campaign; irrespective of whether that information:

(1) was the best available scientific evidence;

(2) was relevant to the patient;

(3) was in the best interests of the patient's health;

(4) was essential for the patient to provide proper informed consent.

b) acting reasonably would have known that such coercion would have resulted in Australian health practitioners being:

1 unable to provide all relevant information to their patients in order to obtain proper informed consent from their patients to vaccination;

2 reluctant to discuss openly with their patients and peers observed AEFI;

3 reluctant to report formally observed AEFI.

Particulars

AHPRA Position Statement on Covid-19 Vaccination dated 9 March, 2021 and distributed to every Australian registered health practitioner and health student.

KNOWN AUSTRALIAN REPORTING DATABASE UNDERREPORTED ADVERSE EVENTS

134. The following factual matters and known risks as to the unreliability of the DAEN reporting system and data in respect of adverse events reporting associated with the Vaccines has been known to the Respondents since prior to the Approvals **("the Known DAEN Structural Deficiencies")**:

a) DAEN is a passive reporting system with a burdensome reporting process for users;

b) such passive systems as the DAEN have been well established prior to the Approvals as to generally result in a rate of underreporting of adverse

events:

1 of 95-98%;

2 by a factor of 31.

c) reporting to the DAEN database is voluntary;

d) doctors were dissuaded from reporting Covid-related adverse events by reason of the AHPRA Covid Vaccine Statement of Prohibited Advices and the TGA Covid Vaccine Statement of Prohibited Advices;

e) the known and exponential underreporting to the DAEN system is readily validated by comparing DAEN Vaccine Adverse Event data to the data from the active reporting system of AusVaxSafety known to the Respondents at all relevant times as follows:

1 as at 31 December, 2021:

(1) DAEN reports of Adverse Events following the Vaccines were:

a) 42,598,706 total vaccine doses administered nationally;

b) 102,763 reports of adverse events;

c) 0.24% reporting rate of adverse events.

(2) AusVaxSafety reports of Adverse Events following the Vaccines were:

a) 5,108,600 safety surveys completed;

b) 49% reported at least 1 adverse event;

(3) an indicated approximate 200-fold underreporting rate of adverse events.

Particulars

See e.g. published studies detailing known underreporting in passive surveillance systems:

Electronic Support for Public Health–Vaccine Adverse Event Reporting System - 12/01/07 - 09/30/10, Lazarus, Ross, MBBS, MPH, MMed, GDCompSci, Harvard Pilgrim Health Care, Inc – see pdf Report at https://www.icandecide.org/wp-content/uploads/2020/12/Lazarus-report.pdf

"Critical Appraisal of VAERS Pharmacovigilance: Is the U.S. Vaccine Adverse Events Reporting System (VAERS) a Functioning Pharmacovigilance System?". Rose, J. The Institute for Pure and Applied Knowledge. Vol 3:100-129, Oct. 2021 https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864_0490c898f7514df4b6fbc5935da07322.pdf

Registered health practitioners and students: What you need to know about the COVID-19 vaccine rollout. https://www.ahpra.gov.au/News/2021-03-09-vaccination-statement.aspx

AHPRA Position Statement on Covid-19 Vaccination dated 9 March, 2021 and distributed to every Australian registered health practitioner and health student.

Australian Government COVID-19 Vaccine Roll-out - 31 December 2021 https://www.health.gov.au/sites/default/files/documents/2021/12/covid-19-vaccine-rollout-update-31-december-2021.pdf

The DAEN database
https://daen.tga.gov.au/medicines-search/

AuxVaxSafety
https://ausvaxsafety.org.au/our-work/covid-19-vaccine-safety-surveillance

KNOWN EARLY STUDIES AND DATA DISCLOSING TRUE LACK OF VACCINES EFFICACY AND SAFETY

135. Numerous and significant international studies and world data were known and made evident to the Respondents as from at least July, 2021, such studies being derived from data further known to the Respondents at and before that time in world populations that had received high proportions of the Vaccines disclosing obviously to the Respondents the following:

a) an utter lack of efficacy in preventing Covid, whether symptomatic or otherwise;

b) negative efficacy of the Vaccines in respect of the Omicron strain, that is, a person vaccinated with the Vaccines were up to 800% more likely to suffer from symptomatic Covid infection then an unvaccinated person;

c) that the greater the number of doses received of the Vaccines, the more one becomes susceptible to COVID-19 infection;

d) countries with higher vaccination rates with the Vaccines have higher proportionate numbers of Covid cases than those with lower vaccination rates with the Vaccines; and

e) that as vaccination of population with the Vaccines increased, there were:

1 more COVID-19 cases per million; and

2 more deaths per million associated with COVID-19.

f) the unprecedented number of over 1,000 scientific studies speaking to the evident side effects arising from injection with the Vaccines;

g) that the vaccinated are showing similar very high viral loads to the unvaccinated and the vaccinated are therefore as infectious;

h) vaccinated people infected by variants such as the Delta variant and who became symptomatic:

1 were as infectious as symptomatic unvaccinated cases; and

2 contributed to the spread of COVID even in highly vaccinated communities;

i) the EU warned that the boosters risk adverse effects to the immune system and may not be warranted;

j) mass vaccination campaigns had failed.

1 these facts arising in circumstances where in truth:

(1) the Respondents acting properly, even without such studies, were obliged, based upon the same empirical data accruing post-Approvals globally to have determined independently the same factual conclusions as to Vaccines inefficacy and safety concerns based upon that available and known data;
(2) despite such reasonably available empirical data accruing post-Approvals globally being known to the Respondents, and reasonably manifesting those conclusions, the Respondents instead continued knowingly and improperly to engage in the Continuing Approvals.

Particulars

See for example the following studies published and known to the Respondents at that time based upon world data further known to the Respondents:

“Resurgence of SARS-CoV-2 infection in a highly vaccinated health system workforce.” Keehner, J et al. 2021. New

England Journal Medicine 385, 1330-1332. doi: 10.1056/NEJMc2112981; https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/

“An observational study of breakthrough SARS-CoV-2 Delta variant infections among vaccinated healthcare workers in Vietnam.” Chau, G.V.V et al. 2021. EClinicalMedicine 41, 101143. https://doi.org/10.1016/j.eclinm.2021.101143.

“An outbreak caused by the SARS-CoV-2 Delta variant (B.1.617.2) in a secondary care hospital in Finland”. Hetemäki Iivo, et al. May 2021. Euro Surveill. 2021;26(30):pii=2100636. https://doi.org/10.2807/1560-7917.ES.2021.26.30.2100636

“Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel”. Shitrit, P et al. 2021. July 2021. Eurosurveillance, 26, 2100822 (2021)

“Patient betrayal: The Corruption of healthcare, informed consent and the physician – patient relationship.” Thorp J.A et al. 2022. The Gaxette of Medical Sciences. https://www.doi.org/10.46766/tjegms

“New Studies Show that the COVID Vaccines Damage your Immune System, Likely Permanently,” Kirsch, S. 2021. Steve Kirsch’s Newsletter, Dec. 24, 2021, https://stevekirsch.substack.com/p/new-stu-dy-shows-vaccines-must-be

“Pfizer CEO says Two Covid Vaccine Doses Aren’t Enough for Omicron,” Kirsch S. 2022. Steve Kirsch’s Newsletter, Jan. 10, 2022, https://stevekirsch.subs-tack.com/p/pfizer-ceo-says-two-covid-vaccine

“Increases in COVID-19 are unrelated to levels of

vaccination across 68 countries and 2947 counties in the United States". Subramanian, S.V., Kumar, A. 2021. European Journal of Epidemiology.
https://doi.org/10.1007/s10654-021-00808-7

"Worldwide Bayesian Causal Impact Analysis of Vaccine Administration on Deaths and Cases Associated with COVID-19: A Big Data Analysis of 145 Countries," Ritchie, H et al. Nov 2021
https://vector-news.github.io/editorials/CausalAnalysisReport_html.html

"Vaccinated and unvaccinated individuals have similar viral loads in communities with a high prevalence of the SARS-CoV-2 delta variant". Riemersma, K et al. 2021.
https://doi.org/10.1101/2021.07.31.21261387

"Viral Load Among Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups When Infected with SARS-CoV-2 Delta Variant." Acharya C.B et al. March 2022. Open Forum Infectious Diseases. Vol 9, Issue 5. https://doi.org/10.1093/ofid/ofac135

"Predominance of antibody-resistant SARS-CoV-2 variants in vaccine breakthrough cases from the San Francisco Bay Area, California." Servellita, V et al. 2022. Nat Microbiol 7, 277–288.
https://doi.org/10.1038/s41564-021-01041-4

"EU Drug Regulator Expresses Doubt on Need for Fourth Booster Dose," Jan. 11, 2022
https://www.reuters.com/business/healthcare-pharmaceuticals/eu-drug-regulator-says-more-data--needed-impact-omicron-vaccines-2022-01-11/

"Top Israeli Immunologist Criticizes Pandemic Response in Open Letter," Kirsch S. Jan, 2022, Steve Kirsch's Newsletter
https://stevekirsch.substack.com/p/top-israeli-

immunologist--criticizes?r=15hae6&utm_campaign=post&utm_medium=email

KNOWN EARLY PROVEN INEFFICACY OF THE VACCINES – AUSTRALIAN DATA

136. The ABS publicly published and reported the following data which was known to the Respondents at the time at which such data accrued:

a) the following numbers of deaths associated with Covid were reported in the respective year:

1 2020: 906 deaths;

2 2021: 1,350 deaths;

3 2022: 9,440 deaths.

(1) such data being known to the Respondents in circumstances where in truth:

a) the Vaccines by reason of the data disclosed to the Respondents at that time that the Vaccines:

i) were not effective at stopping Covid deaths;

ii) were not fit for purpose

b) the lack of efficacy of the Vaccines should have:

i) been obvious to the Respondents based upon available data;

ii) triggered a withdrawal of provisional approval based upon a shift in the risk-benefit analysis whereby:

c) there was a simultaneous disclosure of obvious risk of Adverse Events following vaccination with the Vaccines based upon the data known to the Respondents from the end of 2022 that:

i) approximately 135,000 Adverse Events reported to DAEN;

ii) 49% Adverse Event reporting rate to AusVaxSafety;

iii) 1.2% reporting rate to AusVaxSafety of medical attendance being required following vaccination with the Vaccines;

d) as from 2021 reported data known to the Respondents disclosed that:

i) the proportions of hospitalisations and deaths are as high or higher among vaccinated than among unvaccinated people;

ii) there was an overall low benefit from vaccination based upon the data known to the Respondents of:

1. very low reported Infection Fatality Rates for individuals under 70 years of age;

2. the ABS mortality data which detailed a 942% increase in deaths from or with Covid:

a. in 2022 when 96% of the Australian adult population was

vaccinated;

b. compared to in 2020 prior to the Vaccine rollout commencing in Australia.

e) the Respondents knew at all times that reports of deaths by the ABS as being associated with Covid, included reported deaths wherein:

i) the deceased was merely suspected of having Covid;

ii) the Virus was never identified as the underlying cause of death;

iii) thereby by definition:

1. included a proportion of non-Covid deaths;

2. known to be inflating the covid death numbers.

137. From at least June, 2021 and onward, the Respondents were aware of numerous scientific studies undertaken upon data and scientific assessment as to the potential of the Vaccines to prevent infection, transmission, serious disease and death, disclosing to the Respondents from at least that time the following known scientifically proven facts:

a) the Vaccines do not prevent:

1 infection with the Virus; or

2 person to person spread or transmission of the Virus;

3 serious infection from Covid;

4 death from Covid.

b) such data accruing in circumstances the conclusions from observed data should not have been unexpected by the Respondents where the known facts pre-Approvals disclosed that:

1 the Vaccines were not clinically tested to prevent:

(1) infection with the Virus; or

(2) person to person spread or transmission of the Virus;

(3) serious infection from Covid;

(4) death from Covid.

2 the Vaccines, according to their respective product information disclosure sheets prepared by the Respondents for use, are not indicated to prevent:

(1) infection with the Virus; or

(2) person to person spread or transmission of the Virus;

(3) serious infection from Covid;

(4) death from Covid.

3 infection with the Virus occurs through airborne infection of viral particles entering via the mucosa of the nose;

4 the Vaccines:

(1) do not induce mucosal immunity;

(2) do not affect the viral load in the nasal mucosa of an Infected Person;

(3) instead:

a) seek to induce blood-borne immunity;

b) are thereby wholly ineffective in countering organisms entering and multiplying in the mucosal tract;

(4) thereby cannot and do not prevent, as known by the Respondents prior to the Approvals:

a) infection with the Virus; or

b) person to person spread or transmission of the Virus.

Particulars

"Correlation between 3790 Quantitative Polymerase Chain Reaction-Positives Samples and Positive Cell Cultures, Including 1941 Severe Acute Respiratory Syndrome Coronavirus 2 Isolates Clinical Infectious Diseases" Jaafar, R. et al (2020), Volume 72, Issue 11. https://pubmed.ncbi.nlm.nih.gov/32986798/

"Covid-19: stigmatising the unvaccinated is not justified". Kampf, G. 2021. The Lancet Correspondence. Volume 398, Issue 10314, P1871. https://doi.org/10.1016/S0140-6736(21)02243-1

"Breakthrough infections with SARS-CoV-2 omicron despite mRNA vaccine booster dose". Kuhlmann, C. 2022. The Lancet Correspondence. Volume 399, Issue 10325, P625-626. https://doi.org/10.1016/S0140-6736(22)00090-3

"Transmissibility of SARS-CoV-2 among fully vaccinated individuals". Franco-Paredes, C. 2022. The Lancet Infectious Diseases Correspondence. Volume 22, Issue 1, P16. https://doi.org/10.1016/S1473-3099(21)00768-4

"COVID-19: stigmatising the unvaccinated is not justified". Kampf, G. (2021) The Lancet. Volume 398, Issue 10314, P1871. https://doi.org/10.1016/S0140-6736(21)02243-1

"Outbreak of SARS-CoV-2 infections, including COVID-19 vaccine breakthrough infections, associated with large public gatherings— Barnstable County, Massachusetts". Brown, CM et al (July 2021) CDC MMWR Morb Mortal Wkly Rep 2021;70: 1059–62. https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm

"Shedding of Infectious SARS-CoV-2 Despite Vaccination" Riemersma, KK et al. 2022. PLOS Pathogens. https://doi.org/10.1371/journal.ppat.1010876

KNOWN POST-APPROVAL VACCINES INEFFICACY DATA

138. From early 2022 the publicly available data and reasonably available scientific studies and public health sources in the US, Australia, Denmark, Israel and the UK publicly known and known to the Respondents at that time conclusively show:

a) protective efficacy of the Vaccines had materially waned;

b) the Vaccines were displaying negative efficacy in that:

1 COVID-19 vaccination commenced in Australia early in 2021 and reached 91.4% for "fully vaccinated" individuals aged 16 years and over in December, 2021;

2 the absolute rate of new infection Cases of Covid peaked in Australia and Worldwide in the period of December 2021 to July 2022;

3 vaccinated Persons were at a higher risk by the Omicron Strain and sub-variants of the Omicron Strain prevalent in the Australian and worldwide population at that time;

4 the Vaccines effectiveness has been and remains negative since at least December 20, 2021 as those Vaccinated Persons were and remain:

(1) in publicly available data demonstrably and materially overrepresented proportionally in reported:

a) new cases of Covid;

b) new hospitalisations due to Covid;

c) deaths due to Covid.

(2) at a higher risk than Unvaccinated Persons of:

a) new cases of Covid;

b) new hospitalisations due to Covid;

c) deaths due to Covid.

(3) vaccination with the Vaccines leads a diminished ability to protect from infection by the newer variants.

c) since early 2022, the dominant variant of the Virus is Omicron:

1 whereas the Vaccines:

2 are constructed to produce antibodies towards the Original Strain;

3 tested only for any efficacy in respect of the Original Strain.

Particulars

"Increasing SARS-CoV-2 cases, hospitalizations and deaths among the vaccinated elderly populations during the Omicron (B.1.1.529) variant surge in UK". Emani, V et al.

2022. medRixiV preprint
https://www.medrxiv.org/content/10.1101/2022.06.28.22276926v2

"Immune imprinting, breadth of variant recognition, and germinal center response in human SARS-CoV-2 infection and vaccination". Roltgen, K et al. March 2022. Cell 185,1025-1040
https://doi.org/10.1016/j.cell.2022.01.018

Our World In Data – Coronavirus Pandemic: Explore the Global Situation
https://ourworldindata.org/coronavirus#explore-the-global-situation

KNOWN INEFFICACY IN CHILDREN

139. From at least January, 2022 it was reported and known to the Respondents that:

a) the Swedish Health Agency reversed recommendation on the administration of COVID Vaccines to adolescent children 5-11 on the basis that the demonstrated benefits did not outweigh the risks of vaccination with the Vaccines;

b) children were at a significantly lower risk than adults of developing Covid by infection from the Virus.

Particulars

Sweden decides against recommending COVID vaccines for kids aged 5-11 (27 January 2022) Reuters
https://www.reuters.com/world/europe/sweden-decides-against-recommending-covid-vaccines-kids-aged-5-12-2022-01-27/

"Pre-activated antiviral innate immunity in the upper airways controls early SARS-CoV-2 infection in children." Loske, J. et al. March 2022. Nature Biotechnology: Vol 40, 319-324.

https://www.nature.com/articles/s41587-021-01037-9

KNOWN DECREASING EFFICACY WITH EACH INJECTION

140. It was known to the Respondents since at least December, 2022 by reasonably obtained data and studies that it had been scientifically established that:

a) the Vaccines provided decreasing protection against Covid with every dose of the Pfizer Vaccine:

b) the greater the number of vaccine doses previously received the higher the risk of COVID-19;

c) the more recent the last prior COVID-19 episode was, the lower the risk of reinfection with the Virus;

d) the publicly available data known to the Respondents at that time disclosed that:

1 previous infection with Covid provides lasting naturally acquired immunity;

2 any immunity afforded by the Vaccines wanes with increasing number of doses therefore indicating against any justification for booster doses to be administered;

3 by February 2022, prior Covid infection had occurred in (CDC Study):

(1) 64% of the 18-64 age group population the US; and

(2) 75% of children and adolescents;

(3) almost half of the infections that occurred were:

a) between December 2021 and February 2022;

b) predominantly Omicron BA.1/BA.2 lineage infections.

4 a substantial proportion of individuals may be unlikely to derive substantial benefit from ongoing vaccination with Vaccines or booster doses of the Vaccines.

Particulars

"Effectiveness of the Coronavirus Disease 2019 (COVID-19) Bivalent Vaccine" Shrestha, N et al. December, 2022. https://doi.org/10.1101/2022.12.17.22283625

"Seroprevalence of Infection-Induced SARS-CoV-2 Antibodies — United States, September 2021–February 2022". Clarke, K. 2022. MMWR Morb Mortal Weekly Report 71. https://www.cdc.gov/mmwr/volumes/71/wr/mm7117e3.htm

KNOWN LACK OF EFFICACY – FOURTH DOSE OF MRNA VACCINES

141. It was known to the Respondents since at least February, 2022 by reasonably obtained and observed empirical data and studies known to the Respondents that the following had been scientifically established in respect of those receiving a fourth dose of Pfizer or Moderna Vaccines:

a) breakthrough infections after vaccination with the Vaccines were:

1 common;

2 accompanied by high viral loads.

b) efficacy against Covid infection was displayed by the empirical evidence to be:

1 30% for the fourth dose of the Pfizer Vaccine recipients; and

2 11% for the fourth dose of the Moderna Vaccine recipients;

c) local and systemic adverse reactions were being reported in:

1 80% of the fourth dose Pfizer Vaccine recipients; and

2 40% of the fourth dose Moderna Vaccine cases respectively.

Particulars

"4th Dose COVID mRNA Vaccines' Immunogenicity & Efficacy Against Omicron VOC." Regev-Yochay G., Gonen T.,Gilboa M. 2022. N Engl J Med; 386:1377-1380. https://www.nejm.org/doi/10.1056/NEJMc2202542

KNOWN - INEFFECTIVE TO PREVENT TRANSMISSION

142. It was known to the Respondents since at least April, 2021 by reasonably obtained and observed empirical data and studies known to the Respondents at that time that the following had been scientifically established in respect of Vaccines proven inefficacy:

a) those vaccinated with the Vaccines can still contract and transmit Covid regardless of whether they are symptomatic or not;

b) there is no relationship between the percentage of population fully vaccinated and new Covid cases;

c) countries with higher percentage of a population fully vaccinated have higher COVID cases per million people.

1 these facts arising in circumstances where in truth:

(1) the Respondents acting properly, even without such studies, were obliged, based upon the same empirical data accruing post-Approvals globally to have determined independently the same factual conclusions as to Vaccines inefficacy and safety concerns based upon that available and known data;

(2) despite such reasonably available empirical data accruing post-Approvals globally being known to the Respondents, and

reasonably manifesting those conclusions, the Respondents instead continued knowingly and improperly to engage in the Continuing Approvals.

Particulars

"Covid-19 Vaccinated Individuals Can Be A Source of SARS-CoV-2 Transmission – A Systematic Review". Kampf, 2021. Hygiene. 1(1):1-11.

"Increases in Covid-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States". Subramanian, SV and Kurmar, A. 2021. European Journal of Epidemiology, 36: 1237-1240.

KNOWN VACCINES REDUCED IMMUNITY SIDE EFFECT

143. It was known to the Respondents since at least April, 2021 by reasonably obtained and observed studies known to the Respondents at that time that the following had been scientifically established in respect of Vaccines:

a) vaccination with an mRNA vaccine, including the mRNA Vaccines, initiates a set of biological events that are:

1 different from that induced by natural infection;

2 in several ways demonstrably counterproductive to both short and long-term immune competence and normal cellular function;

b) mRNA vaccines including the mRNA Vaccines:

1 downregulate critical pathways related to:

(1) cancer surveillance;

(2) infection control; and

(3) cellular homeostasis.

2 introduce into the body highly modified genetic material;

3 the biological response to mRNA vaccination as it is employed in the mRNA Vaccines, is demonstrably dissimilar to natural infection;

4 injection with the mRNA Vaccines:

(1) induces a profound impairment in type 1 interferon signaling causing diverse adverse consequences to human health;

(2) causes immune cells to:

a) take up the mRNA Vaccines' nanoparticles;

b) release into circulation:

i) large numbers of exosomes containing spike protein; and

ii) critical microRNAs that induce a signaling response in recipient cells at distant sites.

5 injection with the mRNA Vaccines can potentially:

(1) cause profound disturbances in regulatory control of protein synthesis and cancer surveillance;

(2) thereby have a causal link to:

a) neurodegenerative disease;

b) myocarditis;

c) immune thrombocytopenia;

d) Bell's palsy;

e) liver disease;

f) impaired adaptive immunity;

g) impaired DNA damage response; and

h) tumorigenesis.

Particulars

"Innate immune suppression by SARS-CoV-2 mRNA Vaccinations: The Role of G-quadruplexes, exosomes and MicroRNAs". Seneff et al, Food Chem Toxicol. 2022 Jun.

KNOWN VACCINES INFERIORITY TO NATURAL IMMUNITY

144. It was known to the Respondents by reasonably obtained and observed empirical data and studies known to the Respondents that the following had been scientifically established in respect of Vaccines:

a) since from the time of the Approvals and continuing to the present that the Respondents have known that:

1 there is no evidence in existence which demonstrated that vaccination with the Vaccines provides superior immunity to natural human immunity in respect of infection with the Virus or the development of Covid;

2 natural immunity:

(1) provides a decreased risk of re-infection and extremely low rates of hospitalisation in relation to repeat infection;

(2) provides significant protection against reinfection with Covid with an efficacy ~95% for at least seven months;

3 the frequency of re-infection from Covid after previous infection:

(1) caused hospitalisation in only five out of 14,840 or 0.03% of those previously infected with Covid; and

(2) death in one out of 14,840 or 0.01% of those with previous infection.

b) since from at least August, 2021 and continuing to the present that the Respondents have known that:

1 a person vaccinated with the Pfizer Vaccine had a 13.06-fold increased risk for breakthrough infection with the Delta variant of the Virus and significant risk of symptomatic infection compared to unvaccinated individuals whom had pervious Covid infection;

2 naturally acquired immunity confers stronger protection against infection and symptomatic disease caused by the Delta variant of the Virus compared to Pfizer Vaccine induced immunity;

3 the natural human immune system in those persons whom are unvaccinated following infection with Covid generally:

4 is more effective than each of the Vaccines at preventing:

(1) transmission of Covid;

(2) serious illness or death arising from Covid;

(3) infection or re-infection with Covid;

(4) wanes at a materially slower rate than each of the Vaccines in those effects.

Particulars

"Quit Ignoring Natural COVID Immunity — Antibody testing and proof of prior infection can allow more people to return to normal". Klausner, J., Kojima, N. 2021. Medpage Today, 28 May 2021. www.medpagetoday.com/infectiousdisease/covid19/92836

150 plus research studies affirm naturally acquired immunity to Covid-19: documented, linked, and quoted. https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/

“SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy”. Abu-Raddad, L et al. 2021. eClinicalMedicine, The Lancet Discovery Science, Vol 35, May 2021, https://doi.org/10.1016/j.eclinm.2021.100861

“SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study”. Hall, V. J. 2021. SIREN, Volume 397, Issue 10283, P1459-1469. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00675-9/fulltext

Pilz S et al (2021) SARS-CoV-2 re-infection risk in Austria. European Journal of Clinical Investigation Volume 51, Issue 4 e13520 https://doi.org/10.1111/eci.13520

“Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Naturally Acquired Immunity versus Vaccine-induced Immunity, Reinfections versus Breakthrough Infections: A Retrospective Cohort Study”. Gazit, S et a. 2021. Clinical Diseases Major Article https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9047157/pdf/ciac262.pdf

Evident from the publicly available Israeli Ministry of Health Database data in the period of August to September, 2021 from at least September, 2021.

“Protection and waning of natural and hybrid immunity to SARS-CoV-2”. Goldberg, Y. et al. 2021. N. Eng. J. Med. 386: 2201–2212. (2022). https://doi.org/10.1038/s41467-022-

33096-0

"Viral load dynamics of SARS-CoV-2 Delta and Omicron variants following multiple vaccine doses and previous infection". Woodbridge, Y et al. 2022. Nat Commun. 7;13(1):6706.

KNOWN VIRAL LOAD – VACCINATED INCREASED

145. It was known to the Respondents since at least October, 2021 by reasonably obtained and observed empirical data and studies known to the Respondents at that time that the following had been scientifically established in respect of Vaccines:

a) persons vaccinated with the Vaccines who experienced breakthrough infection with the Delta Variant carry 251 times the Viral load in their nostrils compared to those infected unvaccinated persons who were infected in the March-April 2020 period with older strains.

Particulars

"Transmission of SARS-CoV-2 Delta Variant Among Vaccinated Healthcare Workers, Vietnam". Nguyen, C et al. 2021. The Lancet Preprint.

KNOWN NATURAL IMMUNITY SUPERIOR

146. It was known to the Respondents since at least September, 2021 by reasonably obtained and observed empirical data and studies known to the Respondents at that time that the publicly available data from Israel showed that within 70 days of Vaccination, the person Vaccinated generally had no or negligibly greater protection than an unvaccinated person in respect of preventing:

a) transmission of Covid;

b) serious illness or death arising from Covid; and

c) infection or re-infection with Covid.

Particulars

Evident from the publicly available Israeli Ministry of Health Database data in the period of August to September, 2021 from at least September, 2021.

147. It was known to the Respondents since at least March, 2022 by reasonably obtained and observed empirical data and studies known to the Respondents at that time that the publicly available data in Qatar disclosed that previous natural infection:

a) was associated with lower incidence of Covid infection;

b) regardless of the variant, than mRNA primary-series vaccination.

Particulars

"Protection of prior natural infection compared to mRNA vaccination against SARS-CoV-2 infection and severe COVID-19 in Qatar". Chemaitelly et al. The Lancet Microbe. December 22, Volume 3(12): E944-E955

148. It was known to the Respondents since at least May, 2022 by reasonably obtained and observed empirical data and studies known to the Respondents at that time that the following had been scientifically established in respect of Vaccine:

a) that previous natural infection was associated with lower incidence of Covid infection regardless of the variant, than 2 doses of the mRNA Vaccines;

b) effectiveness of primary natural infection against severe, critical or fatal covid-19 re-infection was 97.3% irrespective of the variant of primary infection or reinfection.

Particulars

"Protection from previous natural infection compared with

mRNA vaccination against SARS-CoV-2 infection and severe COVID-19 in Qatar: a retrospective cohort study". Chemaitelly, H. 2022. Lancet Microbe 2022; 3: e944–55. https://doi.org/10.1016/S2666-5247(22)00287-7

149. It was known to the Respondents since at least September, 2022 by reasonably obtained and observed empirical data and studies known to the Respondents at that time that 65 publicly available studies in 19 countries pertaining to natural immunity against Covid and based upon the publicly available data at that time disclosed and concluded that:

a) natural immunity was high against infection by all variants except omicron BA.1 which was substantially lower than the other variants;

b) for the omicron BA.1 variant mean pooled natural immunity effectiveness:

1 against re-infection was 45.3%;

2 against symptomatic disease 44%.

c) for all variants including Omicron mean pooled effectiveness of natural immunity was greater than 78% against severe disease, including hospitalisation and death;

d) natural immunity protection from reinfection from all ancestral, Alpha and Delta variants:

1 declined over time; but

2 remained at 78.6% at 40 weeks.

3 protection against severe disease remained high for all variants with:

(1) 90.2% natural immunity protection for ancestral, Alpha and Delta variants; and

(2) 88.9% natural immunity protection for the Omicron BA.1 variant at 40 weeks; and

(3) despite protection from past infection waning over time the level of protection is at least as durable, if not more durable than that provided by 2-dose vaccination with the mRNA vaccines for all variants.

Particulars

"Past SARS-CoV-2 infection protection against re-infection: a systematic review and meta-analysis". Covid-19 Forecasting Team. The Lancet Articles. Volume 401, Issue 10379, P833-842.

INTERNATIONAL REPORTS OF ADVERSE EVENTS - KNOWN FDA ADVERSE EVENTS OF SPECIAL INTEREST

150. It was known to the Respondents since at least July, 2021 that based upon real-time monitoring of Serious Adverse Events reports relating to the Pfizer Vaccine the FDA reported detecting four potential adverse events of interest:

a) pulmonary embolism;

b) immune thrombocytopenia;

c) disseminated intravascular coagulation; and

d) acute myocardial infarction;

1 (a) to (c) being the Brighton Adverse Event of Special Interest category:

(1) of coagulation disorder; and

(2) that exhibited the largest excess risk in the vaccine group in both of the mRNA Vaccine Trials.

Particulars

"Initial Results of Near Real-Time Safety Monitoring of

COVID-19 Vaccines in Persons Aged 65 Years and Older". US Food & Drug Administration. July, 2021. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/initial-results-near-real-time-safety-monitoring-covid-19-vaccines-persons-aged-65-years-and-older

KNOWN COUNTRIES BANNING VACCINE TREATMENT

151. The following were known to the Respondents at those respective times as to countries restricting further administration of the Vaccines in their populations following observed empirical data of injury and death as against risk from Covid infection:

a) in September, 2022, Denmark ceased offering the Vaccines to those aged under 50 years unless they were at a higher risk of becoming severely ill from the Virus, citing:

1 the purpose of vaccination is to prevent severe illness, hospitalisation and death not to prevent infection; and

2 people aged under 50 are generally not at higher risk of becoming severely ill from the Virus.

b) in October, 2022, Sweden ceased recommending the vaccine for 12-17 year olds, citing very low risk in that age group.

Particulars

Danish Health Authority – Why are people aged under 50 not to be re-vaccinated? https://www.sst.dk/en/english/corona-eng/vaccination-against-covid-19

Sweeden to stop offering Covid jabs to teenagers. September, 2022. https://medicalxpress.com/news/2022-09-sweden-covid-jabs-teenagers.html

KNOWN FOETAL AND INFANT ADVERSE EVENTS

152. It was known to the Respondents since at least March, 2022 by reasonably obtained and observed empirical data and studies known to the Respondents at that time that the following had been scientifically established in respect of Vaccines side effects in foetuses and infants:

a) miscarriage;

b) foetal death;

c) foetal malformation;

d) chronic autoimmune disease;

e) permanent immune deficiency syndrome;

f) chronic permanent CNS diseases;

g) chronic cognitive disorders;

h) seizure disorders; and

i) neonatal/infant cancers.

Particulars

"Patient betrayal: The Corruption of healthcare, informed consent and the physician – patient relationship". Thorp J.A et al. 2022. The Gazette of Medical Sciences. https://www.thegms.co/medical-ethics/medethics-rw-22021403.pdf

KNOWN INSURANCE COMPANY DATA

153. The following were known at the time of reporting by the Respondents as to insurance data reported by insurance firms globally:

a) in November 2021, it was reported by Aegon Insurance who conducts 2/3 of its business in the United States that it had:

1 paid out $111 million in the third quarter of 2021 which was:

(1) 258% greater than the previous year;

(2) during the pandemic; and

(3) prior to the release of the Vaccines.

2 paid out $80 million greater than the previous year:

(1) during the pandemic; and

(2) prior to the release of the Vaccines.

b) in December, 2021, OneAmerica Insurance Company publicly disclosed that during the 3rd and 4th quarters of 2021, death in people of working age (18 to 64 years) in the U.S:

1 was 40% higher than it was before the Pandemic;

2 was not attributed to Covid in the majority of cases; and

3 the world was experiencing the highest death rates reporting to insurance firms in recorded history.

c) in January, 2022, it was publicly reported by Group Life Insurance company which is responsible for 90% of employer-based sickness and life insurance policies in the United States that beginning in Q3 of 2021, younger age groups were suddenly dying at historically unprecedented rates.

d) in January, 2022, it was publicly reported that as to the insurance sector globally, the life insurance industry had reported claims of:

1 $5.5billion in the first 3 quarters of 2021; compared to

2 $3.5 billion for all of 2020.

Particulars

"Insurance executive says death rates among working-age people up 40 percent". 3 January, 2022. https://www.wfyi.org/news/articles/insurance-death-rates-working-age-people-up-40-percent

"Aegon, other insurers hit by US Covid-19 deaths in third quarter". 12 November, 2021. https://www.reuters.com/business/finance/aegon-q3-operating-result-down-16-us-covid-linked-claims-2021-11-11/

"SOA Research Institute (January 2022) Group Life COVID-19 Mortality Survey Report". Page 23. https://www.soa.org/48ff80/globalassets/assets/files/resources/research-report/2022/group-life-covid-19-mortality.pdf

"Life insurers adapt pandemic risk models after claims jump". 13 January, 2022. https://www.reuters.com/article/health-coronavirus-life-insurance-idCAKBN2JN0HP

INTERNATIONAL REPORTING DATA - KNOWN HIGH ADVERSE EVENTS AND DEATHS FROM VACCINES REPORTED IN US

154. It was known to the Respondents as at 24 December, 2021 through the U.S. data reported in the VAERS Database that:

a) reports of Adverse Events following vaccination with the Vaccines disclosed:

1 total number of reported adverse events: 705,991;

2 total number of reported serious adverse events: 126,418;

3 total number of reported deaths: 10,856;

b) total number of reports of hospitalisation or emergency room visits following vaccination with the Vaccines disclosed:

1 hospitalisation: 46,202;

2 emergency room visits: 87,586.

c) total number of reports of cardiovascular, neurological, immunological, and reproductive Adverse Events following vaccination with the Vaccines disclosed:

1 cardiovascular adverse events: 276,985;

2 neurological adverse events: 297,527;

3 immunological adverse events: 349,175;

4 reproductive adverse events: 12,277.

d) total number of reports of Adverse Events in Children following vaccination with the Vaccines disclosed:

1 for children aged 0-18 years: 41,595;

2 for children aged 5-11: 4,777.

e) as at 8 December, 2021 the total number of doses administered in the United States of America of the Vaccines was 119.6 million doses;

f) disclosing reported adverse events rates of:

1 5.9 adverse events per 1,000 doses administered;

2 1.1 serious adverse events per 1,000 doses administered;

3 0.9 deaths per 10,000 doses administered.

Particulars

The VAERS database.

CDC Covid Data Tracker – Covid-19 Vaccinations in the United States.
https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total

g) by way of comparison, in respect of the Flu Vaccine over the preceding period:

1 the number of doses administered in the U.S. ranged from about 110 million per year to more than 190 million per year since 2008 being in an average single year 25% more doses than all of the Covid Vaccines doses administered to 8 December, 2021;

2 the average number of reported deaths from all non-Covid vaccines in that period in the U.S. was 155 deaths per year which discloses that the rate of deaths in the Covid Vaccines on average has been 7000% higher than non-Covid vaccines.

Particulars

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

Centers for Disease Control and Prevention – Historical Reference of Seasonal influenza Vaccine Doses Distributed. Revised 4 August 2021. https://www.cdc.gov/flu/prevent/vaccine-supply-historical.htm

Covid-19 Vaccine Pharmacovigilance Report. World Council for Health. Updated 4 August 2022.Worldcouncilforhealth.org: https://worldcouncilforhealth.org/resources/covid-19-vaccine-pharmacovigilance-report

KNOWN EXPONENTIAL INCREASE IN ADVERSE EVENTS AND FETAL DEATHS REPORTED SINCE APPROVAL OF THE VACCINES IN US

155. The following was disclosed and known to the Respondents as at 11 November, 2022 through the U.S. data reported in the VAERS DatabasE:

a) 4,546 fetal deaths had been reported following the Vaccines being given to pregnant women;

b) Examining the preceding 32 years since the database was started in 1990:

1 the Vaccines represent 62% of all adverse events reported to VAERS for any reason in the 32 year period;

2 the Vaccines represent 77% of all vaccine-related deaths reported to VAERS for any reason in the 32 year period.

Particulars

The VAERS database.
https://vaers.hhs.gov/

KNOWN EXPONENTIAL INCREASE IN ADVERSE EVENTS AND DEATHS REPORTED SINCE APPROVAL OF THE VACCINES IN US

156. It was known to the Respondents as at December, 2021 through the U.S. data reported in the VAERS Database that:

a) the mean number of adverse events reported annually from 2011 until 2020 for Conventional Vaccines was 39,218 Adverse Events per annum;

b) the number of reported Adverse Events in 2021 inclusive of the Vaccines was 705,991;

1 the reporting of adverse events had thereby increased by 1,700% compared to the 9 years prior for all vaccines in the first year after the Vaccines were approved;

c) the mean number of deaths reported annually from 2011 until 2020 for Conventional Vaccines was 155 deaths per annum;

d) the number of reported deaths in 2021 inclusive of the Vaccines was 10,856;

1 the reporting of adverse events had thereby increased by 6,900% compared to the 9 years prior for all vaccines in the first year after the Vaccines were approved;

e) the increase was not attributable to excess administered doses since:

1 the Vaccines are a small proportion of all vaccines given in the US;

2 influenza vaccines administered since the 2008/2009 flu season number 1,720,400,000;

3 the approximate total number of doses the Vaccines administered by 31 December, 2021 was 521,620,000;

f) cumulative increases in the VAERS adverse events reporting precisely correlated with:

1 the number of people fully vaccinated against Covid-19; and

2 the times at which people became fully vaccinated with the Vaccines cumulatively increased.

Particulars

The VAERS database.

Cumulative Covid Vaccinations.
https://ourworldindata.org/grapher/cumulative-covid-vaccinations

KNOWN HIGH REPORTED RATES OF VACCINES ADVERSE EVENTS IN US

157. It was known to the Respondents as at 4 October, 2022, that the publicly released and available data from the US Government V-Safe active surveillance program in respect of the Vaccines safety disclosed the following data in respect of the Vaccines adverse event reporting:

a) 10,108,273 people reported to the V-Safe program following vaccination with the Vaccines, of which:

1 33.2% reported an adverse event following vaccination;

2 6,458,751 total health impacts were reported including:

(1) 7.7% of persons reported requiring medical care following vaccination;

(2) 11.9% of persons reported being unable to undertake normal activities following vaccination;

(3) 12.9% of persons missed school or work following vaccination.

Particulars

V-Safe Vaccine Surveillance Program
https://data.cdc.gov/Public-Health-Surveillance/v-safe/dqgu-gg5d

KNOWN HIGH REPORTED MYOCARDITIS/PERICARDITIS IN THE YOUNG IN US

158. It was known to the Respondents as at 31 March, 2022, that the publicly released and available data from the US Government Vaccine Safety Datalink (VSD) of the CDC active surveillance program in respect of the Vaccines safety disclosed the following data in respect of the Vaccines adverse event reporting:

a) verified myocarditis/pericarditis 0-7 days following mRNA vaccination (14 Dec, 2020 – 31 March, 2022) was reported as follows:

1 in Males aged 12-15 years after 2 Pfizer doses - 153.4 cases per 1 million doses;

2 in Males aged 16-17 years after:

(1) 2 Pfizer doses – 139.3 cases per 1 million doses;

(2) 3 Pfizer doses – 198.1 cases per 1 million doses;

3 in Males aged 18-29 years after:

(1) 2 Pfizer doses – 81.4 cases per 1 million doses;

(2) 3 Pfizer doses – 47.6 cases per 1 million doses;

(3) 2 Moderna doses – 97.3 cases per 1 million doses;

(4) 3 Moderna doses – 70.3 cases per 1 million doses;

4 in Females aged 16-17 years after:

(1) 3 Pfizer doses – 43.4 cases per 1 million doses;

Particulars

The CDC Vaccine Safety Datalink (VSD) database. https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html

KNOWN HIGH REPORTED RATES OF VACCINES ADVERSE EVENTS IN EUROPE

159. It was known to the Respondents as at 25 December, 2021, that the publicly released and available data from the EU EMA Eurdravigilance System database

passive surveillance program in respect of the Vaccines safety disclosed the following data in respect of the Vaccines adverse event reporting:

a) there were 1,304,635 reports of adverse events related to the Vaccines detailed as follows:

1 the Moderna Vaccine:

(1) 182,225 reported adverse events;

(2) 76.5% reported in 18-64 years age group;

(3) 16.6% reported in 65-85 years age group;

2 the Pfizer Vaccine:

(1) 654,735 reported adverse events;

(2) 2.2% reported in 12-17 years age group;

(3) 74.8% reported in 18-64 years age group;

(4) 13.9% reported in 65-85 years age group;

3 the AstraZeneca Vaccine:

(1) 425,561 reported adverse events;

(2) 77.7% reported in 18-64 years age group;

(3) 14.3% reported in 65-85 years age group.

Particulars

The Eurdravigilance System database.
https://www.ema.europa.eu/en/human-regulatory/research-development/pharmacovigilance/eudravigilance

KNOWN HIGH REPORTED RATES OF VACCINES FEMALE REPRODUCTIVE SIDE EFFECTS – UK

160. In the UK in respect of the Pfizer Vaccine, it was known from at least April, 2022 that there had been reported between 9 December, 2020 and 20 April, 2022 as caused by the Pfizer Vaccine:

a) 31,195 reproductive and breast disorders;

b) greater than 10,000 menstruation and uterine bleedings;

c) greater than 7000 menstruations with increased bleeding; and

d) 1000 breast-related signs or symptoms.

Particulars

COVID-19 mRNA Pfizer-BioNTech Vaccine Analysis Print. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1069177/COVID-19_Pfizer-BioNTech_Vaccine_Analysis_Print_DLP_6.04.2022.pdf

KNOWN HIGH ADVERSE DATA WORLDWIDE REPORTING

161. It was known to the Respondents since at least June, 2022 by reasonably obtained and observed empirical data from international reporting databases at that time and as concluded in known scientific analysis at that time that:

a) the total number of adverse events related to Covid-19 vaccines on WHO VigiAccess, VAERS, Eudravigilance, and UK Yellow Card Scheme individually were in each database unprecedented in history;

b) the magnitude of disparity in the number of adverse events from the Covid Vaccines compared to other commonly administered vaccines and therapies was sufficient to indicate an alarming safety signal for these products;

c) the total number of adverse events on VigiAccess for common vaccines was as follows:

1 Tetanus vaccine:

(1) data collected since 1968;

(2) 15,381;

2 Polio vaccine:

(1) data collected since 1968;

(2) 123,732;

3 Influenza B vaccine;

(1) data collected since 1986;

(2) 90,044;

4 Covid-19 Vaccine;

(1) Data collected since 2020;

(2) 4,000,000;

a) being 1,646% higher in 18 months than those other vaccines combined since 1968.

d) risk of death as reported in VAERS:

1 Influenza Vaccines: 1 in 5,074,171 (based on 33 deaths in 167,447,642 vaccinations);

2 Covid-19 Vaccines: 1 in 30,041 (based on 5770 deaths in 173,335,866 vaccinations);

(1) being a 16,791% higher rate of death reported in the Covid Vaccines.

e) Total Number Adverse Events on EudraVigilance for common vaccines:

1 all measles vaccines:

(1) approximately 673,200,000 vaccinations;

(2) 48,913 adverse events;

2 all polio vaccines:

(1) approximately 673,200,000 vaccinations;

(2) 8,982 adverse events;

a) being a combined 0.0043% adverse event rate.

3 Covid-19 vaccines:

(1) 341,628,772 vaccinations;

(2) 1,800,000 adverse events being

a) a 0.53% adverse event rate;

b) 12,200% higher than the known typical adverse event rate for the polio and measles vaccines.

4 in circumstances where in truth it was further known to the Respondents historically that:

(1) in 1976, the swine flu vaccination campaign was halted after a series of adverse event reports including 53 deaths;

(2) in 1955, the polio vaccine was recalled in less than 1 year after 10 reported deaths.

Particulars

The World Council for Health Covid-19 Pharmacovigilance Report
https://worldcouncilforhealth.org/wp-content/uploads/2022/12/Pharmacovigilance-Report-20.12.22-LR3.pdf

KNOWN GLOBAL DATA - MORE LIKELY TO DIE FROM VACCINES THAN COVID

162. It was known to the Respondents since at least February, 2022 by reasonably obtained and observed empirical all-cause mortality data and reasonably available scientific analysis contained in the publicly available COVID and All-Cause Mortality Data from US and U.K demonstrated conclusively that:

a) children under 18 are 51 times more likely to die from vaccination with the Vaccines than they are to die from COVID if not vaccinated;

b) in the age range of 18 to 29 those persons are eight times more likely to die from vaccination with the Vaccines than from COVID if not vaccinated;

c) in the age range of 30 to 39 those persons are seven times more likely to die from vaccination with the Vaccines than from COVID if not vaccinated;

d) in the age range of 40 to 49 those persons are five times more likely to die from vaccination with the Vaccines than from COVID if not vaccinated;

e) in the age range of 50 to 59 those persons are two times more likely to die from vaccination with the Vaccines than from COVID if not vaccinated;

f) in the age range of 60 years and over, those persons are equally likely to die from vaccination with the Vaccines than from COVID if not vaccinated;

g) only in the 80 years of age and over age group is a person less likely to die from vaccination with the mRNA Vaccines than from COVID if not vaccinated, being 0.13% less likely to die from vaccination with the Vaccines than from COVID if not vaccinated;

h) the risk benefit ratio for taking the mRNA Vaccines under the age of 60 is determinatively against taking the Vaccines.

Particulars

"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". Dopp K. and Seneff S. 2022. https://www.skirsch.com/covid/Seneff_costBenefit.pdf

KNOWN VACCINES CAUSE OF EXCESS MORTALITY - AUSTRALIAN MORTALITY DATA

163. It was known to the Respondents since at least September 2021 on an ongoing continuum of data to September, 2022 by reasonably obtained and observed empirical data and studies known to the Respondents at that time that the following had been scientifically established in respect of Mortality in Australia statistics published by the Australian Government – Australian Bureau of statistics:

a) from the beginning of 2022 until 30 September, 2022:

1 there were 144,650 deaths of which:

(1) 19,986 deaths or 16.0% were above the historical average;

(2) only 8,160 deaths are certified Covid deaths.

b) the excess mortality rates began to rise in September, 2021:

1 the mortality rate has at no time fallen back to the 5 year average range;

2 as at 30 September, 2021, 77.8% of the Australian population aged 16 years and over had received at least one dose of the Vaccines;

c) in the period of December 2021 to March 2022:

1 the mortality rate exhibited a peak in excess deaths over the baseline average;

2 there were less than 500 deaths attributed to Covid;

3 there were approximately 3,800 deaths;

d) in the period of March 2022 to August 2022 a further peaking of deaths occurred;

e) prior to the highly anomalous year of 2022, the highest annual increase in deaths per population was 4.4%, which occurred in 1964;

f) on average, over the following 66 year period, there was an annual 1.6% decrease in the death rate;

g) by 30th November 2022, according to the ABS, 9,115 of the deaths were recorded as being attributed to Covid;

1 making known to the Respondents at and prior to that time based upon the flow of mortality data that:

(1) that Covid was not solely responsible for the excess mortality;

(2) the rollout of the Vaccines is associated with excess mortality.

Particulars

ABS Provisional Mortality Statistics,
https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/latest-release#covid-19-mortality

COVID-19 Vaccine Rollout - 30 September 2021
https://www.health.gov.au/sites/default/files/documents/2021/09/covid-19-vaccine-rollout-update-30-september-2021.pdf

BRADFORD-HILL ANALYSIS OF AUSTRALIAN MORTALITY DATA – VACCINES CAUSAL OF EXCESS MORTALITY IN AUSTRALIA

164. It was known to the Respondents since at least July 2021 on an ongoing continuum of data to December, 2022 by reasonably obtained and observed empirical data produced by the Australian Bureau of Statistics known to the Respondents at that time and by the application of proper Bradford-Hill Analysis in causality assessment that:

a) since prior to the Approvals, the Bradford Hill Analysis:

1 was and remains one of the most widely used and superior methods of adverse event causality assessment historically and globally;

2 ought to have been at all times applied by the Respondents to the known data in respect of excess deaths in the Australian population and with regard to the rollout of the Vaccines post-Approvals;

b) that reasonably applying the internationally accepted standard of causality, being the Bradford Hill Analysis, to the data known to the Respondents at that time scientifically discloses that:

1 the significant excess mortality occurring in the Australian population at that time was 74% positively correlated with the volume of injections of the Vaccines in the Australian population;

2 strength of foremost Bradford Hill criteria being, correlation, consistency, specificity, temporality and dose-response relationship by application to the post-Approvals excess mortality data known to the Respondents at that time confirms that:

(1) the excess mortality observed in that period is iatrogenesis caused by the Vaccines;

a) thereby, that:

i) the increase in excess mortality in Australia at that period was causally

related to the Vaccines;

ii) harm, or risk of harm, outweighs from the Vaccines significantly outweighs any benefit of the Vaccines.

Particulars

ABS Provisional Mortality Statistics
https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/latest-release#covid-19-mortality

"Australian COVID-19 pandemic: A Bradford Hill Analysis of Iatrogenic Excess Mortality." Sy, W. 2023. J Clin Exp Immunol, 8(2), 542-556.

KNOWN UK EXCESS MORTALITY IN YEAR OF VACCINES APPROVALS

165. It was known to the Respondents since at least September, 2021 by reasonably obtained and observed empirical data known to the Respondents at that time that excess mortality increased significantly in all working ages in Q3 2021 in the UK to:

a) aged 25-34 years: 181%;

b) aged 35-44 years: 217%;

c) aged 45-54 years: 208%;

d) aged 55-64 years: 170%.

1 such exponential increases occurring concurrently with the Approval and release of the Vaccines;

2 at least apparently causally correlated to the release of the Vaccines.

Particulars

Society of Actuaries Research Institute published its COVID-19 Mortality Survey Report.
www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/deathsbyvaccinationstatusengland

KNOWN GERMANY EXCESS MORTALITY IN YEAR OF VACCINES APPROVALS

166. It was known to the Respondents since at least August 2022 by reasonably obtained and observed empirical data that the excess mortality rates in Germany, whilst remaining stable in 2020 during the pandemic but prior to the use of the Vaccines, began increasing significantly from April 2021 onwards and was:

a) almost entirely due to an increase in deaths in the age groups between 15 and 79;

b) a similar pattern was observed for stillbirths with an increase of:

1 9.4% in the second quarter of 2021; and

2 19.6% in the fourth quarter of 2021.

Particulars

"Excess mortality in Germany 2020-2022". Kuhbandner, C and Reitzner, M. August, 2022.
DOI: 10.13140/RG.2.2.27319.19365.
https://www.researchgate.net/publication/362777743_Excess_mortality_in_Germany_2020-2022

KNOWN AUTOPSY DATA – SUDDEN DEATH AFTER VACCINATION

167. It was known to the Respondents since at least 27 November, 2022 by reasonably obtained and observed empirical data and reported autopsy results following autopsies of 35 cases of people with sudden death at home occurring within 20 days of injection with the Vaccine that:

a) 14.3% were found to have:

1 died as a result of Vaccine related myocarditis;

2 died within 5 days of injection with the Vaccine;

3 not had previous Covid infection;

4 a degree and type of myocardial inflammatory infiltration and cardiac pathology never before observed in the 20 years prior autopsy service at Heidelberg University Hospital.

Particulars

"Autopsy-based histopathological characterization of myocarditis after anti-SARS-CoV-2-vaccination". Schwab, C et al, 2023. Clin Res Cardiol 112, 431–440. https://doi.org/10.1007/s00392-022-02129-5

ADVERSE EVENT REPORTING TO THE TGA - KNOWN PFIZER POST-APPROVAL DATA AND SERIOUS SAFETY SIGNALS IN DEATH RATE AND MISCARRIAGE

168. In the Pfizer Post-Marketing Data, dated 28 February, 2021, Pfizer reported and it was thereby known to the Respondents at that time that:

a) between 1 December 2020 and 28 February 2021:

1 1223 fatalities were reported to Pfizer following vaccination with the Pfizer vaccine;

2 being approximately 407 deaths per month

3 in circumstances where in truth:

(1) the Respondents did not consider the extraordinary post-Approvals deaths to be a cause for:

a) concern; or

b) withdrawal of the Pfizer Vaccine Approval

(2) comparatively:

a) in 1976, the swine flu vaccination which after 3 months and 26 deaths related to the vaccine:

i) was removed from the market until the issue could be explored;

ii) displayed a death rate of 1 in 100,000 persons receiving the vaccine.

b) in 1999, Rotavirus vaccine which after 0 deaths and a few cases of intussusception in toddlers:

i) was removed from the market permanently;

ii) displayed 1-2 serious adverse events per 10,000 persons receiving the vaccine.

c) in 2010, the seasonal influenza vaccine after 0 deaths and 22 reported cases of febrile convulsions in children:

i) was suspended from use by the Australian population;

ii) displayed 9 febrile convulsions per 1,000 persons receiving the vaccine.

b) in 270 pregnant women vaccinated with the Pfizer Vaccine:

1 there was a 46% complication rate;

2 wherein, 238 women weren't followed-up at all by Pfizer, despite the

obligation to do so under:

(1) the Pfizer Trial Protocol; and

(2) TGA's Pharmacovigilance Requirements for Medicine Sponsors requires Sponsors to follow up and report upon all women pregnant during the study;

a) in circumstances where in truth:

b) the Respondents did not consider the extraordinary post-Approvals pregnancy complication rate to be a cause for:

i) concern; or

ii) withdrawal of the Pfizer Vaccine Approval from use in pregnant women.

Particulars

The Pfizer Post-Marketing Data. Pages 7, 12.

"Ministerial Review into the Public Health Response into the Adverse Events to the Seasonal Influenza Vaccine". https://www.health.wa.gov.au/~/media/Files/Corporate/Reports-and-publications/PDF/Stokes_Report.pdf

"Pharmacovigilance responsibilities of medicine sponsors". https://www.tga.gov.au/resources/resource/guidance/pharmacovigilance-responsibilities-medicine-sponsors

TGA ANNOUNCES 60-FOLD INCREASE IN POST-APPROVALS ADVERSE EVENT REPORTING

169. It was known to the Respondents since at least 6 May, 2021 that subsequent to the Approvals:

a) there had been a significant increase in adverse events reported to the TGA overall as compared to 2020 as a consequence of adverse events related to the Vaccines occurring after the Approvals being reported;

b) adverse events reported to the TGA overall as compared to 2020 had increased 60-fold as a consequence of adverse events related to the Vaccines occurring after the Approvals being reported.

Particulars

Announcement of Therapeutic Goods Administration, Professor John Skerritt and Commodore Eric Young's press conference on 6 May, 2021.
https://www.health.gov.au/news/therapeutic-goods-administration-professor-john-skerritt-and-commodore-eric-youngs-press-conference-on-6-may-2021

AUSVAXSAFETY – AUSTRALIAN ACTIVE ADVERSE EVENT REPORTING

170. AusVaxSafety is:

a) a national vaccine safety system;

b) led by the National Centre for Immunisation Research and Surveillance (NCIRS);

c) monitors adverse events following taking of the Vaccines with the stated purpose of facilitating early detection of potential vaccine safety issues;

d) states that:

1 "Post-licensure surveillance of adverse events following immunisation is an important component of any national immunisation program and is essential to maintaining the confidence of general public and immunisation providers in the national immunisation program";

2 "Analysis of de-identified responses occurs frequently and is

reviewed by vaccine experts as well as the Australian Government of Health and Aged Care, including the Therapeutic Goods Administration (TGA).

Particulars

"AusVaxSafety – An NCIRS led collaboration". https://ausvaxsafety.org.au

"COVID-19 vaccine safety surveillance". https://ausvaxsafety.org.au/our-work/covid-19-vaccine-safety-surveillance

KNOWN AUSVAXSAFETY DATA – EXTRAORDINARY RATE OF ADVERSE EVENTS

171. The AusVaxSafety COVID-19 Vaccine Surveillance Summary Report 2021 included safety surveillance data collected by AusVaxSafety for all Covid-19 vaccine brands used in Australia from 22 February, 2021 to 31 December, 2021 and stated:

a) the following data shows the responses of all individuals aged 12 years and older who received the Pfizer Vaccine and completed the AusVaxSafety survey sent on day 3 after vaccination:

1 number of safety surveys completed: 4,094,999;

2 percentage of respondents who reported at least one adverse event:

(1) Pfizer dose 1: 37%;

(2) Pfizer dose 2: 53%;

(3) Pfizer dose 3: 54%;

3 percentage of respondents who required medical attendance:

(1) Pfizer dose 1: 0.7%;

(2) Pfizer dose 2: 1.3%;

(3) Pfizer dose 3: 0.9%;

4 percentage of respondents who reported missing work, study or routine duties in the 3 days following vaccination:

(1) Pfizer dose 1: 8%;

(2) Pfizer dose 2: 21%;

(3) Pfizer dose 3: 15%;

b) the following data shows the responses of all individuals aged 18 years and older who received the AstraZeneca Vaccine and completed the AusVaxSafety survey sent on day 3 after vaccination:

1 number of safety surveys completed: 972,044;

2 percentage of respondents who reported at least one adverse event:

(1) AstraZeneca dose 1: 56%;

(2) AstraZeneca dose 2: 25%;

3 percentage of respondents who required medical attendance:

(1) AstraZeneca dose 1: 1.1%;

(2) AstraZeneca dose 2: 0.4%;

4 percentage of respondents who reported missing work, study or routine duties in the 3 days following vaccination:

(1) AstraZeneca dose 1: 19%;

(2) AstraZeneca dose 2: 5%;

c) the following data shows the responses of all individuals aged 12 years and older who received the Moderna Vaccine and completed the AusVaxSafety survey sent on day 3 after vaccination:

1 number of safety surveys completed: 41,557;

2 percentage of respondents who reported at least one adverse event:

(1) Moderna dose 1: 40%;

(2) Moderna dose 2: 65%;

(3) Moderna dose 3: 62%;

3 percentage of respondents who required medical attendance:

(1) Moderna dose 1: 1.4%;

(2) Moderna dose 2: 3.1%;

(3) Moderna dose 3: 0.4%;

4 percentage of respondents who reported missing work, study or routine duties in the 3 days following vaccination:

(1) Moderna dose 1: 13%;

(2) Moderna dose 2: 36%;

(3) Moderna dose 3: 19%;

a) in circumstances where in truth the Australian Immunisation Handbook reports that adverse reaction to vaccinations occur at an average rate ranging from 1 in 1000 to 1 in 10,000; or

b) 0.1% to 0.01%.

Particulars

National Health and Medical Research Council, "The Australian Immunisation Handbook". 9th ed. 2008: Commonwealth Government of Australia. https://immunisationhandbook.health.gov.au/

"AusVaxSafety COVID-19 Vaccine Surveillance Summary Report 2021". https://www.health.gov.au/sites/default/files/documents/2022/09/ausvaxsafety-covid-19-vaccine-surveillance-summary-report-2021_0.pdf

KNOWN PROLIFIC ADVERSE EVENTS REPORTS LISTED IN THE DAEN DATABASE – DECEMBER 2021

172. As at 31 December, 2021, the Respondents knew that the publicly available DAEN database recorded the following reported adverse events associated with the Vaccines:

a) Pfizer Vaccine - 25/01/2021 to 31/12/2021:

1 No. of cases: 52,695;

2 No. of cases with a single suspected medicine: 51,641;

3 No. of cases of death: 264.

b) AstraZeneca Vaccine - 16/02/201 to 31/12/2021:

1 No. of cases: 43,874;

2 No. of cases with a single suspected medicine: 43,108;

3 No. of cases of death: 439.

c) Moderna Vaccine - 09/08/2021 to 31/12/2021:

1 No. of cases: 3,234;

2 No. of cases with a single suspected medicine: 3,180;

3 No. of cases of death: 7.

d) Unspecified COVID vaccines 01/01/2021 to 31/12/2021:

1 No. of cases: 465;

2 No. of cases with a single suspected medicine: 446;

3 No. of cases of death: 25.

e) Total for all COVID vaccines plus unspecified COVID vaccines:

1 No. of cases: 100,268;

2 No. of cases with a single suspected medicine: 98,375;

3 No. of cases of death: 735.

Particulars

The DAEN database. https://www.tga.gov.au/safety/safety/safety-monitoring-daen-database-adverse-event-notifications/database-adverse-event-notifications-daen

KNOWN PROLIFIC ADVERSE EVENTS REPORTS LISTED IN THE DAEN DATABASE – JUNE

173. As at 8 June, 2022, the Respondents knew that the publicly available DAEN database recorded the following reported adverse events associated with the Vaccines:

a) since the roll out of the Pfizer Vaccine commenced for 5-11 year olds, in that age group there were:

1 1,390 Adverse Events; and

2 5 Deaths;

(1) being:

a) a 7 year old male, caused by

i) cardiac arrest;

ii) generalised tonic-clonic seizure;

b) a 9 year old female;

i) caused by cardiac arrest;

c) a 6 year old male;

i) caused by adverse event following immunisation;

d) a 10 year old male;

i) caused by adverse event following immunisation;

e) a 5 year old male;

i) caused by:

1. cardiac arrest;

2. abdominal pain.

b) since there rollout of the vaccines there were a total of:

1 108,542 Adverse Events; and

2 723 Deaths reported in adolescents and adults following vaccination.

3 across all ages (including instances of unspecified ages), a total of:

(1) 131,991 Adverse Events; and

(2) 884 Deaths reported following vaccination.

c) on 16 June, 2022, the TGA's COVID-19 vaccine weekly safety report reported:

1 1,480 Adverse Events in 5-11 year olds following approximately 2.2M doses of Pfizer Vaccine; and

2 130,887 Adverse Events in all ages following 59,707,387 doses of Covid-19 Vaccines.

Particulars

The DAEN database.

"COVID-19 vaccine weekly safety report - 16-06-2022". https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-weekly-safety-report-16-06-2022

KNOWN UNPRECEDENTED EXPONENTIAL INCREASE IN REPORTED VACCINES ADVERSE EVENTS

174. It was known to the Respondents since at least since the date of the Approvals and on an ongoing continuum of data until 31 December, 2021 of the known reported adverse events data reported in DAEN in respect of the Vaccines and all other vaccines that the reported adverse events associated with the Vaccines were of a magnitude unprecedented in the history of adverse events recorded data in Australia as follows:

a) for all vaccines, excluding the Covid Vaccines, used in the 50 year period from 1 January 1971 to 31 December 2021:

1 a total number of reported adverse events of 19,330;

2 a total number reported deaths of 59;

b) for the Vaccines in the 1 year period of 2021:

1 a total number of reported adverse events of 100,180;

2 a total number reported deaths of 749;

c) adverse event frequency:

1 from 2010 to 2020 for the non-Covid Vaccines as being 0.9 adverse events in every 10,000 doses;

2 in 2021, inclusive of the COVID Vaccines, as being 23 adverse events in every 10,000 doses;

3 in the year 2021 immediately subsequent to the release of the Vaccines, an increase in adverse event frequency per dose of vaccines of 2,555%.

d) death events:

1 from 2010 to 2020 for the non-Covid Vaccines:

(1) a total of 29 reported deaths.

(2) the incidence of reported death from an adverse reaction to a vaccine was:

a) 0.22 to 0.27 reported deaths per million doses; or

b) approximately 1 death in every 4 million doses.

2 in 2021 only inclusive of the Covid Vaccines as:

(1) a total of 749 reported deaths;

(2) 42,598,706 total vaccine doses administered nationally;

(3) the incidence of reported death from an adverse reaction to a vaccine was:

a) 17 reported deaths per million doses; or

b) approximately 1 death in every 58,823 doses.

c) an increase in the year 2021 immediately subsequent to the release of the Vaccines, in reported deaths per dose of vaccines of 30,442%.

e) deaths from vaccines data indicating that receiving the Covid Vaccine is 68 times more likely to result in death than traditional vaccines;

f) the number of cases where death was a reported outcome associated with the Vaccines in 2021 was 749 as compared to ABS reports that:

1 the total reported deaths from or with Covid in 2020: 905;

2 the total reported deaths from or with Covid in 2021: 1,306, of which:

(1) 114 occurred in January to August, 2021;

(2) 1,192 occurred in September to December, 2021;

g) the DAEN reported adverse events cases categorised by specific reaction type reported on average per annum are for:

1 Myocarditis:

(1) in the 50 year period of 1971 to 2021 for non-Covid vaccines:

a) 16 cases;

b) 0.32 cases per annum;

(2) in 2021 only for the Covid Vaccines:

a) 1110 cases;

b) 3,469 times the rate per annum of the non-Covid vaccines;

c) 69.38 times the total number of non-Covid vaccines in the preceding 50 year period.

2 Pericarditis:

(1) in the 50 year period of 1971 to 2021 for non-Covid vaccines:

a) 12 cases;

b) 0.24 cases per annum;

(2) in 2021 only for the Covid Vaccines:

a) 2394 cases;

b) 9,975 times the rate per annum of the non-Covid vaccines;

c) 200 times the total number of non-Covid vaccines in the preceding 50 year period.

3 Guillain-Barre Syndrome:

(1) in the 50 year period of 1971 to 2021 for non-Covid vaccines:

a) 67 cases;

b) 1.34 cases per annum;

(2) in 2021 only for the Covid Vaccines:

a) 217 cases;

b) 9,975 times the rate per annum of the non-Covid vaccines;

c) 3.24 times the total number of non-Covid vaccines in the preceding 50 year period.

4 Immune Thrombocytopenia:

(1) in the 50 year period of 1971 to 2021 for non-Covid vaccines:

a) 21 cases;

b) 0.42 cases per annum;

(2) in 2021 only for the Covid Vaccines:

a) 114 cases;

b) 271.4 times the rate per annum of the non-Covid vaccines;

c) 5.4 times the total number of non-Covid vaccines in the preceding 50 year period.

5 Thrombosis with Thrombocytopenia Syndrome:

(1) in the 50 year period of 1971 to 2021 for non-Covid vaccines:

a) 1 case;

b) 0.02 cases per annum;

(2) in 2021 only for the Covid Vaccines:

a) 154 cases;

b) 7,700 times the rate per annum of the non-Covid vaccines;

c) 154 times the total number of non-Covid vaccines in the preceding 50 year period.

6 Thrombocytopenia Syndrome:

(1) in the 50 year period of 1971 to 2021 for non-Covid vaccines:

a) 43 cases;

b) 0.86 cases per annum

(2) in 2021 only for the Covid Vaccines:

a) 741 cases;

b) 861 times the rate per annum of the non-Covid vaccines;

c) 17.2 times the total number of non-Covid vaccines in the preceding 50 year period.

7 Abortions and Spontaneous miscarriages:

(1) in the 50 year period of 1971 to 2021 for non-Covid vaccines:

a) 33 cases;

b) 0.66 cases per annum;

(2) in 2021 only for the Covid Vaccines:

a) 227 cases;

b) 344 times the rate per annum of the non-Covid vaccines;

c) 6.8 times the total number of non-Covid vaccines in the preceding 50 year period.

h) As to reported adverse events to DAEN:

1 number of Adverse Events:

(1) in 1971 to 2021 related to all non-Covid vaccines: 19,330;

(2) in 2021 related to the Vaccines: 100,180.

2 number of deaths:

(1) in 1971 to 2021 related to all non-Covid vaccines: 59;

(2) in 2021 related to the Vaccines: 749;

3 number of adverse reactions reported per Adverse Event:

(1) in 1971 to 2021 related to all non-Covid vaccines: 2.27 Reactions per Event

(2) in 2021 related to the Vaccines: 3.26 Reactions per Event.

a) in circumstances where in truth the increase in reported adverse events was and remains of such magnitude in excess of previous vaccines as to be an act of gross negligence and profound indifference to obligations to act within the constraints of the Act and the consequential harm of retaining the Approvals after the Approvals to date as such data became apparent.

Particulars

The DAEN database. https://www.tga.gov.au/safety/safety/safety-monitoring-daen-database-adverse-event-notifications/database-adverse-event-notifications-daen

"Covid-19 Vaccine Rollout Update – 31 December, 2021". https://www.health.gov.au/sites/default/files/documents/2021/12/covid-19-vaccine-rollout-update-31-december-2021.pdf

"COVID-19 Mortality in Australia: Deaths registered until 31 March 2022". https://www.abs.gov.au/articles/covid-19-mortality-australia-deaths-registered-until-31-march-2022

KNOWN EARLY PFIZER POST APPROVAL ADVERSE EVENTS SAFETY ALARMS

175. On or about 19 August, 2021, Pfizer published to the Respondents, thereby known to them by at least 19 August, 2021, through a Periodic Safety Update Report in respect of the Pfizer Vaccine **("the Pfizer PSUR")**, the following data and determinations obtained and formed in the reporting period of 19 December 2020 through 18 June 2021 and in fact commencing January, 2021 onward:

a) that Pfizer had identified and was reporting the following adverse events with safety signals which are determined to be risks associated with the Pfizer Vaccine:

1 dizziness;

2 hyperhidrosis;

3 night sweats;

4 asthenia;

5 lethargy;

6 decreased appetite;

7 vaccine stress-related responses;

8 tachycardia;

9 diarrhea;

10 pain in extremity (arm);

11 anaphylaxis;

12 vomiting;

13 hypersensitivity other than anaphylaxis; and

14 paresthesia.

b) that Pfizer had identified and was reporting that there were at that time the following adverse events with ongoing safety signals associated with the Pfizer Vaccine:

1 immune thrombocytopenia;

2 trigeminal neuralgia;

3 myocarditis;

4 pericarditis;

5 hypertensive crisis with intracranial haemorrhage.

(1) in circumstances where in truth:

a) according to the EU Product Information Guidance:

i) each of this should have at least been mentioned in Section 4.8 of the Pfizer

Product Information either;

ii) in the safety profile summary; or

iii) in the tabulated list of adverse reactions from clinical studies.

c) that Pfizer had identified and was reporting that the following adverse events with safety signals which were determined not to be risks associated with the Pfizer Vaccine:

1 seizure;

2 thromboembolic events;

3 delayed skin reaction;

4 delayed syncope;

5 eye pain and eye swelling;

6 herpes zoster including ophthalmic herpes zoster;

7 appendicitis;

8 hearing loss and tinnitus;

9 extensive swelling of the limbs;

10 reaction associated with dermal fillers;

11 injection site pruritis;

12 insomnia;

13 overdose;

14 deaths (including elderly or frail individuals);

15 facial nerve palsy.

(1) in circumstances where in truth:

a) the evaluation of signals was ultimately the purview also of the Respondents who had purported to be independently determining or addressing all safety signals;

b) that “deaths (including elderly or frail individuals)” is listed as a signal determined not to be a risk;

c) the TGA at that time had the Norwegian information that the deaths in elderly were a risk;

d) there were voluminous reports of deaths already on DAEN;

e) therefore that the TGA ought to have concluded that Pfizer was not accurately reporting on signals; and

f) therefore rejected Pfizer’s conclusions regarding their own safety signal evaluation but did nothing.

d) that Pfizer reported to the TGA that during the reporting period monitoring was requested or was proposed by Pfizer in previous Summary Monthly Safety Reports for:

1 lymphopenia;

2 immune thrombocytopenia;

3 hearing loss and tinnitus;

4 hypoglycaemia;

5 serious hypertension;

6 hemophagocytic syndrome;

7 serious arrhythmias;

8 acute pancreatitis;

9 acquired haemophilia; and

10 menstrual disorders.

(1) in circumstances where in truth:

a) these should all have been listed in the PI Section 4.4 Special warnings and precautions for use;

(2) the EU Risk Management Plan identified important risks;

(3) these should have appeared under special precautions so that prescribers would be alerted to watch for these events, and also to assist in benefit risk evaluation in these patient groups

e) that Pfizer had determined and reported to the TGA that:

1 in accordance with the European Union Risk Management Plant (EU-RMP) in effect at the beginning of the reporting period 1.0 dated 21 December 2020:

(1) the important identified risk is anaphylaxis; and

(2) the important potential risk is Vaccine-associated Enhanced Disease (VAED) including Vaccine-associated Enhances Respiratory Disease (VAERD);

(3) missing information incorporates the complete absence of data and testing in:

a) use in pregnancy and while breast feeding;

b) use in immunocompromised patients;

c) use in frail patients with co-morbidities, including:

i) chronic obstructive pulmonary disease;

ii) diabetes;

iii) chronic neurological disorders; and

iv) cardiovascular disorders.

d) use in patients with:

i) autoimmune; or

ii) inflammatory disorders.

e) interaction with other vaccines; and

f) long term safety data.

i) in circumstances where in truth these were important risks never communicated to the Australian public;

f) that Pfizer had determined and reported to the TGA that risks had been evaluated by Pfizer in the context of the benefits of the Pfizer Vaccine:

1 based upon the available safety and efficacy/effectiveness data from the reporting interval for Pfizer Vaccine; and

2 Pfizer had determined based upon such evaluation that:

(1) the benefit-risk profile of the Pfizer Vaccine remained favourable; and

(2) no additional changes to the Pfizer Vaccine RSI or additional risk minimisation activities are warranted.

a) accepted by the Respondents fully in circumstances where in truth they knew:

i) from the re-evaluation of the clinical trial data was 1 in 800 suffering serious adverse events; and

ii) also the effect on efficacy in omitting ~4000 symptomatic patients from the analysis because they didn't PCR test them

1. the above statement re risk/benefit is questionable.

iii) the TGA should have conducted their own due diligence instead of just accepting the assertions of Pfizer and other sponsors but instead did not and instead acquiesced without basis or logic.

g) Pfizer had determined and reported to the TGA that in composing the Pfizer PSUR and its conclusions in that document, Pfizer acted in accordance with the EU benefit-risk evaluation guideline.

1 in circumstances where in truth:

(1) the Guideline carries obligations to review how the benefit / risk changes over time;

(2) Page 4 of the EU guideline states that - "These factors underlie the need for continuing analysis of relevant safety, efficacy, and effectiveness information throughout the lifecycle of a medicinal product – promptly, as important findings occur – and periodically, to allow an overall assessment of the accumulating

data. Although the majority of new information will be safety-related, new information about effectiveness, limitations of use, alternative treatments, and many other aspects of the drug's place in therapy may be pertinent to its benefit-risk assessment."

h) Pfizer determined and reported to the TGA that data from the Pfizer Clinical Trial in respect of the Pfizer Vaccine demonstrated:

1 883 severe adverse events had occurred:

2 in the 23,514 participants in the Pfizer Vaccine group;

3 demonstrating a severe adverse event reporting rate of 3.7% in recipients of the Pfizer Vaccine;

4 that the severe adverse events in the Pfizer Vaccine group:

(1) included a case of:

a) acute myeloid leukemia;

b) anaphylactoid reaction;

c) cystitis;

d) hyperthyroidism;

e) myalgia;

f) myocardial infarction;

g) polymyalgia rheumatica;

h) portal vein thrombosis; and

i) thyroid mass.

(2) each of the adverse events in (a) was determined by the TGA

investigator working under the authority and direction of the Respondents to be causally linked to the Pfizer Vaccine.

(3) in circumstances where in truth:

a) these safety matters should all have been included in the Pfizer Product Information from this time point of August 2021 onwards but were not

b) from at least August 2021, the Respondents had knowledge that the Pfizer Vaccine had a Severe Adverse Event Rate of 3.7%;

i) that Pfizer had observed and reported to the TGA that post-marketing sources had disclosed:

1 the occurrence of 329,919 severe adverse events in an estimated 635.7 million doses of the Pfizer Vaccine;

2 indicated a severe adverse events rate of 1 in 962 fully vaccinated persons.

(1) In circumstances where in truth:

a) this would be expected to be a large underestimation because:

i) a lower percentage of people or doctors would report the event directly to Pfizer;

ii) most do not report to their country's regulatory authority, or not at all as underreporting data shows;

b) consequently the volume of Adverse Events reported to Pfizer that were provided in this PSUR should have been extremely concerning to the Respondents.

j) that Pfizer had concluded and reported to the TGA that of the reported events:

1 the frequency are not listed or consistent with listed events as per the current Investigators Brochure;

2 none were considered to be related to Pfizer Vaccine by either the Investigator acting for the Respondents or Pfizer;

(1) in circumstances where in truth:

a) the Respondents refer to table 6 on page 33;

b) the table has a post script of the clinical trial data SAE's assessed as related to the Pfizer Vaccine (as above) and all except 2 of these are subscript 'a' which says assessed as related by the Investigator and unrelated by the sponsor;

c) this should have immediately raised an alarm for the Respondents that almost all Serious Adverse Events were considered related by the investigator, but that Pfizer was falsely stating in the PSUR that the investigator considered the Serious Adverse Events unrelated.

k) that Pfizer had concluded and reported to the TGA that as to lot numbers of the Pfizer Vaccine:

1 lot numbers list several lots with high numbers of cases;

2 the table does not have a % or state the number of doses for each lot;

3 it is apparent that some lots have higher adverse event reports or possibly rates which is supposed to be reviewed according to the EMA Guideline on Good Pharmacovigilance Practices.

l) that Pfizer had concluded and reported to the TGA that as to a review of new safety information arising by Pfizer, Pfizer:

1 cited a study dated 1 July, 2021 relating to risk in pregnancy of the Pfizer Vaccine which stated in fact, inter alia, that the following had been observed in the child or pregnant Pfizer Vaccine recipients:

(1) fetal vascular malperfusion lesion – chronic vessel with intramural fibrin deposition;

(2) placental tissue examined had a much higher rate of malperfusion lesions in the placental tissue for vaccinated patients.

a) in circumstances where in truth his should have triggered caution, and represents a fetal anomaly reported in the clinical literature.

2 cited a study dated 31 May, 2021 that in fact reported intracranial haemorrhage in the recipients of the Pfizer Vaccine;

3 stated that a search of the Medline and Embase databases identified no new safety findings for the Pfizer Vaccine;

(1) wherein in truth:

(2) this was asserted by Pfizer and accepted by the Respondents despite there being dozens of articles by that stage that raised concerns in the clinical literature.

(3) the search results were never presented;

(4) in fact any simple search on the subject returns over 1000 studies results;

m) that Pfizer had concluded and reported to the TGA that safety signal in relation to the majority of adverse event signals had been closed, or closed and refuted;

1 In circumstances wherein:

(1) this is accepted without question again by the Respondents;

(2) details are not provided by Pfizer or the Respondents and:

a) some are closed as “non-validated signals”;

b) no further detail is provided by Pfizer or the Respondents; and

c) no inquiry by the Respondents is made.

n) that Pfizer had concluded and reported to the Respondents that the safety signal in relation to the majority of Adverse Event signals were not causal;

1 wherein in truth:

(1) the conclusions simply dismiss the events and state not causal without any basis or explanation;

(2) subsequently accepted by the Respondents without question or further inquiry.

o) that Pfizer had concluded and reported to the Respondents that a safety signal in relation to serious hypertension:

1 is dismissed by Pfizer after being asked by the Respondents to perform a cumulative review;

2 has no plausible mechanism to explain any sustained elevated serious hypertension caused by the Covid Vaccine.

(1) wherein in truth:

a) there are in fact several mechanisms for serious hypertension;

b) cases are on DAEN, VAERS and in the clinical literature;

c) by consistently asserting that a repetitive side effect of the Vaccines is not associated with the Vaccines allows that assertion to continue on the basis that even when arising in volume over a long period, is consistently dismissed as unassociated.

p) that Pfizer had concluded and reported to the Respondents that VAED is listed as an ongoing safety concern;

1 in circumstances wherein VAED still never appears in any of the Vaccines' Product Information;

q) that Pfizer had concluded and reported to the Respondents that with respect to pregnancy, the Pfizer Vaccine trial recipients reported adverse events at the rate of:

1 35%; or

2 51 recipients.

r) that Pfizer had concluded and reported to the Respondents that there were 144 pregnancies recorded prospectively in Pfizer Vaccine trial recipients, after commencement of the reporting period of which:

1 17 (11.8%) miscarried;

2 35 (24%) ended either in pregnancy loss or congenital anomaly;

3 109 (76%) went to full delivery without a congenital anomaly.

s) that Pfizer had concluded and reported to the Respondents that of the 144 pregnancies reported:

1 there were 73 pregnancies in Pfizer Vaccine trial recipients during the reporting period where the mother received the Pfizer Vaccine

during the first trimester;

2 of which 12 pregnancies (16.4%) miscarried;

t) that the miscarriage rates were profoundly higher in Pfizer Vaccine trial recipients than the expected pregnancy loss rate following diagnosis of pregnancy by ultrasound (i.e. prospectively) known to Pfizer and the Respondents at that time as follows:

1 the risk of miscarriage after diagnosis decreases significantly as gestation advances as follows:

(1) 9.4% at 6 weeks of gestation;

(2) 4.2% at 7 weeks of gestation;

(3) 1.5% at 8 weeks of gestation;

(4) 0.5% at 9 weeks of gestation;

(5) 0.7% at 10 weeks of gestation.

2 most miscarriages occur within the 1st week of gestation;

3 an overall expected miscarriage rate after diagnosis of pregnancy (prospective) of 1.6 to 6.3% miscarriage rate;

4 the miscarriage rate in Pfizer Vaccine recipients was between 87% and 638% higher than the expected miscarriage rate known to the Respondents;

5 that Pfizer had concluded and reported to the Respondents in respect of reported outcomes for a cohort from the wider population reporting an Adverse Event in pregnancy associated with the Pfizer Vaccine exposure, the following were reported:

(1) total reported pregnancies of 1089 (including both prospective and retrospective cases);

(2) miscarriages and terminations of 232 (21.3%) wherein 90% of terminations recorded were due to foetal defects;

(3) pregnancies wherein the Pfizer Vaccine was received in the first trimester were 215 (20%) of the total;

(4) miscarriages and terminations of 92 (43% of the first trimester pregnancies) wherein 83% of terminations recorded were due to foetal defects.

6 the Respondents were, as a consequence of the data contained therein, aware that:

(1) the pregnancy loss rate was profoundly higher than expected in the Pfizer Vaccine group;

(2) the Pfizer Vaccine could not be reasonably or otherwise deemed to be safe for use in pregnant women, and in particular, those whom were in the first trimester of gestation;

(3) the knowledge by the Respondents of those matters stated by Pfizer formed a basis for immediate suspension of the use of the Pfizer Vaccine in pregnant women;

(4) pregnant women who didn't benefit from this treatment at all were coerced into taking an investigational product that was known to have a higher rate of fetal loss:

a) known before the product came onto the market in Australia;

b) known at the time of the Pfizer Post-Marketing Data safety assessment provided to the Respondents on or around 28 February, 2021;

c) known by the Respondents under proportional reporting ratio (PRR) safety signals;

d) on the basis of the available evidence, the Vaccines should never have been provided to pregnant women and should have been paused or halted at the first significant sign of a safety signal in February 2021.

u) that Pfizer had concluded and reported to the Respondents that there were 3 reports of infants who appear to have suffered a stroke where:

1 their mother was either:

(1) vaccinated with the Pfizer Vaccine during pregnancy; or

(2) vaccinated with the Pfizer Vaccine when breastfeeding.

2 1 died;

3 the outcome for 2 is not reported;

v) that Pfizer had concluded and reported to the Respondents that in respect of the important risk of VAED in recipients of the Pfizer Vaccine:

1 there were 584 reported cases in Pfizer Vaccine recipients in the reporting period that:

(1) that met the criteria for potential VAED;

a) wherein:

i) 221 cases were medically significant;

ii) 166 cases required hospitalisation;

iii) 37 cases were life threatening;

iv) 160 cases resulted in death.

v) a wide range of severe medical

conditions are reported associated with this condition by Pfizer.

1. In circumstances wherein:

a. the data presented is confusing; and

b. this confirms the Brighton Collaboration information on VAED was known to Pfizer and reported to TGA Respondents in the PSUR's.

w) that Pfizer had concluded and reported to the Respondents that there were 425 confirmed breakthrough cases of Covid in the reporting period wherein:

1 290 (68.2%) of the cases were severe;

2 the severe cases resulted variously in one or more of:

(1) hospitalisation;

(2) disability;

(3) life threatening complications; or

(4) death.

a) in circumstances wherein in truth:

i) that was unequivocal evidence of VAED:

1. given the low rates of severe illness and death from covid without vaccination, and

2. given the data never supported an indication to prevent severe illness and death should have immediately resulted in a review of the risk-benefit analysis.

ii) Pfizer stated that VAED remains a theoretical risk for the vaccine and surveillance will continue, which was fully accepted by the Respondents.

x) that Pfizer had concluded and reported to the TGA that Covid and VAED are an adverse event of special interest, wherein:

1 there were reported in the reporting period 12,058 cases of breakthrough infection;

2 8,633 of the breakthrough cases are described as serious;

3 658 (7.6%) of the breakthrough cases were reported as fatal.

(1) wherein in truth:

a) this represented a 7.6% fatality rate from breakthrough infection which should have called into question any claims of the vaccine reducing the incidence of death from Covid;

b) this fatality rate is exponentially higher than Covid;

c) the relative seriousness of the outcomes following breakthrough infection compared with infection with the Virus in unvaccinated individuals is a unequivocal

proof of VAED.

Particulars

The Pfizer PSUR. Pages 4, 5, 6, 22, 32, 34, 39, 56, 81, 83, 85-87, 88, 91, 96, 100, 119-123, 128, 237, 244.

The Pfizer Post-Marketing Data. Pages 12-13.

Committee for medicinal products for human use (CHMP) ICH guideline E2C (R2) Periodic benefit-risk evaluation report. April 2012. https://www.ema.europa.eu/en/ich-e2c-r2-periodic-benefit-risk-evaluation-report-scientific-guideline

EU Product Information Guidance – https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information-requirements

Australian Product Information – Comirnaty Covid-19 Vaccine. https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2021-PI-02442-1&d=20230418172310101

COMIRNATY, COMIRNATY ORIGINAL/OMICRON BA.1, COMIRNATY ORIGINAL/OMICRON BA.4-5 (COVID-19 mRNA VACCINE) RISK MANAGEMENT PLAN https://www.ema.europa.eu/en/documents/rmp-summary/comirnaty-epar-risk-management-plan_en.pdf

Rose, J (October 2021) Critical Appraisal of VAERS Pharmacovigilance: Is the U.S. Vaccine Adverse Events Reporting System (VAERS) a Functioning Pharmacovigilance System? The Institute for Pure and Applied Knowledge. Vol 3:100-129, Oct. 2021 https://cf5e727d-d02d-4d71-89ff-

9fe2d3ad957f.filesusr.com/ugd/adf864_0490c898f7514df4b6fbc5935da07322.pdf

EMA - Guideline on good pharmacovigilance practices https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-product-population-specific-considerations-i-vaccines_en.pdf

J Clin Invest. 2021 Jul 1; 131(13): e150319. Published online 2021 Jul 1. doi: 10.1172/JCI150319
PMCID: PMC8245182PMID: 34014840 Efficient maternal to neonatal transfer of antibodies against SARS-CoV-2 and BNT162b2 mRNA COVID-19 vaccine , Ofer Beharier et al. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8245182/.
Page 5 of study: Fetal vascular malperfusion lesion – chronic vessel with intramural fibrin deposition
Page 10 of study: the placental tissue examined had a much higher rate of malperfusion lesions in the placental tissue for vaccinated patients

Journal of Pharmaceutical Policy and Practice Commentary Open Access Published: 31 May 2021 Potential adverse events in Japanese women who received tozinameran (BNT162b2, Pfizer-BioNTech) Rumiko Shimazawa & Masayuki Ikeda Journal of Pharmaceutical Policy and Practice volume 14, Article number: 46 (2021) https://joppp.biomedcentral.com/articles/10.1186/s40545-021-00326-7.

Vaccine-associated Enhanced Disease: Case Definition and Guidelines for Data Collection, Analysis, and Presentation of Immunization Safety Data October 19, 2020Case Definitions / English / News / Publications and Related Tools / Relevant for COVID-19

This is a Brighton Collaboration case definition of the term “Vaccine-associated Enhanced Disease” (VAED) to be

utilized in the evaluation of adverse events following immunization. The case definition was developed by a group of experts convened by the Coalition for Epidemic Preparedness Innovations (CEPI) as part of the Safety Platform for Emergency Vaccines (SPEAC) project, in the context of active development of vaccines for COVID-19 and other emerging pathogens. The case definition format of the Brighton Collaboration was followed to develop a consensus case definition and defined levels of diagnostic certainty, after an exhaustive review of the literature and expert consultation.
https://brightoncollaboration.us/vaed/
https://brightoncollaboration.us/wp-content/uploads/2021/07/VAED-vaccine-publication.pdf

PART K - REGULATORY ACTIONS/ FAILURES

FAILURE TO ISSUE SAFETY ALERTS ISSUED - TGA

176. The Respondents through the TGA is obliged under the TGA Safety Alert Policy to issue safety alerts where the medicine carries a possible risk, including:

a) known safety problems;

b) changes in the reporting pattern of known safety problems;

c) new problems; and

d) coincidental event.

177. The Respondents, notwithstanding the matters and knowledge of the Respondents pleaded herein, has never issued a Safety Alert for any reason in relation to:

a) the Pfizer Vaccine;

b) the Moderna Vaccine.

178. With respect to causality assessment of Adverse Events in respect of a medicine,

including the Vaccines and the internationally accepted standards applicable to the assessment of adverse events causality including those:

a) in practice few adverse reactions are 'certain' or 'unlikely';

b) most are 'possible' or 'probable';

c) causality assessment is a common routine procedure in pharmacovigilance;

d) systems have been developed for a structured and harmonised assessment of causality including:

1 the Naranjo Scale;

2 the WHO Causality Assessment for Adverse Events; and

3 Bradford-Hill Criteria.

Particulars

Naranjo Adverse Drug Reaction Probability Scale
https://www.evidencio.com/models/show/661

"The use of the WHO-UMC system for standardised case causality assessment".
https://who-umc.org/media/164200/who-umc-causality-assessment_new-logo.pdf

Bradford Hill Criteria
https://www.edwardtufte.com/tufte/hill

NARANJO SCALE – APPLICATION TO POPULATION AND APPLICANTS

179. The international standardised assessment of causality for all adverse drug reactions is the Naranjo Adverse Drug Reaction Probability Scale **("the Naranjo Scale")** which:

a) was developed in 1991;

b) is a system developed for the structured and harmonised assessment of causality;

c) was developed to help standardise assessment of causality for all adverse drug reaction;

d) was in widespread and pervasive use and acceptance internationally at the time of the Approvals as a pharmacovigilance tool to determine causality;

e) is applied to data obtained by the imposition of known and well-defined causality questions;

f) in receiving data in response to the relevant causality questions to determine a category of causality, requires that:

1 a response of “Do not know” to relevant causality question:

(1) should be used:

a) sparingly;

b) only when the quality of the data does not permit a “Yes” or “No” answer;

(2) is applicable if the information is not available; and

(3) also if the question is inapplicable to the case.

g) provided score interpretation categorised as one of:

1 definite;

2 probable;

3 possible; or

4 doubtful.

h) the attribution of “possible” arises under the Naranjo Scale when the following are applicable - the reaction:

1 followed a temporal sequence after a drug;

2 possibly followed a recognized pattern to the suspected drug; and

3 could be explained by characteristics of the patient’s disease.

i) where applied to those reported adverse events known to the Respondents **(“the Known Reported Adverse Events”)**:

1 manifested an adverse reaction probability score as being causally related to the Vaccines of at least possible:

(1) in all events reported to regulatory authorities in Australia, including the DAEN and AusVaxSafety;

(2) where temporally associated with receipt of the Vaccines;

(3) until other further supporting or controverting factors are investigated, identified and applied.

2 manifests a probability score of at least probable in the Applicants.

Particulars

“Naranjo Adverse Drug Reaction Probability Scale”.
https://www.ncbi.nlm.nih.gov/books/NBK548069/

WHO SAFETY SURVEILLANCE MANUAL

180. The COVID-19 Vaccines: Safety Surveillance Manual produced by the WHO in April 2021, states in respect of the assessment of causality:

a) the selection of cases for causality assessment should focus on:

1 serious AEFI that:

(1) results in death;

(2) is life-threatening;

(3) requires inpatient hospitalization or prolongation of existing hospitalization;

(4) results in persistent or significant disability/incapacity; or
(5) is a congenital anomaly/birth defect;

2 the occurrence of events above the expected rate or of unusual severity;

b) signals generated as a result of individual or clustered cases as these could signify a potential for large public health impact.

c) allegations that vaccines/vaccination cause adverse events must be dealt with rapidly and effectively;

d) appropriate action(s) must be taken to respond promptly, efficiently, and with scientific rigor to vaccine safety issues;

e) causality assessment of AEFI is a vital component of AEFI risk assessment, decision-making and the initiation of action;

f) the scientific basis for the criteria which are assessed in the process include:

1 temporal relationship: The vaccine exposure must precede the occurrence of the event;

2 definitive proof that the vaccine caused the event;

3 population-based evidence for causality – i.e. what is known about

"Can it?";

4 a definitive "yes" at the population level is consistent with causality at the individual level;

5 a strong "no" at the population level is inconsistent with causality at the individual level;

6 no clear answer to the question at the population level, will often lead to an indeterminate conclusion at the individual level;

7 biological plausibility: the association should be compatible with existing theory and knowledge related to how the vaccine works;

8 consideration of alternative explanations: In doing causality assessment on an individual case report, it must be remembered that in essence one is conducting a differential diagnosis;

9 prior evidence that the vaccine in question could cause a similar event in the vaccinee.

Particulars

"Naranjo Adverse Drug Reaction Probability Scale".
https://www.ncbi.nlm.nih.gov/books/NBK548069/

WHO SAFETY SURVEILLANCE MANUAL – APPLICATION TO POPULATION AND APPLICANTS

181. The WHO-UMC System For Standardised Case Causality Assessment **("the WHO Causality Assessment for Adverse Events")**:

a) was developed in 2013;

b) is a system developed for the structured and harmonised assessment of causality;

c) was developed to help standardise assessment of causality for all adverse

drug reaction;

d) was in widespread and pervasive use and acceptance internationally at the time of the Approvals as a system for pharmacovigilance;

e) provides a score interpretation categorised as one of:

1 definite;

2 probable/likely;

3 possible;

4 unlikely;

5 conditional/unclassified; and

6 unassessable / unclassifiable.

7 has been declared by the WHO to, in practice, produce:

(1) few adverse reactions defined as ‘certain’ or ‘unlikely’;

(2) most adverse reactions defined as ‘possible’ or ‘probable’;

8 WHO declared that the usual approach to using the system is, as the most frequent categories in causality assessments of case reports are ‘Possible’ and ‘Probable’:

(1) to choose one of these categories (depending on the impression of the assessor); then

(2) to test if the various criteria fit with the content of the case report; then

(3) if the report seems stronger one can go one step ‘higher’ (e.g. from ‘Possible’ to ‘Probable’); then

(4) if the evidence seems weaker one should try a 'lower' category.

9 the attribution of "possible" arises under the WHO Causality Assessment for Adverse Events when the following are applicable, which are applicable in the proportion of reported DAEN adverse events pleaded above:

(1) event or laboratory test abnormality, with reasonable time relationship to drug intake;

(2) could also be explained by disease or other drugs; and

(3) information on drug withdrawal may be lacking or unclear.

10 when applied to:

a) the Known Reported Adverse Events known to the Respondents:

i) manifests an adverse reaction probability score of causality in relation to the Vaccines of at least, "possible";

ii) where there is temporal proximity and sequence after receiving one of the Vaccines;

iii) until other further supporting or controverting factors are investigated, identified and applied.

b) the Applicants, manifests a score of at least "probable".

Particulars

"The use of the WHO-UMC system for standardised case causality assessment" Published 5 June, 2013.
https://who-umc.org/media/164200/who-umc-causality-

assessment_new-logo.pdf

CAUSALITY ASSESSMENT OF REPORTED EVENTS

182. By reason of the above and in application of the Naranjo Scale and the WHO Causality Assessment for Adverse Events:

a) adverse drug reactions are only graded as “unlikely” wherein:

1 a clinical event, including laboratory test abnormality, with a temporal relationship to drug administration which makes a causal relationship improbable; and/or

2 in which other drugs, chemicals or underlying disease provide plausible explanations;

b) the temporal relationship would only allow an unlikely causality assessment where:

1 the event occurred before the drug exposure; or

2 if it was so long afterwards to be considered improbable;

3 and when there is a more plausible alternative explanation.

c) relevantly on average over 98% of adverse events reported to the Respondents in respect of the Vaccines involved single suspected medicine, being one of the Vaccines.

TGA CAUSALITY ASSESSMENTS - TGA RESPONDENTS SUPPRESSION OF CAUSALITY ASSESSMENT TO THE PUBLIC AND BREACH OF ASSSESSMENT PROTOCOL, DEATHS IN CHILDREN YOUNG ADULTS

183. On 5 April, 2022, an FOI request (FOI Request 3727) was made to the TGA seeking documents that could provide clarity on the TGA’s assessment process investigating deaths that had been reported to the TGA following vaccination with the Vaccines, in circumstances where reported deaths were in excess of 900 yet the TGA had only determined causality in 14 of those cases;

184. On or about 20 July, 2022, the following information was detailed in the documents produced by the Respondents in respect of internal memoranda relating to the causality of deaths reported to be associated with the Vaccines in young persons pursuant to FOI Request 3727 **("the Fatal Causality Documents")**:

1 21 year old female:

(1) died from myocarditis and cardiac arrest;

(2) causality assessment outcome = awaiting;

(3) this case has since been determined causal by VSIG; and

(4) appears on the safety report;

2 14 year old female:

(1) cause of death redacted by the TGA;

(2) assessment decisions: "unlikely causality";

3 21 year old male:

(1) cause of death was redacted by the TGA;

(2) assessment decisions: "? causality";

4 24 year old female:

(1) died of cardiac arrest;

(2) assessment decisions: "Causality" **("the First Apparent Causality Document")**;

5 9 year old whose sex was redacted by the TGA:

(1) died of cardiac arrest; and

(2) assessment decisions: “causality assessment outcome” **(“the Second Apparent Causality Document”);**

6 7 year old male:

(1) died of cardiac arrest; and

(2) assessment decisions: “Causality” and “WHO=U” **(“the Third Apparent Causality Document”)**;

7 19 year old female:

(1) died of cardiac arrest; and

(2) assessment decisions: “Unlikely Causality – Update should any further pathology become available”.

185. The Fatal Causality Documents:

a) relate to those fatality assessments reviews by a TGA team in meetings:

1 including several doctors, medical officers and others employed by the TGA whom have expertise and training in review of adverse events;

2 seeking to determine a consistent causal association of fatality with the vaccine in question or otherwise based upon the information available; and

3 by which a determination as to causality or otherwise is recorded under the heading of ‘decisions’, including those Fatal Causality Documents;

b) appeared in the instance of the First Apparent Causality Document, the Second Apparent Causality Document, and the Third Apparent Causality Document inclusive to display a finding of death causally related to the respective Covid vaccine;

c) despite having been produced under FOI request 3727, were refused by the TGA for publication to the public disclosure log on the express purported basis that "disclosure of the documents could undermine public confidence and reduce the willingness of the public to report adverse events to the TGA";

1 thereby displaying the primacy placed upon increased vaccination rates by the Respondents above all other considerations, including:

(1) keeping the Australian public fully informed upon Vaccines-related safety matters; or

(2) matters bringing into doubt the actual safety of the Vaccines.

d) the subject matter of which was at no time referred to VSIG despite being required to do so under the TGA VSIG Policy (particularised below) in breach of that policy:

1 without proper basis;

2 which would otherwise invoke proper application of WHO Causality Assessment;

3 thereby circumventing the application of proper and independent causality assessment in respect of the deaths.

Particulars

"Vaccine Safety Investigation Group – Work Instruction Pharmacovigilance and Special Access Branch Signal Investigation Unit". January 2019. https://www.tga.gov.au/sites/default/files/2023-01/foi-4029-06.PDF

Letter to Dr McCann from the TGA, dated 24 August 2022.

VSIG was not convened. VSIG meeting starting with the

comments that: (FOI 4029 document 5, page 4) https://www.tga.gov.au/sites/default/files/2023-01/foi-4029-05.PDF

"Prior to this meeting, a TGA assessment found that this case of myocarditis demonstrated a consistent causal association with the vaccine based on the information available. It was explained that the purpose of causality assessment from a regulatory perspective is to identify and characterise the strength of the evidence supporting the likelihood of a causal association between an adverse event and a vaccine and to consider potential public health action. It was noted that a definitive causal association (or absence of association) often cannot be established for an individual event. It was emphasised that regulatory assessment does not pre-empt or replace other reviews of this case. In particular, it was acknowledged that there is an open Coroner's investigation and there have been multiple expert panel assessments of the case at the state level."

TGA assessments (documents - FOI 3727) can and do allow for the assessment to determine a consistent causal association with the vaccine based on the information available, and that decision is recorded under the heading of 'decisions' on the Fatal Causality Documents.

"Vaccine Safety Investigation Group – Work Instruction Pharmacovigilance and Special Access Branch Signal Investigation Unit". January 2019. https://www.tga.gov.au/sites/default/files/2023-01/foi-4029-06.PDF

FURTHER DEATH 5 YEAR OLD – CARDIAC ARREST

186. On or about 10 May, 2022, the death of a 5 year old male from cardiac arrest was reported to DAEN due to myocarditis:

a) wherein subsequent to the Report, the TGA Safety Reports continued to

state that no deaths in children causally linked to the Vaccines has occurred;

b) which has not been subject to:

1 identification to the public as a reported death in a child associated with the Vaccines;

2 VSIG assessment, which must invoke application of WHO Causality Assessment;

3 public scrutiny or comment;

4 comment by the Respondents or any representative of the Commonwealth.

Particulars

The DAEN Database. https://www.tga.gov.au/safety/safety/safety-monitoring-daen-database-adverse-event-notifications/database-adverse-event-notifications-daen-medicines

IMPROPER FAILURE TO REFER VACCINES RELATED DEATHS TO VSIG FOR CAUSALITY ASSESSMENT

187. Despite meeting the criteria under the TGA VSIG Policy:

a) VSIG was not convened for the children who died of cardiac arrest;

b) the details of the deaths were never brought before VSIG for a determination as to causality despite an obligation to do so;

c) concurrently, the Respondents continue to assert that causality in respect of the Child Deaths had not been determined:

1 despite the apparent indication of causality upon the Causality

Memoranda;

2 whilst continuing to maintain that causality has still not finally been determined by the Respondents in respect of those deaths;

3 further or alternatively, the TGA Respondents continue to evade a determination of causality in the circumstances of the death of children at least possibly caused by the Vaccines by:

(1) failing to act in accord with policy;

(2) failing to take any positive steps to concluding causality;

(3) maintaining a perpetually unresolved and open status on causality assessment.

4 falsely asserting and or/concluding that the basis for a failure or refusal to refer the Child Deaths to VSIG was the assertion that nowhere in the world had cardiac arrest been identified as a safety signal;

5 that the release of the Child Deaths data was appropriately prevented from release upon the FOI log maintained by the TGA on the basis of 'the potential to undermine public confidence' which in and of itself requires the convening and causality assessment of VSIG under the TGA VSIG Policy.

d) the Respondents have improperly prevented:

1 active and independent assessment of the causality of the Child Deaths;

2 public knowledge of the causality of the Child Deaths including from:

(1) the Australian population;

(2) Australian health practitioners.

3 the possibility of regulatory action in appropriate response to the Child Deaths.

Particulars

"Vaccine Safety Investigation Group – Work Instruction Pharmacovigilance and Special Access Branch Signal Investigation Unit". January 2019. https://www.tga.gov.au/sites/default/files/2023-01/foi-4029-06.PDF

The false statement in respect of reasons for avoiding reference of the deaths to VSIS made by Skerritt in the Australian Senate - Estimates Committee meeting of 16 Feb 2023 whereas the Respondents knew since at least January, 2021 that acute myocardial infarction (MEDRA - term cardiac arrest) was an adverse event of special interest from at least January, 2021 and prior to the statement.

IMPROPER FAILURE TO REFER VACCINES RELATED SAFETY ISSUES TO THE ACV FOR ASSESSMENT

188. ACV meetings, have almost entirely for the past 2 years has the statement under section B "The ACV was not asked to review any safety issue" in circumstances wherein:

a) the TGA deciding when to refer to ACV to review safety issues and not requesting review for hundreds of deaths and over 100,000 adverse events, many of the them serious and life changing;

b) the TGA continues to abrogate its own policies in:

c) failing to refer extraordinarily high number of adverse events connected with the Vaccines to the ACV; and

d) failing or refusing to convene VSIG and referring to VSIG these serious unexpected events including the Child Deaths

Particulars

The ACV Meeting Minutes, accessible on the TGA website. https://www.tga.gov.au/about-tga/advisory-bodies-and-committees/advisory-committee-vaccines-acv

PROPORTIONAL REPORTING RATIO DATA (PRR) GENERALLY – MEASURE OF ADVERSE EVENT PROBABLITY IN VACCINES

189. A proportional reporting ratio:

a) is a statistic that is used to summarise the extent to which a particular Adverse Event is reported for individuals taking a specific drug compared to the frequency at which the same adverse event is reported for patients taking some other drug;

b) is used to measure how common an Adverse Event for a particular drug is compared to how common the event is overall in the database;

c) is used to measure the strength of the statistical association between a risk factor, being the use of the drug, and a specific Adverse Event;

d) greater than 1:

1 suggests that the Adverse Event is more commonly reported for individuals taking the drug of interest, relative to the comparison drugs;

2 is an indication that the Adverse Event is:

(1) caused by the drug of interest; and

(2) therefore a side-effect of that drug.

PRR BENCHMARK ADOPTED BY TGA RESPONDENTS – 29 SEPTEMBER, 2021

190. On or about 29 September, 2021, the Respondents through the TGA:

a) adopted the use of a Proportional Reporting Ratio (PRR) calculation for

Adverse Events following vaccination pairs; and

b) revised the previous disproportionality analysis methods for COVID-19 vaccines to:

1 increase the frequency of PRR analysis and reporting from bimonthly to weekly; and

2 use PRR analysis by vaccine trade name rather than active ingredient; and

3 adopt a standard of:

(1) a lower threshold of a PRR > 1 **("the Benchmark PRR Rate")**; and

(2) a case count of great of 2 or more event affected people to identify:

a) vaccine-event pairs for assessment;

b) safety concerns in the Vaccines specifically.

4 Whereas data for the Vaccines exceeding 1 was deemed to indicate a safety concern or signal in respect of the Vaccines

Particulars

"Advisory Committee on Vaccines. Minutes - Meeting 25, held 29 September 2021. COMMITTEE IN CONFIDENCE. Reference no. D21-3141615".
https://www.tga.gov.au/sites/default/files/2023-01/foi-4029-03.PDF

PRR SAFETY SIGNAL – ESSENTIAL TOOL OF DETECTION

191. From at least November 1, 2019 it was scientifically and publicly known, including to the Respondents that:

a) timely Adverse Events Following Vaccination signal event detection is essential to minimise further recipients receiving unsafe vaccines;

b) PRR is:

1 a measure of disproportionality of Adverse Events Following Vaccination; and

2 is an established signal detection algorithm (SDA) in pharmacovigilance.

c) PRR provides sensitive signal detection when calculated cumulatively by individual year or by all previous years;

d) PRR is defined as the ratio between:

1 the frequency with which a specific Adverse Event is reported for the vaccine of interest (relative to all Adverse Events reported for the vaccine); and

2 the frequency with which the same Adverse Event is reported for all vaccines in the comparison group (relative to all Adverse Events for vaccines in the comparison group).

e) PRR data is an important performance requirement if monitoring:

1 new vaccines;

2 new brands or formulations;

3 population subgroups (e.g. in pregnancy);

f) the PRR algorithm is relatively easy to implement and analyse;

g) known signal events can be detected earlier than traditional methods using PRR;

h) PRR calculation, analysis and application should be routine in any national Adverse Event surveillance system;

i) a safety "signal" can be defined as incidence of Adverse Events Following Vaccination occurring at a higher level than is normally expected;

j) safety signal detection in vaccine vigilance requires a multi-faceted approach as Adverse Events Following Vaccination range from:

1 a rare occurrence of a severe Adverse Events Following Vaccination; to

2 increased incidence or increased severity of a known, often frequently occurring Adverse Events Following Vaccination.

k) the potential for prospective analyses to inform signal detection must also be viewed commensurate with known limitations of passive surveillance systems:

1 namely under-reporting—particularly of reactions perceived as mild; and

2 the time lag from symptom onset to report submission.

Particulars

"Early signal detection of adverse events following influenza vaccination using proportional reporting ratio, Victoria, Australia". Clothier HJ et al. (2019) PLoS ONE 14(11): e0224702. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6824574/

KNOWN EXPONENTIALLY HIGH SAFETY SIGNALS - ACTUAL PRR DATA FOR VACCINES IN AUSTRALIA

192. As from at least 19 July, 2021, the Respondents had assessed and knew the following Proportional Reporting Ratio data in respect of the Vaccines which:

a) exponentially exceeded the Benchmark PRR Rate;

b) were unquestionably indicative of extreme safety risks and concern in the Vaccines;

c) were in fact as follows:

	19/07/21	29/09/21	29/11/21	17/01/22	24/3/22	11/05/22	15/07/22	15/09/22
Appendicitis/ appendicitis Perforated/Epiploic appendicitis	4.8	9.56	6.52	12.01	15.69	13.67	6.78	6.87
Epiploic appendagitis		7.31						
Mesenteric panniculitis		7.31						
Pancreatitits acute	11.32	5.48	3.31					
Abnormal uterine bleeding			4.14				3.79	
Blood pressure increased	3.94	4.49	3.74	3.25				
Hypertensive crisis			9.82					
Malignant hypertension							3.16	
Pulmonary hypertension		9.74	7.36					
Amenorrhoea, delayed menstrual bleeding, oligomenorrheoea	15.51	19.23	29.5	31.87	12.65	19.78	19.35	19.09
Dysmenorrhoea,	7.45	7.47	11.82	29.5	12.04	6.47	3.82	5.81

mentometorrhagia								
Heavy menstrual bleeding, polymennorrhoea	39.23	23.18	26.86	21.37	16.52	15.15	15.01	14.38
Irregular Menstrual bleeding, Intermenstrual bleeding	7.92	10.49	22.88	22.11	10.34	12.57	11.88	11.65
Cardiac ventricular thrombosis		9.74		13.46				
Cerebral thrombosis		6.16						
Cerebral venous sinus	21.53	24.96	14.73	16.42	17.24			
Coagulopathy	5.14	5.36		4.94	5.5	4.38		
Disseminated intravascular coagulation		3.25						
Embolism		17.05		8.08				
Peripheral artery thrombosis				29.61	35.56			
Retinal artery occlusion		17.05	8.18	7.4				
Retinal artery thrombosis		9.74						
Splenic vein thrombosis		9.74	14.73					
Portal vein thrombosis			31.91	35	39.51	32.08		
Mesenteric vein thrombosis		31.66	13.91	16.15				

Jugular vein thrombosis		19.48	22.02					
Retinal vein occlusion					7.54		7.44	
Thrombocytosis	5.87	4.06	4.91					
Thromboembolism	14.68	8.96	7.33					
Thrombosis							4.73	4.62
Pulmonary embolism	17.45	17.65	13.73	11.31	9.84	9.39	9.13	8.8
Pulmonary thrombosis	17.62	19.48				9.38	10.75	
Deep vein thrombosis	14.12	13.9	12.78	11.51	10.52	10.41	10.22	
Thrombocytopenia	5.36	9.22	10.14	10.69	10.15	9.79	9.85	9.71
Immune thrombocytopenia		3.42	2.95	3.95			3.52	
Transverse sinus thrombosis			9.82					
Venous thrombosis	7.34	8.12		6.06		11.48		
Acute myocardial infarction	15.42	9.01	9.33	6.88	5.93	4.85		3.54
Myocardial infarction	7.49	6.39	5.69	3.99	3.3	2.65		
Coronary artery thrombosis				10.77	3.56		4.56	3.26
Arteriosclerosis coronary artery		3.25		7.18	8.89			
Atrial fibrilation	4.28	5.01	4.46	4.35	3.52			
Atrial flutter	32.1	8.28	4.09			9.28		
Cardiac arrest	2.31	2.58	2.4	2.57	2.61			
Cardiac failure	2.94	3.35	3.68	3.59	2.96			

Cardiac failure congestive	8.81	4.87		4.04				
Cardiac flutter			12.95		6.4	5.44	5.25	5.3
Cardiac tamponade		12.33	4.14	4.23				7.8
Cardiogenic shock		6.09	5.73	3.59	3.7			
Cardiomyopathy	4.4	2.09					3.01	2.6
Carditis						22.79	17.22	17.28
Congestive cardiomyopathy								3.12
Coronary artery disease			29.41	7.54		3.85		
Coronary artery occlusion							3.23	
Acute coronary syndrome		9.74						
Myocardial ischaemia		3.25	9.82	5.05	3.36		3.21	
Myocardial strain imaging		14.61	17.18	14.13				
Myopericarditis						5.76	5.45	5.43
Pericarditis	4.95	12.33	22.39	24.02	13.93	9.17	8.71	8.44
Myocarditis		9.62	20.05	21.68	8.48	3.86	3.46	
Stress cardiomyopathy		7.31					5.07	
Blindness	3.1	2.86						
Blindness unilateral		3.65						
Basal ganglia haemorrhage			7.36					
Cerebellar infarction/ stroke				10.77	17.78			
Cerebral haemorrhage	5.03	3.99	5.11	5.03				

Cerebral infarction	6.85	5.36	4.91	4.88		6.26		
Transient ischaemic attack	5.87	6.29	12.77	5.5	5.02	4.11	4.09	
Cerebrovascular accident	7.27	6.37	3.09	5.44	4.94	4.31	4.19	4.21
Haemorrhagic stroke	5.87	7.31	3.68	4.04	4.15			
Ischaemic stroke			7.01	5.38	5.14	5.84		
Subarachnoid haemorrhage	14.68	5.68	7.36	7.54	5.56			4.62
Haemorrhage intracranial	5.87	9.74	13.91	10.77		8.22		
Subdural haematoma	8.81	14.61	27	20.19				
Subdural haemorrhage	22.63	3.25	7.36					
Embolic stroke			3.65					
Embolism		17.05						
Gastrointestinal haemorrhage	8.81	9.74	8.18					
Colitis ischaemic		21.92	24.55		11.85			
Intestinal ischaemia	5.87	3.29	13.68				3.23	
Pulmonary infarction		36.53	51.54	19.74				
Renal infarct				24.23				
Splenic infarction		15.83	17.18	21.54				
Thrombotic stroke		7.31						
Aneurysm	4.4	4		4.04	4.94			
Aortic aneurysm		4.31	12.27	8.08				

Aortic aneurysm rupture		7.31	9.82					
Aortic dissection	12.18		7.36					
Intracranial aneurysm	7.31		4.91		4.94	3.65		
Ruptured cerebral aneurysm		7.31						
Vertebral artery dissection		12.33	13.8	19.03				5.2
Hepatic failure	4.4	6.09	4.3	4.31				
Respiratory Failure	3.91	5.28	5.26	4.16				
Plasma cell myeloma				8.08				
Malignant melanoma		7.31	6.14			7.14		
prostate cancer				6.73	10.37			
Neoplasm malignant		3.04	3.93	5.92	3.65	4.1	4.36	
ovarian cancer							6.31	
Leukaemia						2.35		
Acute lymphocytic leukaemia						3.33	10.67	
Breast cancer		3.65						
Gastrointestinal cancer		7.31						
Lymphoma	5.87	3.65	6.44	6.95				
Thyroid mass				6.34				
Uterine leiomyoma					9.26			
Breast mass	11.32	6.16						
Limb mass	14.68	14.61	5.73					
Brain injury								9.19

Coma scale abnormal	15.09	5.75						
Demyelination	3.2	3.18						
Facial paralysis	3.48	3.46	3.13	3.17				
Facial paresia	4.04	3.04	3.78					
Giant cell arteritis	7.34	8.12	14.73	9.69			10.14	
Guillain- Barre syndrome						2.1		
Hemiplegia								3.18
Meningitis aseptic		3.08						
Monoplegia	3.2							
Myasthenia gravis		6.09			8.89			
Peripheral sensory neuropathy				3.59				
Small fibre neuropathy			3.68	6.34	8.64	8.34		
Transient global amnesia	14.68	17.05	12.27	10.77		5.07		
Vestibular disorder		14.61						
Vestibular neuronitis	3.91				3.36	3.24		
Fifth nerve paralysis		4.06		5.38		5.37		
Alopecia							5.37	
Alopecia areata							5.92	6.24
Autoimmune hepatitis			3.68					
Mast cell activation syndrome								3.34
Multisystem Inflammatory						5		

syndrome in adults								
Systemic immune respiratory syndrome		3.65						
Toxic epidermal necrolysis			7.36					
Endocarditis			6.9					
Mastoiditis						3.91		
Staphylococcal sepsis				8.08				
Tooth abscess		7.31						
Urosepsis		3.25						
Eosinophil count increased		7.31						
White blood cell count decreased	4.91	4.87	3.96	3.1		3.21		
Diabetic ketoacidosis			16.56	14.8	5.09	5.84		
Multiple organ dysfunction syndrome		3.04	5.04	5.38				
Multisystem Inflammatory syndrome in children					5.56	11.67		7.82
Haemophagocystic lymphosistosis			3.68	5.38		3.13	4.52	
Herpes virus infection	8.28	3.65						
Herpes zoster reactivation		6.09		3.23				
Immunodeficiency						5	7.89	9.36

Giant cell arteritis	7.34	8.12	14.73	9.69			10.14	
Mastitis			11.96	12.69	6.35	7.29		5.95
Diverticulitis	19.57	9.5	6.06	4.62				
Post acute Covid 19 syndrome								6.63
Abortion spontaneous			4	4.81	5.44	5.27	5.3	
Stillbirth				4.76	6.02		4.73	
Ectopic pregnancy					8.64		6.31	
Foetal cardiac disorder							7.73	
Pre-eclampsia						8.34		

193. Despite the extraordinary nature of the Known PRR Data and exponential breaches of the Respondents' PRR Benchmark, such data has never been:

a) disclosed by the Respondents to the public other than by express FOI request;

b) determined or acknowledged by the Respondents as a basis of:

1 action to withdraw or suspend the use of the Vaccines in Australia; or

2 concern or safety signal.

Particulars

PRR data released by the Respondents under FOI Request 4032.

KNOWN ADVERSE EVENTS OF SPECIAL INTEREST – IMPROPER REFUSAL TO RECOGNISE OR ALERT PUBLIC

194. An Adverse Event of Special Interest:

a) is a defined condition or event that occurs in some individuals:

1 following immunisation;

2 which possesses a known potential to be causally associated with a vaccine product;

3 are required to be carefully monitored and confirmed by further research studies;

Particulars

AusVaxSafety NCIRS– Adverse Events of Special Interest - https://ausvaxsafety.org.au/our-work/adverse-event-special-interest-aesi-long-term-follow-program.
AusVaxSafety receives funding from the Australian G Government Department of Health and Aged Care.

195. In or about January 2021 and before the Approvals, the CDC was known by the Respondents to have published guidelines for the enhanced safety monitoring of the Vaccines which:

a) defined the following adverse events of special interest **("the CDC Reported Adverse Events of Special Interest")**:

1 death,

2 COVID19 disease;

3 Guillain-Barre Syndrome;

4 seizure;

stroke;

narcolepsy/cataplexy;

anaphylaxis;

vaccination during pregnancy;

acute myocardial infarction;

myopericarditis;

coagulopathy (including thrombocytopenia;

disseminated intravascular coagulopathy;

deep venous thrombosis;

Kawasaki's disease;

multisystemic inflammatory syndrome in children;

multisystemic inflammatory syndrome in adults;

transverse myelitis;

Bell's Palsy; and

appendicitis.

Particulars

"Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19" (as of 29 January 2021).
https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf

196. the DAEN Database which is managed and monitored by the TGA, reveals the

following reported events which accord with the CDC Reported Adverse Events of Special Interest known to the Respondents since and from at least January 2021, reported to the TGA in the period of 25 January, 2021 to 9 September, 2022 **("the Known AESI Occurrences")**:

DAEN Database Results Corresponding to CDC Adverse Events of Special Interest 25/01/2021 – 09/09/2022:

Adverse Event of Special Interest	**MedDRA Reaction Term**	**Number of Cases**	**Cases With a Single Suspected Medicine**	**Cases with Death as Reported Outcome**
Acute Myocardial Infarction	- Acute Myocardial Infarction	142	137	20
	- Cardiac Arrest	145	138	86
	- Myocardial Infarction	366	359	39
Anaphylaxis	- Anaphylactic Reaction	1,343	1,317	0
	- Anaphylactic Shock	27	27	0
Appendicitis	- Appendicitis Perforated	20	20	0
	- Appendicitis	248	246	1
Bell's Palsy	- Bell's Palsy	673	650	0
Coagulopathy	- Pulmonary embolism	1,554	1,489	72
	- Deep vein thrombosis	1,460	1,399	37
	- Thrombosis	497	473	11
	- Thrombosis with thrombocytopenia syndrome	162	157	9
	- Immune thrombocytopenia	133	124	7
	- Cerebral venous sinus thrombosis	76	72	4
	- Coronary artery thrombosis	12	11	3
	- Cerebral artery thrombosis	7	6	3
	- Mesenteric artery thrombosis	3	3	2
	- Mesenteric vein thrombosis	22	20	2
	- Visceral venous thrombosis	12	11	2
	- Portal vein thrombosis	45	42	2
	- Splenic thrombosis	8	8	1
	- Atrial thrombosis	2	2	1
	- Cardiac ventricular thrombosis	7	7	1
	- Basilar artery thrombosis	1	0	1

	- Carotid artery thrombosis	4	4	1
	- Cerebral venous thrombosis	7	6	1
	- Thrombotic stroke	3	3	1
	- Pulmonary thrombosis	15	14	1
	- Splenic artery thrombosis	2	2	0
	- Splenic vein thrombosis	9	9	0
	- Thrombocytosis	13	12	0
	- Retinal artery thrombosis	6	6	0
	- Retinal vascular thrombosis	2	2	0
	- Retinal vein thrombosis	6	6	0
	- Thrombosis mesenteric vessel	1	1	0
	- Hepatic vascular thrombosis	2	2	0
	- Hepatic vein thrombosis	1	1	0
	- Cavernous sinus thrombosis	1	1	0
	- Arteriovenous fistula thrombosis	1	1	0
	- Cerebellar artery thrombosis	1	1	0
	- Cerebral thrombosis	12	12	0
	- Spinal artery thrombosis	1	1	0
	- Superior sagittal sinus thrombosis	12	11	0
	- Transverse sinus thrombosis	4	2	0
	- Vertebral artery thrombosis	2	2	0
	- Foetal placental thrombosis	1	1	0
	- Renal artery thrombosis	1	1	0
	- Renal vein thrombosis	4	4	0
	- Aortic thrombosis	5	5	0
	- Arterial thrombosis	10	10	0
	- Axillary vein thrombosis	1	1	0
	- Brachiocephalic vein thrombosis	1	1	0
	- Jugular vein thrombosis	10	10	0
	- Peripheral artery thrombosis	15	15	0
	- Subclavian artery thrombosis	3	2	0
	- Subclavian vein thrombosis	4	4	0
	- Superficial vein thrombosis	262	256	0
	- Vena cava thrombosis	3	3	0
	- Venous thrombosis	13	12	0
	- Venous thrombosis limb	1	1	0

COVID-19 Disease	- COVID-19 - Breakthrough COVID-19 infection - Post-acute COVID-19 syndrome - COVID-19 pneumonia	381 20 18 3	191 18 18 3	5 0 0 0
Guillain-Barre Syndrome	- Guillain-Barre Syndrome	267	245	7
Kawasaki's Disease	- Kawasaki's disease	8	8	0
Multisystem Inflammatory Syndrome in Children (MIS-C)	- Multisystem inflammatory syndrome in children	7	7	0
Multisystem Inflammatory Syndrome in Adults (MIS-A)	- Multisystem inflammatory syndrome in adults - Multisystem inflammatory syndrome	4 3	3 3	0 0
Myopericarditis	- Pericarditis - Myocarditis - Myopericarditis - Eosinophilic myocarditis - Pleuropericarditis - Giant cell myocarditis - Pericarditis constrictive	3,527 1,282 425 2 2 1 1	3,401 1,241 408 2 2 1 1	5 14 1 1 0 0 0
Narcolepsy/Cataplexy	- Narcolepsy	5	5	0
Vaccination During Pregnancy	- Abortion spontaneous - Stillbirth - Foetal hypokinesia - Ectopic pregnancy - Foetal death - Premature labour - Premature rupture of membranes - Haemorrhage in pregnancy - Pre-eclampsia - Premature baby - HELLP syndrome	293 16 15 14 12 11 11 10 10 10 4	285 16 15 14 12 10 11 10 10 10 4	0 0 1 0 1 0 0 0 0 0 0

	- Premature delivery	4	3	0
	- Foetal cardiac disorder	3	3	0
	- Premature separation of placenta	3	2	0
	- Preterm premature rupture of membranes	3	3	0
	- Complication of pregnancy	2	2	0
	- Foetal growth restriction	2	2	0
	- Gestational hypertension	2	2	0
	- Placenta praevia haemorrhage	2	2	0
	- Placental disorder	2	2	0
	- Polyhydramnios	2	2	0
	- Subchorionic haematoma	2	2	0
	- Subchorionic haemorrhage	2	2	0
	- Uterine contractions abnormal	2	2	0
	- Abortion missed	1	1	0
	- Abortion spontaneous incomplete	1	1	0
	- Anembryonic gestation	1	1	0
	- Foetal growth abnormality	1	1	0
	- Foetal placental thrombosis	1	1	0
	- Foetal-maternal haemorrhage	1	1	0
	- Haemorrhage foetal	1	1	0
	- Maternal condition affecting foetus	1	1	0
	- Postpartum haemorrhage	1	1	0
Seizure	- Seizure	816	791	8
	- Generalised tonic-clonic seizure	71	66	3
	- Partial seizures	12	10	0
Stroke	- Cerebral haemorrhage	51	48	13
	- Cerebral infarction	47	45	14
	- Ischaemic stroke	43	43	5
	- Lacunar infarction	14	14	1
	- Cerebral thrombosis	12	12	0
	- Haemorrhagic stroke	12	12	3
	- Cerebellar stroke	10	9	0
	- Embolic stroke	10	9	1
	- Cerebral artery thrombosis	7	6	3
	- Cerebral venous thrombosis	7	6	1
	- Thalamic infarction	6	6	0

	- Cerebellar infarction	5	5	2
	- Brain stem infarction	4	4	0
	- Cerebral ischaemia	3	3	0
	- Lacunar stroke	3	3	0
	- Thrombotic stroke	3	3	10
	- Basal ganglia infarction	2	2	0
	- Brain stem stroke	2	2	0
	- Cerebral artery occlusion	2	2	0
	- Haemorrhagic transformation stroke	2	2	1
	- Basal ganglia stroke	1	1	0
	- Cerebellar haemorrhage	1	1	0
	- Cerebral artery stenosis	1	1	0
	- Cerebral microhaemorrhage	1	1	0
	- Embolic cerebellar infarction	1	1	0
	- Embolic cerebral infarction	1	1	0
	- Internal capsule infarction	1	1	0
	- Spinal stroke	1	1	0
	- Vertebrobasilar stroke	1	1	1
Transverse Myelitis	- Myelitis transverse	38	36	1

197. Despite the known CDC Reported Adverse Events of Special Interest and the Known AESI Occurrences, the Respondents have knowingly failed to act according to their own guidelines with respect to the above DAEN data:

1 add the adverse events constituting the Known AESI Occurrences **("the Unrecognised Adverse Events of Special Interest")** to the AESI register;

2 there has been no communication of Known AESI Occurrences to the public;

3 the Vaccines continue to maintain their Approvals by the Continuing Approvals despite the multitude of Adverse Event reports of the specific conditions being the Unrecognised Adverse Events of Special Interest that have been raised as a potential safety signal.

Particulars

The DAEN Database. https://www.tga.gov.au/safety/safety/safety-monitoring-daen-database-adverse-event-notifications/database-adverse-event-notifications-daen

KNOWN TEMPORAL ASSOCIATION OF SHINGLES WITH THE VACCINES

198. It was known to the Respondents since at least October, 2021 by reasonably obtained and observed empirical data and studies known to the Respondents at that time that the following had been scientifically established in respect of Vaccines:

a) reactivation of the dormant virus Herpes Zoster responsible for shingles has been reported in relation to vaccination with the Vaccines;

b) wherein 96% of patients developed shingles within a temporal timeframe defined by WHO as indicative of a causal relationship.

199. The association of the Vaccines with the development of shingles known to the Respondents:

a) has not been advised to the public;

b) has not been raised as a safety signal, alert or AESI.

Particulars

"Can SARS-CoV-2 vaccine increase the risk of reactivation of Varicella zoster? A systematic review". Desai, H.D. et al. 2021. Journal of Cosmetic Dermatology Volume 20, Issue 11, Pages 3350-3361 https://doi.org/10.1111/jocd.14521

KNOWN INFLAMMATORY, VASCULAR AND BLOOD RESPONSE

200. The Respondents since at least March, 2022 by reasonably obtained and observed empirical data and studies known to the Respondents at that time have known that

the following had been scientifically established in respect of the Pfizer Vaccine, being that the Pfizer Vaccine is considered:

a) to generate a significant rise in inflammatory markers, notably after the second dose;

b) to be associated with a transient worsening of endothelial function;

c) to detrimentally affect vascular function;

d) through the Pfizer Spike Protein to:

1 enter into the brain endothelial cells of recipients after injection ;

2 cause the formation of microthrombi in the brain;

3 allow pseudo virions (spike, envelope, and membrane proteins) without viral RNA to be present in the endothelia of cerebral micro-vessels causing microvascular injury;

4 enter cardiac pericytes and pulmonary vascular cells causing:

(1) cell signaling leading to:

a) vascular cell dysfunction; and

b) cell growth/hypertrophy.

5 enter into the plasma with unknown effects.

Particulars

See e.g. “The effect of an mRNA vaccine against COVID-19 on endothelial function and arterial stiffness”, Terentes-Printzios, D et al, Hypertension Research, 45, 846-855(2022)

KNOWN LONG TERM ILLNESS ASSOCIATED WITH VACCINES

201. The Respondents have known since at least December, 2020 by reasonably obtained and observed empirical data and studies known to the Respondents at that time have known that the following had been scientifically established in respect of the mRNA Vaccines effects in humans:

a) vaccine-induced autoimmunity;

b) pathogenic priming and multisystem inflammatory disease and autoimmunity;

c) antibody dependent enhancement;

d) activation of latent viral infections;

e) neurodegeneration and prion disease;

f) inhibition of DNA damage repair;

g) increased thrombosis, cardiomyopathy and other vascular events following vaccination;

h) babies suffering enduring adverse consequences;

i) mRNA reverse transcribing intracellularly into the DNA; and

j) death due to autoimmune disease subsequent to vaccination.

Particulars

Kelleni M.T. 2021. SARS CoV-2 vaccination autoimmunity, antibody dependent Covid-19 enhancement and other potential risks: beneath the tip of the iceberg. International Journal of Pulmonary & Respiratory Sciences. 5, DOI: 10.19080/IJOPRS.2021.05.555658.

Seneff, S. and Nigh, G. 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, 38 – 79.

Hasan A., Al-Mulla M.R., Abubaker J., Al-Mulla F. (2021). Early insight into antibody-dependent enhancement after SARS-CoV-2 mRNA vaccination, Human Vaccines & Immunotherapeutics,
DOI: 10.1080/21645515.2021.1969855;

Classen JB. 2021. COVID-19 RNA based vaccines and the risk of prion disease. Microbiological Infectious Diseases. 5, 1-3.
https://scivisionpub.com/pdfs/covid19-rna-based-vaccines-and-the-risk-of-prion-disease-1503.pdf

Idrees D., Kumar V. 2021. SARS-CoV-2 spike protein interactions with amyloidogenic proteins: Potential clues to neurodegeneration. Biochemical and Biophysical Research Communication 554, 94-98. doi:10.1016/j.bbrc.2021.03.100; Kuvandik A., Özcan E. Serin, S., Sungurtekin H. 2021.

Anand, P., Stahel, V.P. 2021. The safety of Covid-19 mRNA vaccines: a review. Patient Safety in Surgery 15, 20. https://doi.org/10.1186/s13037-021-00291-9

Aldén, M.; Olofsson Falla, F.; Yang, D.; Barghouth, M.; Luan, C.; Rasmussen, M.; De Marinis, Y. 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

KNOWN VACCINES ASSOCIATED ADVERSE REACTIONS – VAED

202. The Respondents since at least May, 2021 by public and reasonably obtained and observed empirical data and studies known to the Respondents at that time, known the following matters in respect of that the following established in respect of Vaccine-Associated Enhanced Disease associated with the Vaccines:

a) the Brighton Collaboration case definition and guideline for VAED known determined the following:

1 that VAED is defined under the Brighton Collaboration as an illness that occurs:

(1) in a person who receive a vaccine; and

(2) who is subsequently infected with the pathogen that the vaccine is meant to protect against;

2 all cases of vaccine failure should be evaluated for VAED;

3 Vaccine-associated enhanced respiratory (VAERD) disease refers to disease with predominant involvement of the lower respiratory tract.

b) VAED is an abnormal immune response and an exuberant immune inflammatory response that includes the following symptoms:

1 cough;

2 tachypnoea;

3 pulmonary haemorrhage;

4 acute cardiac injury;

5 tachycardia;

6 vasculitis;

7 myocarditis;

8 heart failure;

9 bleeding/thrombotic events;

10 pro-inflammatory state;

11 renal dysfunction;

12 acute kidney injury;

13 abdominal pain;

14 diarrhea;

15 liver dysfunction;

16 acute liver failure;

17 altered mental state;

18 convulsions/seizures;

19 cranial nerve involvement;

20 fatigue;

21 myalgia;

22 arthritis;

23 multi-organ failure; and

24 death.

c) VAED:

1 was an identified potential complication of the Vaccines prior to their development;

2 is a complication known to occur in other vaccines and based on the vaccine design;

3 was confirmed by Pfizer in August, 2021 to be a theoretical risk for the vaccine requiring ongoing surveillance;

4 has exacerbated the outcome of the Covid Pandemic;

5 is evident in the use of the Vaccines by reason of the facts that:

(1) the rate of injury from infection with Covid is materially higher in those persons Vaccinated as compared to the Unvaccinated;

(2) there are high rates of complications from Covid in the Vaccinated;

d) the rate of incidence of VAED is correlated precisely with:

1 the uptake of the Vaccines; and

2 worldwide excess deaths;

e) in the Pfizer PSUR document dated 19 August, 2021 and provided to the Respondents:

1 Pfizer identified 584 cases potentially indicative of VAED-VAERD;

2 wherein:

(1) 221 cases were medically significant;

(2) 166 cases required hospitalisation;

(3) 37 cases were life threatening;

(4) 160 cases resulted in death.

f) so-called “Long Covid”:

1 is defined by the Department as:

(1) ongoing symptomatic COVID-19 – COVID-19 symptoms lasting more than 4 weeks; or

(2) post-COVID-19 condition/syndrome – COVID-19 symptoms after 12 weeks that are not explained by an alternative diagnosis.

2 results in a range of medical conditions after infection with Covid;

3 generally affects the young and healthy;

4 is in fact vaccine-associated enhanced disease **("VAED")** when it occurs subsequent to a vaccinated individual experiencing breakthrough infection with the Virus and therefore:

(1) the Respondents should have evaluated every such case of Long Covid as VAED.

a) wherein despite these known matters the Respondents have at no time evaluated or investigated VAED in the deaths of persons vaccinated with the Vaccines.

Particulars

"COVID-19 mRNA vaccine (nucleoside modified) Periodic Safety Update Report (PSUR) Reporting Period 19 December 2020 through 18 June 202, Dated 19 August, 2021". Pages 119-123.

"Vaccine-associated enhanced disease: Case definition and guidelines for data collection, analysis, and presentation of immunization safety data". Munoz, F.M et al. Vaccine. 39(2021) 3053-3066. https://brightoncollaboration.us/wp-content/uploads/2021/07/VAED-vaccine-publication.pdf

"Vaccine-associated enhanced disease: Case definition and guidelines for data collection, analysis, and presentation of immunization safety data". Munoz, F.M et al. Vaccine. 39(2021) 3053-3066. https://brightoncollaboration.us/wp-content/uploads/2021/07/VAED-vaccine-publication.pdf

KNOWN VACCINES ASSOCIATED ADVERSE REACTIONS – MYOCARDITIS

203. The Respondents knew at the material times by reasonably obtained and observed empirical data and studies known to the Respondents and data and documents published to them at that time establishing scientifically the following in respect of myocarditis as a side-effect of the Vaccines:

a) myocarditis is an inflammation of the heart muscle that can lead to serious illness and is a known Adverse Event of Special Interest arising from vaccination with the Vaccines;

b) in January 2021, the CDC listed myocarditis as an Adverse Event of Special Interest in their published guidelines for the enhanced safety monitoring for Covid 19 vaccine;

c) Myocarditis, has been known since the time of the Approvals to cause:

1 permanent heart damage;

2 death.

3 reduced life expectancy especially in categories of:

(1) younger age groups; and

(2) males.

d) the following facts have been established scientifically In respect of myocarditis:

1 the myocarditis disease process can rapidly become life-threatening;

2 myocarditis can cause sudden cardiac death, with no symptoms until death;

3 in a study of a multicentre cohort of 171 paediatric patients with myocarditis, 13% died or underwent cardiac transplant during their

initial hospitalization;

4 for those with an underlying etiology of myocarditis, the incidence of transplant or death at 5 years after diagnosis was 27%;

5 myocarditis can also lead to the development of a chronic dilated cardiomyopathy (DCM), which is the leading cause of paediatric heart transplant in children older than 1 year and;

6 in a large cohort of paediatric patients with DCM from the Paediatric Cardiomyopathy Registry, myocarditis was the most common known cause of DCM;

7 of children with a known cause for DCM, up to 46% have been reported to be due to myocarditis;

8 the prognosis for individuals with myocarditis is as variable as the clinical presentation wherein:

(1) patients with acute myocarditis and normal cardiac function have a good prognosis overall, with a high likelihood for spontaneous recovery;

(2) those with fulminant viral myocarditis are more likely to have recovery if adequately supported with medications or MCS during the initial phase;

(3) those with giant cell myocarditis have a poor prognosis in both children and adults, with median survival of less than 6 months without cardiac transplant.

9 when evaluated from a sudden death perspective, myocarditis accounts for approximately 5% to 6% of sudden deaths in young athletes in the United States;

10 myocarditis can result in life-threatening arrhythmias and conduction abnormalities, including variable degrees of:

(1) atrioventricular block;

(2) ventricular fibrillation/flutter; or

(3) ventricular tachycardia.

11 based upon extensive and reasonably available empirical historical data that **("Established Scientific Facts of Myocarditis")**:

(1) myocarditis and pericarditis are in every instance serious and life-threatening conditions;

(2) neither prognosis nor treatment can be determined without a histological based understanding of the underlying pathophysiological processes;

(3) following myocarditis there is:

a) generally across all aetiologies 30-40% chance of progression to death or cardiac failure within 5 years;

b) some aetiologies attended by a 25% survival rate within a 6 month period;

c) at least 50% of patients develop cardiomyopathy in the long term;

d) a one-year mortality rate for acute myocarditis generally of 20% which increases to 56% on four-year follow-up.

e) discernible changes to a patients ECG results are rare;

f) assessment requires a minimum of an MRI to confirm the diagnosis;

g) proper treatment can only be guided by the result of a

myocardial biopsy;

h) outcomes of acute myocarditis are often life threatening;

i) the risk of sudden cardiac death in patients with acute myocarditis is not always associated with the severity of myocardial inflammation and can persist after the acute phase of myocarditis is resolved;

j) acute myocarditis can also present as sudden cardiac death, accounting for approximately 10% of deaths from sudden cardiac death in young individuals aged under 35 years;

k) life-threatening bradyarrhythmia and tachyarrhythmia can occur at any stage of the disease and lead to sudden cardiac death.

e) the publicly available data since at least August, 2021, has conclusively shown that:

1 myocarditis is causally linked to the mRNA Spike Protein;

2 infection with Covid does not significantly elevate the risk of myocarditis, since at least;

f) the Vaccines;

1 increase risk of myocarditis in those younger than 40 years of age in the mRNA Vaccines;

2 increase the risk of myocarditis within a week of receiving the first dose of any of the Vaccines;

3 increase the risk of myocarditis after the second dose of both mRNA vaccines;

g) myocarditis is historically underdiagnosed in practice, with clinical bias being directed towards myocardial ischemia or infarction;

h) the risk of myocarditis and pericarditis in recipients of either of the mRNA Vaccines:

1 increased both after the first and second doses;

2 is statistically significant;

3 is in respect of the Moderna Vaccine a 3000% increased risk;

4 higher in younger age groups;

5 observable internationally.

i) Covid infection:

1 in unvaccinated patients is not associated with any increased risk of myocarditis and pericarditis;

2 causes no increased incidence of either pericarditis nor myocarditis in adult patients post-infection.

j) at the time of the Approvals the Respondents knew that the background rate of incidence of myocarditis in children aged 15 years and under was:

1 1.95 per 100,000 persons; or

2 0.00195%.

k) The Respondents knew from at least August 2021 that in the period between December 2020 and August 2021, reports of myocarditis in individuals older than 12 years old to the VAERS that occurred after administration of the mRNA Vaccines disclosed that:

1 the reported cases of myocarditis in VAERS within 7 days after vaccination exceeded the expected rates across multiple age and

sex strata;

2 rates of myocarditis were highest after the second vaccination dose in:

(1) adolescent males aged 12-15 years (70.7 per million doses of the Pfizer Vaccine);

(2) adolescent males aged 16-17 years (105.9 per million doses of the Pfizer Vaccine); and

(3) young men aged 18 to 24 years (52.4 and 56.3 per million doses of the Pfizer Vaccine and the Modern Vaccine, respectively).

l) vaccination with the Pfizer Vaccine was known from at least September, 2021 by the Respondents to be associated with an increased risk of myocarditis:

1 of 5 events per 100,000 persons; and

2 which is substantially increased after Covid infection.

m) the European Medicines Agency Pharmacovigilance Risk Assessment Committee (PRAC) had by 28 October, 2021, which was known to the Respondents at that time:

1 confirmed a safety signal in the Vaccines for myocarditis and pericarditis, as well as capillary leak syndrome in the Moderna Vaccine;

2 recommended changes to the product information to reflect this in the Moderna Vaccine and the Pfizer Vaccine;

3 stated that any cardiac arrest or death in young people must constitute a safety signal.

n) the Respondents knew from at least October, 2021, it was known via publicly available data that:

1 within the 28-day period post-vaccination with the mRNA Vaccines:

(1) for males and females 12 years or older combined the second dose was associated with higher excess risk of myocarditis being:

a) 1.75 times higher risk for the Pfizer vaccine; and

b) 6.57 times higher risk for the Moderna Vaccine.

(2) for males 16 to 24 years of age the second dose was associated with higher excess risk of myocarditis being:

a) 5.31 times higher risk for the Pfizer vaccine; and

b) 13.83 times higher risk for the Moderna Vaccine.

(3) numbers of excess events of myocarditis per 100,000 vaccinees after the second dose were:

a) 5.55 excess events for the Pfizer vaccine; and

b) 18.39 excess events for the Moderna Vaccine.

(4) similar rates as those were evident in respect of Pericarditis.

o) from at least April, 2022, the Respondents knew that the Pfizer Vaccine was known to cause increased risk of myocarditis in younger males of approximately:

1 1.316 per 10,000 additional instances of myocarditis among men 12–19 years old in the week following receiving the second dose of the Moderna Vaccine than those unvaccinated;

2 1.88 per 10,000 additional instances of myocarditis 4 weeks after

receiving the second dose of the Moderna Vaccine in boys 16–24 years old compared to the unvaccinated.

p) the Commonwealth report on Guidance on Myocarditis and Pericarditis after mRNA COVID-19 Vaccines dated 29 April, 2022, known to the Respondents at that time stated the following rates of myocarditis per million doses by age cohort and sex:

1 Pfizer:

(1) 12-17 years of age:

a) males: 107;

b) females: 24;

(2) 18-29 years of age:

a) males: 67;

b) females: 20;

(3) 30-39 years of age:

a) males: 19;

b) females: 6.

2 Moderna:

(1) 12-17 years of age:

a) males: 159;

b) females: 26;

(2) 18-29 years of age:

a) males: 142;

b) females: 12;

(3) 30-39 years of age:

a) males: 52;

b) females: 0.

q) from at least August, 2022, the Respondents knew that in adolescents taking two doses of the Pfizer Vaccine:

1 cardiovascular manifestations were found in 29.24% of patients including:

(1) tachycardia - 7.64%;

(2) shortness of breath - 6.64%;

(3) palpitation - 4.32%;

(4) chest pain 4.32%; and

(5) hypertension 3.99%.

2 confirmed or suspected myocarditis or pericarditis in 2.3%.

Particulars

"Acute Myocarditis and Pericarditis in Children" Tunuguntla H, et al. 2019. Ped. Rev. 40(1):14-25" https://publications.aap.org/pediatricsinreview/article-abstract/40/1/14/35218/Acute-Myocarditis-and-Pericarditis-in-Children?redirectedFrom=fulltext

"Acute Myocarditis". Al-Akchar, M et al. 2022. In: StatPearls [Internet].

https://www.ncbi.nlm.nih.gov/books/NBK441847/

“Myocarditis and inflammatory cardiomyopathy: current evidence and future directions”. Tschöpe, C et al. 2021. Nat Rev Cardiol. 2021;18(3):169-193.

“Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection”. Patone, M et al. 2022. Nature Medicine, 28, pages 410–422.
https://pubmed.ncbi.nlm.nih.gov/34907393/

“Age and sex-specific risks of myocarditis and pericarditis following Covid-19 messenger RNA vaccines”. Le Vu, S. 2022. NATURE COMMUNICATIONS 13, Article number: 3633. https://www.nature.com/articles/s41467-022-31401-5

“The Incidence of Myocarditis and Pericarditis in Post COVID-19 Unvaccinated Patients – a Large Population-Based Study”. Tuvali, O et al. 2022. J. Clin. Med. 2022, 11, 2219. https://doi.org/10.3390/jcm11082219

“Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection”. Patone, M et al. 2022. Nature Medicine, 28, pages 410–422.
https://pubmed.ncbi.nlm.nih.gov/34907393/

“Occurrence and Features of Childhood Myocarditis: A Nationwide Study in Finland”, Arola et al. 2017. Journal American Heath Association, v6(11).

“Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the US From December 2020 to August 2021”, Oster et al, 2022. JAMA. 327(4):331-340

“Safety of the BNT162b2 MRNA COVID-19 Vaccine in a Nationwide Setting”. Barda, N et al. 2021. N. Engl. J. Med.

385, 1078–1090

SARS-CoV-2 Vaccination and Myocarditis in a Nordic Cohort Study of 23 Million Residents, Karlstad et al. JAMA Cardiol.2022;7(6):600-612. doi:10.1001/jamacardio.2022.0583. Published online April 20, 2022. October 5, 2021 Study End – Confirmed Data on SARS-CoV-2 vaccinations, hospital diagnoses of myocarditis or pericarditis, and covariates for the participants were obtained from linked nationwide health registers in Denmark, Finland, Norway, and Sweden.

“Current Evidence in SARS-CoV-2 mRNA Vaccines and Post-Vaccination Adverse Reports: Knowns and Unknowns”. Mouliou, Dimitra S. and Dardiotis, Efthimios. Diagnostics (Basel). 2022 Jun 26; 12(7):1555 citing data from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1072043/COVID-19_mRNA_Pfizer-_BioNTech_vaccine_analysis_print.pdf-

“PRAC recommendations on signals”, Adopted at the 25-28 October 2021 PRAC meeting. European Medicines Agency Pharmacovigilance Risk Assessment Committee.

Analysis of all UK spontaneous reports to the Yellow Card Scheme between 9 December, 2020 and 20 April, 2022 for Pfizer Vaccine.

Australian Government report (Updated 28 April 2022) “Guidance on Myocarditis and Pericarditis after mRNA COVID-19 Vaccines”. 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

“Cardiovascular Manifestation of the BNT162b2 mRNA

Covid-19 Vaccine in Adolescents", Mansanguan et al, Trop. Med. Infect. Dis. 2022, 7(8), 196.

Analysed 301 Thai adolescents aged 13-18 who received 2 doses of BNT162b2 Covid-19 vaccine. 7 cases.

KNOWN VACCINES ASSOCIATED ADVERSE REACTIONS – ANAPHYLAXIS

204. It was known to the Respondents since at least May, 2021 by reasonably obtained and observed empirical data and studies known to the Respondents at that time that the following had been scientifically established in respect of the anaphylaxis as a side-effect of the Vaccines that:

a) approximately 2.5 million doses of the Vaccines had been administered in Australia at that time;

b) confirmed anaphylaxis was being reported at a rate of 1 case per 156,250 injections of the Vaccines;

c) international long-term surveillance of vaccine-related anaphylaxis is approximately 1 in one million;

d) the rate of reported anaphylaxis related to the Vaccines was:

1 unexpectedly high as compared to the expected rate for vaccines generally;

2 more than 6 times higher than the expected rate for vaccines generally;

3 indicated as causally related to the Vaccines;

4 not considered by the Respondents to be of sufficient concern to withdraw the Vaccines.

e) anaphylaxis is:

1 a serious adverse event;

2 as to its rate of occurrence, a critical indicator of vaccine safety;

3 related to the immunogenicity of a medication;

4 indicative of a higher risk of other immunological adverse events.

Particulars

DAEN Database
https://daen.tga.gov.au/medicines-search/

Jens U. Rüggeberg, Anaphylaxis: Case definition and guidelines for data collection, analysis, and presentation of immunization safety data, Vaccine, Volume 25, Issue 31,2007, Pages 5675-5684, ISSN 0264-410X, https://doi.org/10.1016/j.vaccine.2007.02.064.

KNOWN VACCINES ASSOCIATED ADVERSE REACTIONS – THROMBOCYTOPENIA AND THROMBOEMBOLISM

205. It was known to the Respondents from at least April, 2021 by reasonably obtained and observed empirical data and studies known to the Respondents at that time that the Vaccines cause significantly increased risk of haematological and vascular events:

a) causing:

1 hospital admission; or

2 death;

b) specifically:

1 thrombocytopenia;

2 venous thromboembolism;

3 arterial thromboembolism;

4 cerebral venous sinus thrombosis;

5 ischaemic stroke; and

6 other normally rare arterial thrombotic events.

c) within a short time interval after first doses of the either of the mRNA Vaccines

Particulars

"Risk of Thrombocytopenia and Thromboembolism after COVID-19 Vaccination and SARS-CoV-2 Positive Testing: Self-Controlled Case Series Study". Hippisley-Cox, J et al. BMJ 2021, 374, n1931

KNOWN VACCINES ASSOCIATED ADVERSE REACTIONS – THYROID EFFECTS

206. It was known to the Respondents from at least November, 2021 by reasonably obtained and observed empirical data and studies known to the Respondents at that time that the Vaccines were known:

a) to cause:

1 Spontaneous Subacute Thyroiditis; and

2 Grave's disease;

b) to possess adjuvants which combine into potential cross-reactivity between the Virus and thyroid antigens to cause during and after Covid infection and injection with the mRNA Vaccines:

1 autoimmune reactions; and

2 inflammatory reactions.

Particulars

"Thyroid as a Target of Adjuvant Autoimmunity/Inflammatory Syndrome Due to MRNA-Based SARS-CoV2 Vaccination: From Graves' Disease to Silent Thyroiditis". Pujol, et al. 2022. J. Endocrinol. Investig. 45, 875–882.

KNOWN VACCINES ASSOCIATED ADVERSE REACTIONS – NEUROLOGICAL EFFECTS

207. As from at least May, 2022 based upon reasonably obtained and observed empirical data and studies known to the Respondents, the Vaccines were scientifically established as causally related to neuropathy in recipients of the Vaccines including:

a) severe face and/or limb paraesthesia;

b) orthostasis, heat intolerance and palpitations; and

c) small-fibre peripheral neuropathy;

d) Bell's Palsy;

e) transverse myelitis;

f) acute disseminated encephalomyelitis;

g) Guillain-Barre Syndrome.

Particulars

"Neuropathic symptoms with SARS-CoV-2 vaccination". Safavi et al, medRxiv. May 17, 2022.

Allahyari, et al. "Covid-19 vaccines and neurological complications: a systematic review" *Zeitschrift für Naturforschung C*, vol. 78, no. 1-2, 2023, pp. 1-8. https://doi.org/10.1515/znc-2022-0092

KNOWN VACCINES ASSOCIATED ADVERSE REACTIONS – CANCER

208. As from at least 15 July, 2022, the Respondents had in their possession and were aware of PRR data relating to multiple forms of cancer, showing PRR values that were significantly higher than the TGA's own prescribed threshold for what constitutes a safety signal:

a) 19 July, 2021

1	PRR for Lymphoma	5.87

b) 29 September, 2021

1	PRR for Malignant Melanoma	7.31
2	PRR for Malignant Neoplasm	3.04
3	PRR for Breast Cancer	3.65
4	PRR for Gastrointestinal Cancer	7.31
5	PRR for Lymphoma	3.65

c) 29 November, 2021

1	PRR for Malignant Melanoma	6.14
2	PRR for Malignant Neoplasm	3.93
3	PRR for Lymphoma	6.44

d) 17 January, 2021

1	PRR for Plasma Cell Myeloma	8.08
2	PRR for Prostate Cancer	6.73
3	PRR for Malignant Neoplasm	5.92

	4	PRR for Lymphoma	6.95
e)	24 March, 2022		
	1	PRR for Prostate Cancer	10.37
	2	PRR for Malignant Neoplasm	3.65
f)	11 May, 2022		
	1	PRR for Malignant Melanoma	7.1
	2	PRR for Malignant Neoplasm	4.1
	3	PRR for Leukaemia	2.35
	4	PRR for Acute Lymphocytic Leukaemia	3.33
g)	15 July, 2022		
	1	PRR for Malignant Neoplasm	4.36
	2	PRR for Ovarian Cancer	6.31
	3	PRR for Acute Lymphocytic Leukaemia	10.67

Particulars

TGA Data obtained by FOI Request 4029

KNOWN VACCINES ASSOCIATED ADVERSE REACTIONS - PREGNANT WOMEN

209. The Respondents knew at the material times by reasonably obtained and observed empirical data and studies known to the Respondents and data and documents published to them at that time establishing scientifically the following in respect of the dangers of the Vaccines in pregnant women:

a) worldwide data indicates:

1 material increases in stillbirths, perinatal, and neonatal deaths from late 2021 leading into 2022;

2 decreases in birth rates in:

(1) Germany;

(2) Taiwan;

(3) US states;

(4) Sweden;

(5) Canada;

(6) Hungary.

b) the Pfizer Post-Marketing Data dated 28 February, 2021 and provided to the Respondents:

1 had in Table 6 missing Information in respect of the Safety In Pregnancy of the Pfizer Vaccine because:

(1) the Vaccines were not studied for safety in pregnancy in any of the Vaccines clinical trials; and

(2) the data collected in those trials for pregnant women were subjects whom incidentally became or were pregnant during the clinical trials.

2 table 6 lists 270 pregnancies reported during the trial as having had exposure to the Pfizer Vaccine, from which:

(1) in 238 cases Pfizer failed or refused to follow-up and/or report to the TGA on the outcome of the pregnancy, being 88% of cases;

3 in 32 of the cases Pfizer followed-up and reported the outcome of the pregnancy to the TGA:

(1) 23 cases (72% of those reported) suffered spontaneous abortion with intrauterine death;

(2) 2 cases (6% of those reported) suffered premature birth with neonatal death;

(3) 2 cases (6% of those reported) suffered premature birth;

(4) 1 case of a normal outcome (3% of those reported);

(5) 4 reported as outcome pending (13% of those reported).

c) VAERS reports of pregnancy-related adverse events CDC VAERS entries from January 1, 1998 to June 30, 2022 calculations of PRR of adverse pregnancy events compared to Influenza vaccine known to the Respondents found:

1 1200-fold higher rate of severe menstrual abnormalities;

2 57 fold higher rate of miscarriage;

3 38 fold higher rate of foetal death/stillbirth;

4 15 other major pregnancy complications far exceeding the regulator's safety threshold.

d) in Australia, PRR data known to and produced by the Respondents show:

1 a PRR for miscarriage of 5.3;

2 an increase of adverse event reporting of 5.3 times higher than for any other vaccine.

e) in August, 2022 it was publicly reported and known to the Respondents that Dr Luke McLindon, former head of fertility services at the Mater

Hospital in Brisbane and former President of the Australasian Institute for Restorative Reproductive Medicine, reported miscarriages:

1 at a typical rate of occurrence of 12-15% in his cohort of patients which is higher than the usual miscarriage rate because his patients are all typically high-risk pregnancies;

2 increasing to a rate of occurrence in excess of 70% among the subset of patients who had been injected with the Vaccines prior to conception.

f) on or about 8 October, 2022, Dr James Thorp, a board-certified OBGYN and Maternal Fetal Medicine Physician with over 43 years of clinical experience stated publicly which was known to the Respondents that:

1 in the two years prior, since the mRNA Vaccine was introduced, he has seen in his patients an “off the charts” rise among vaccinated patient in:

(1) sudden fetal death;

(2) adverse pregnancy outcomes;

(3) fetal malformation;

(4) fetal cardiac arrest;

(5) severe placental problems causing inter-uterine growth restrictions.

2 the significant increase was compared with appropriate controls like the influenza vaccine;

3 his observations showed relative risk p-values of the mRNA Vaccines above 1,000,000;

4 the CDC and the FDA state if you have a relative risk of (p-value) 2 or greater, that’s a severe danger signal that should be looked at;

and

5 the adverse events were causally related to receipt of the mRNA Vaccines by the pregnant women.

6 the clinical standard/cardinal rule of obstetrics:

(1) is to never use a substance in pregnancy that is new, untested and even has any potential to do harm;

(2) is violated by injecting pregnant women with a novel untested vaccine was a gross violation of that cardinal rule.

Particulars

Guetzkow, J (July 2022) “Springtime for Stillbirths in Germany Winter for women and babies”. Substack. https://jackanapes.substack.com/p/springtime-for-stillbirths-in-germany

Chudov, I (July 2022) “Hungary: Highest Vaccinated Counties Have Worst Birth Rate Drops”. Substack. https://igorchudov.substack.com/p/hungary-most-vaccinated-counties

Jestre (July 2022) “Birth rate declines come to Canada”. Substack. https://jestre.substack.com/p/birth-rate-declines-come-to-canada

The Pfizer Post-Marketing Data. Page 12.

COVID-19 Vaccines: The Impact on Pregnancy Outcomes and Menstrual Function. Thorp et al. Preprint Dec 2022 https://www.preprints.org/manuscript/202209.0430/v1

PRR data released under FOI Request 4032

“Brisbane doctor details how he came to be sacked by major

hospital". Brisbane Times, 17 August, 2022. https://www.brisbanetimes.com.au/national/queensland/brisbane-doctor-details-how-he-came-to-be-sacked-by-major-hospital-20220817-p5baiw.html

Interview broadcast on the Ask Dr Drew Show on 8 October, 2022.

KNOWN VACCINES ASSOCIATED ADVERSE REACTIONS - CHILDREN

210. It was known to the Respondents since at least October 2022 by reasonably obtained and observed empirical data and studies known to the Respondents at that time that the following had been scientifically established in respect of adverse events associated with children receiving the Pfizer Vaccine that in those children aged 5 years and under following taking the Pfizer Vaccine:

a) 0.9% required emergency care (ambulatory);

b) 0.1% required hospitalisation (inpatient);

c) the rate requiring emergency care was 80% higher than those in the same age group taking a non-Covid vaccine;

d) the rate requiring hospitalisation was 80% higher than those in the same age group taking a non-Covid vaccine;

e) 1.02 in every 2 children receiving the Pfizer Vaccine suffered an adverse event following vaccination;

f) the risk of children suffering an adverse event is 36% higher following the Pfizer Vaccine than it is following a non-Covid vaccine.

Particulars

"Comparative Safety of the BNT162b2 mRNA COVID-19 Vaccine vs Other Approved Vaccines in Children Younger Than 5 Years". Toepfner et al, Oct 2022. JAMA Network Open. 5(10).

KNOWN EXPLOSION IN VACCINES-RELATED ADVERSE EVENTS

211. It was known to the Respondents at least April, 2021 and ongoing that by reasonably obtained and observed empirical data at that time available on the DAEN demonstrated an exponential increase in Vaccines-related adverse events recorded as follows subsequent to the initial Approvals and at the relevant time of subsequent Approvals:

a) as at 23 July, 2021 and from the release of the first of the Vaccines, being the Pfizer Vaccine on 25 January, 2021:

1 the following approvals were granted by the TGA despite there having been unprecedented reports of Adverse Events following vaccination with the Vaccines:

(1) the Pfizer Adolescent Approval on 22 July, 2021;

a) as at 22 July, 2021, the DAEN had recorded in respect of the Vaccines:

i) 45,188 reported adverse events;

ii) 427 reported deaths.

(2) the Moderna Approval on 9 August, 2021:

a) as at 9 August, 2021 the DAEN had recorded in respect of the Vaccines:

i) 51,489 reported adverse events;

ii) 472 reported deaths.

(3) the Moderna Adolescent Approval on 3 September, 2021:

a) as at 3 September, 2021 the DAEN had recorded in respect of the Vaccines:

i) 62,167 reported adverse events;

ii) 540 reported deaths.

(4) the Pfizer booster dose was approved by the TGA for use in ages 18 years and older on 26 October, 2021:

a) as at 26 October, 2021, the DAEN had recorded in respect of the Vaccines:

i) 81,594 reported adverse events;

ii) 641 reported deaths.

(5) the Pfizer Child Approval on 3 December, 2021:

a) as at 3 December 2021, the DAEN had recorded in respect of the Vaccines:

i) 95,384 reported adverse events;

ii) 707 reported deaths.

(6) the Moderna booster dose was approved by the TGA for use in ages 18 years and older on 7 December, 2021:

a) as at 7 December, 2021, the DAEN had recorded in respect of the Vaccines:

i) 96,312 reported adverse events;

ii) 711 reported deaths.

(7) the Pfizer booster dose was approved by the TGA for use in ages 16-17 year olds on 27 January, 2022:

a) as at 27 January 2022, the DAEN had recorded in

respect of the Vaccines:

i) 110,383 reported adverse events;

ii) 763 reported deaths.

(8) the AstraZeneca booster dose was approved by the TGA for use in ages 18 years and older on 8 February, 2022:

a) as at 8 February, 2022, the DAEN had recorded in respect of the Vaccines:

i) 114,208 reported adverse events;

ii) 769 reported deaths.

(9) the Moderna Child Approval on 17 February, 2021:

a) as at 17 February, 2022, the DAEN had recorded in respect of the Vaccines:

i) 116,590 reported adverse events;

ii) 774 reported deaths.

(10) the Pfizer booster dose was approved by the TGA for use in ages 12-15 year olds on 17 April, 2022:

a) as at 17 April, 2022, the DAEN had recorded in respect of the Vaccines:

i) 126,774 reported adverse events;

ii) 827 reported deaths.

(11) the Moderna Infant Approval on 19 July, 2022:

a) as at 19 July, 2022, the DAEN had recorded in respect

of the Vaccines:

i) 134,224 reported adverse events;

ii) 908 reported deaths.

Particulars

DAEN Database
https://daen.tga.gov.au/medicines-search/

PART L - MISLEADING STATEMENTS

SKERRITT

212. Skerritt made the following public statements expressly or by reasonable inference **("the Skerritt Misleading Vaccines Statements")**:

a) on 6 February, 2021 in respect of the preliminary approval of the Vaccines, Skerritt stated that:

1 the TGA had conducted a thorough investigation of the safety of the Vaccines;

2 the adverse events observed were not causally connected with the Vaccines;

3 the TGA was carefully examining the ongoing safety data in respect of the Vaccines to continually establish safety.

Particulars

Sky News Interview

"The safety evidence is pretty thorough and generally even the very serious safety effects that arise, tend to happen 4 to 6 weeks after the first shots and we're just not seeing, thank God, we're not seeing those safety problems from the

overseas experience”

https://www.facebook.com/SkyNewsAustralia/videos/safety-evidence-for-the-pfizer-vaccine-is-pretty-thorough-tga-head/421193715601288/

b) on 16 February, 2021 that in respect of the rollout of the Vaccines Skerritt stated that:

1 the objective of increasing numbers of Vaccines recipients in Australia was more important ~~a higher priority~~ than the safety and efficacy data;

2 the Vaccines generally are safe and effective for consumption;

3 the actual efficacy of the Vaccines is not relevant;

4 the Vaccines are proven safe in pregnancy.

Particulars

Parliament House – Press Conference

“So I would emphasise that a lot of the discussion on numbers is not particularly relevant. What is important is to get vaccines into people's arms.”

In respect of the outcomes of the women who became pregnant during the Phase III Pfizer clinical trials:

“Obviously, those babies are yet to be born and so forth, again, there’s no evidence of anything untoward such as miscarriage or illness during pregnancy. But as the weeks and months go on, we’ll know a lot more about pregnancy with these vaccines. The aim, of course, is as time goes on we’ll know more about the vaccines in all the groups in the community, including children.”

c) on 29 April, 2021 that in respect of the escalating number of adverse events being reported to the TGA in respect of the Vaccines after the Approvals Skerritt stated that:

1 the escalating number of adverse events being reported to the TGA in respect of the Vaccines after the Approvals were merely:

(1) coincidental; and

(2) of no concern or consequence.

Particulars

Skerritt expressly stated in respect of the proliferation of adverse events after the Approvals that - "We do have to remember that, sadly, every week in Australia, 3,000 people die of all sorts of causes."

https://www.abc.net.au/news/2021-04-29/health-authorities-update-covid-vaccine-deaths-bood-clot/100105130 Accessed 2nd Jan 2021.

d) on 6 May, 2021 Skerritt stated that:

1 he had seen a significant 60-fold increase in adverse events reported to the TGA overall as compared to 2020 as a consequence of adverse events related to the Vaccines occurring after the Approvals being reported;

2 the adverse events reported were of no concern;

3 the increasing volume in reported adverse events were encouraging;

4 the proliferation of adverse events related to the Vaccines was of no consequence or concern;

5 in no way impacted upon any determination as to the Vaccines safety for use by all Australians;

6 ~~he knew~~ that 16 cases of a severe allergic reaction to the Vaccines being anaphylaxis had been reported to the TGA which were of no particular safety concern;

7 such statements being made in circumstances of the facts known to the Respondents that:

(1) approximately 2.5 million doses of the Vaccines had been administered in Australia at that time;

(2) confirmed anaphylaxis was being reported at a rate of 1 case per 156,250 injections of the Vaccines;

(3) international long-term surveillance of vaccine related anaphylaxis is typically only 1 in one million;

(4) the rate of reported anaphylaxis related to the Vaccines was:

a) unexpectedly high as compared to the expected rate for vaccines generally;

b) more than 6 times higher than the expected rate for vaccines generally.

(5) anaphylaxis is:

a) a serious adverse event;

b) as to its rate of occurrence, a critical indicator of vaccine safety;

c) related to the immunogenicity of a medication;

d) indicative of a higher risk of other immunological adverse events.

Particulars

Skerritt expressly stated in respect of the proliferation of adverse events after the Approvals that - “And so we've seen a very significant increase and we're actually- it might sound funny but we're actually encouraged by the fact because we want consumers to report adverse events directly to us, whether it's any vaccine or any medicine. And we've had a 60-fold increase in the number of adverse event reports made to us by consumers since- compared to, say, 2020. And so, over 3200 of those adverse events have actually been reported to us by consumers, and again, we see that as a good thing”.

https://www.health.gov.au/news/therapeutic-goods-administration-professor-john-skerritt-and-commodore-eric-youngs-press-conference-on-6-may-2021.

e) on 8 June, 2021 Skerritt stated that:

1 at that time the Vaccines had been thoroughly assessed for safety and efficacy;

2 injecting the Vaccines involved only an extremely rare chance of anything other than the most minor side effects being:

(1) a few in a million;

(2) 0.00001%;

3 that on balance the risks of taking the Vaccines was so small that they were significantly outweighed by the protection against Covid that the Vaccines would provide;

4 the risk of a serious adverse event related to taking the Vaccines was almost nil;

Particulars

Skerritt expressly stated in respect of the Vaccines that - “They have been thoroughly assessed for safety and effectiveness. As people know, there's a very rare chance of side effects with both vaccines. But these are a few in a million. And so, for 99.99999 per cent of people, these are very safe vaccines. They - in some people, probably 30 or 40 per cent, will give you a sore arm, fatigue, nausea. Some people even have to end up in bed for a day. But that's a small price to pay compared with protection against coronavirus.”

https://www.health.gov.au/news/therapeutic-goods-administration-adj-professor-john-skerritts-interview-on-2sm-on-8-june-2021

f) on 9 August, 2021, Skerritt stated that:

1 the Moderna Vaccine provides long-lasting efficacy against Covid;

2 the Moderna Vaccine is 93% effective against Covid infection for over six months;

3 the Moderna Vaccine is 98% effective against severe disease from Covid for over six months;

4 the Moderna Vaccine is 100% effective against death for over six months;

Particulars

Press Conference at Parliament House

“The other really encouraging thing about Moderna is, even after six months, it is proving to be 93% efficacious against any infection, 98% against severe disease and 100%

against death and that's really exciting."

Accessed: https://www.theguardian.com/australia-news/live/2021/aug/09/australia-politics-business-vaccine-covid-morrison-gladys-berejiklian-sydney-brisbane-victoria-melbourne-health-moderna-pfizer-astrazeneca?page=with:block-6110caef8f0892081f6d0bf3

g) on 10 August, 2021 Skerritt stated that:

1 the Vaccines mRNA technology do not alter the genes of the recipient;

2 there have been no safety signals raised about the Vaccines with respect to pregnancy;

3 the Moderna Vaccine is safe for pregnant women;

4 every dose of the Vaccine is manufactured identically every time;

5 the statements made in circumstances where in truth:

(1) Skerritt made a directly contrary statement on the same day in an interview publicly broadcast on 6PR stating:

a) where the Vaccines are being made at different sites they may be different in composition - https://www.health.gov.au/news/therapeutic-goods-administration-adj-professor-john-skerritts-interview-on-6pr-on-10-august-2021;

(2) the statements contradicts data published in the scientific literature in April 2021 which demonstrated that the SARS-CoV-2 RNA can integrate into the genome, and by producing this RNA in humans it is likely the vaccines can result in the same genomic integration;

Particulars

Proc Natl Acad. Sci U S. 2021, May 25; 118(21):e2105968118. doi: 10.1073/pnas.2105968118. Reverse-transcribed SARS-CoV-2 RNA can integrate into the genome of cultured human cells and can be expressed in patient-derived tissues Liguo Zhang https://pubmed.ncbi.nlm.nih.gov/33958444/

(3) the Respondents knew that:

a) neither genotoxicity nor mutagenicity studies were performed were ever performed upon the Vaccines without which the statement content could not have been known to Skerritt;

b) genotoxicity was evident in the Vaccines trials.

Particulars

Skerritt expressly stated that – in respect of the Moderna Vaccine "it's one of those messenger RNA vaccines. It doesn't alter your genes. But once vaccinated into the body, it produces the corona virus proteins, and that means that it stimulates your immune system to protect you against viral infection."

Skerritt expressly stated that – in respect of the Moderna Vaccine being safe for pregnant women "But there don't seem to be any signals that are telling us that there's a problem with pregnancy."

Skerritt expressly stated that – in respect of the Moderna Vaccine's manufacture process "And that's very important because it's important that the vaccine is made the same way every time."

https://www.health.gov.au/news/therapeutic-goods-administration-adj-professor-john-skerritts-interview-on-5aa-on-10-august-2021

h) on 7 September, 2021 Skerritt stated that:

1 it could be presumed without any further evidence that deaths reported in respect of the Vaccines including the 495 deaths reported (other than 9) at that time as associated with the taking of the Vaccines were:

(1) attributable to the background death rate;

(2) not attributable to the Vaccines;

(3) are made by the reporter based upon nothing more than the fact that the death occurred after taking one of the Vaccines;

(4) coincidence;

(5) the reported deaths were of no concern or consequence in respect of the safety of the Vaccines;

(6) the Vaccines were still deemed to be safe;

(7) Panadol suffered a similarly high number of adverse events (hundreds or thousands) which were similarly of no consequence;

2 such statement being made in circumstances where in truth:

(1) it was in fact, and was known by the Respondents, that a requirement of all reported deaths to DAEN was that the reporter:

a) was required to indicate that the death was suspected to be related to taking the Vaccines or otherwise with almost all reports being suspected;

b) was in most instances made by the decedent's physician or a person close to the decedent.

(2) it was in fact, and was known by the Respondents that:

a) the DAEN at that time contained report of adverse events for the Vaccines being for a less than one year period:

i) 95,043 adverse event reports;

ii) 714 reported deaths.

b) the DAEN at that time contained report of adverse events for all of the 77 commercially available products with paracetamol as the sole active ingredient:

i) for the same period reports:

1. 126 adverse event reports;

2. 13 reported deaths (10 of which are apparently intentional or accidental overdose).

ii) for the period of more than 50 years since and in use since the 1950's:

1. 2951 adverse event reports;

2. 197 reported deaths.

Particulars

Skerritt expressly stated the following:

"Well, without the explanation, it's quite misleading. So, what it says is that 495 people have had reports given to us that there was a death, sometime, days or perhaps a week or so after they had a COVID vaccine. Now, as you know, thankfully more and more people every day are being vaccinated. And sadly, in Australia, 170,000 people die every year, 3250 Australians die every single week. And so, it's not surprising that two days after, say, a Pfizer vaccine, some people will die, the same way two days after going and seeing a doctor about something totally unrelated, they will die or two days after catching a bus. So really, it's not the cause-and-effect thing. And when we've looked at cause and effect, we believe that there's a total of nine reports of deaths that can be associated to vaccines, and this is against a background of 20 million doses of COVID-19 vaccines being given in Australia. Nine out of 20 million doses"

…….

SKERRITT: "I mean, every medicine or vaccine and even Panadol are associated with adverse events, but the adverse events with the COVID vaccines are extremely rare.

RICHARD GLOVER: "And if I generated a report on Panadol, to take that example, there would be a mix of adverse effects which had been caused by the Panadol, but lots which just happened to be connected with my use, but not causal?"

SKERRITT: "You would find hundreds, if not thousands, of adverse events with Panadol and some of which are related to the Panadol, but the vast majority, again, will be coincidental in time."

https://www.health.gov.au/news/therapeutic-goods-administration-adj-professor-john-skerritts-interview-on-abc-drive-on-7-september-2021.

DAEN Database - https://daen.tga.gov.au/medicines-search/

i) on 28 October, 2021 Skerritt stated that:

1 blood clots do not form in seconds;

(1) such statement being made in circumstances of the scientific facts known at that time to the Respondents blood clots can begin to form within seconds as platelets begin to aggregate;

2 there are many cases where a third Vaccine dose having produced immunity for many months or years;

(1) such statement being made in circumstances of the scientific facts known at that time to the Respondents that at the time, the Vaccines had not been in existence for a matter of years making his statement an impossibility;

3 that the sole purpose of adverse event reporting is to obtain an overall impression of Vaccine side effects;

4 that a stroke, a myocardial infarction or a blood clot cannot be caused by vaccination if it occurred within 15 minutes of vaccination;

(1) such statement being made in circumstances of the scientific facts known at that time to the Respondents that at the time that:

a) blood clots can form in a matter of minutes and can travel from an extremity to the heart or brain within a matter of minutes;

b) it is thereby possible for a stroke, myocardial infarction or blood clot caused by the Vaccine to have occurred within 15 minutes of vaccination;

5 that the human body is incapable of forming a blood clot that results in stroke or myocardial infarction within 15 minutes;

6 it is not uncommon for young persons to die of a stroke within a short period of time following vaccination;

7 it is usually presumed a coincidence not causality when people aged in their 70's, 80's and 90's die within a month following Covid vaccination;

8 it is safe for an individual who has experienced an anaphylactic reaction that has causally been related to vaccination by their doctor, to have any of the alternative Vaccines for their next dose;

9 the risk of Covid infection outweighs the risk of anaphylaxis for all individuals who have previously experienced an anaphylactic reaction to a Vaccine;

(1) such statement being made in circumstances of the scientific facts known at that time to the Respondents that at the time that that:

a) in June 2021 WHO and ICMRA, in a Statement to Healthcare Professionals that was adopted by the TGA, state that:

i) "these vaccines should not be given to people with a known history of a severe allergic reaction to any of the vaccine components"; and

ii) "a second dose of mRNA vaccine should not be given to those who have experienced anaphylaxis to the first dose";

10 a 12mg Ivermectin dose administered over 5 consecutive days is unsafe;

(1) such statement being made in circumstances of the scientific facts known at that time to the Respondents that at the time that:

a) Ivermectin has been found to be generally well tolerated as safe at doses of 30mg or 60 mg (administered three times in a week); or

b) 90mg or 120mg (administered as a single dose) (see particulars)

11 two doses of the Vaccines provides extremely high protection against serious illness or hospitalisation from Covid infection for a lengthy period of time;

(1) such statement being made in circumstances of the facts known at that time to the Respondents that at the time that:

a) the nonclinical assessment of the Pfizer vaccine showed antibodies and T cells in monkeys declined quickly over 5 weeks after the second dose of BNT162b2 raising concerns over long term immunity – the Pfizer Original AUSPAR pg. 14;

b) none of the Vaccines Clinical Trials tested for the ability of the Vaccines to prevent hospitalisation, serious disease, or death;

12 a third dose of Vaccines will provide sustained immunity against Covid;

13 the above statements regarding strokes being made in circumstances of the facts known at that time to the Respondents that at the time that:

(1) safety data from the Pfizer PSUR and others in the Respondents' possession since at least October 2021 discloses:

a) 300 spontaneous reports of stokes;

b) all regarded as serious; and

c) the relevant event onset latency range was <24 hours to 41 days, with a median of 2 days;

d) strokes related to the Vaccines:

i) are physiologically different to a stroke related to hypertension or smoking or similar;

ii) are likely due to pathological inflammation due to the lipid nanoparticles which were known by the Respondents at that time to distribute widely and quickly throughout the body including crossing the blood brain barrier.

Particulars

The statements were made by Skerritt in the following express statements in response:

Rennick: “A 37-year-old with complications after Pfizer commencing within 15 mins of having the vaccine and eventually diagnosed as a stroke which was categorised as B1 status - unsure if likely to be caused by vaccine (sic)”
In response – Skerritt’s medical opinion regarding the pathophysiology of adverse events and the process for assessment of causality:

Skerritt: “Apart from anaphylaxis which is allergic type response with circulatory components, stroke, myocardial infarction, clot is almost unheard of 15 minutes post vaccination, the human body just does not work that quickly. The panels of experts look at this and consider the biological process and the temporal relationship. Sadly, young people do have strokes. (sic)”

Video of those statements can be accessed at: https://www.bitchute.com/video/h5tFqWnpGpDp/

"Statement for healthcare professionals: How COVID-19 vaccines are regulated for safety and effectiveness" (Revised 11 June 2021)

https://www.youtube.com/watch?v=W2AxtSvEGV0

https://www.icmra.info/drupal/en/covid-19/icmra_who_vaccines_confidence_statement_for_hcps

Guzzo, C et al "Safety, tolerability, and pharmacokinetics of escalating high doses of ivermectin in healthy adult subjects" J Clin Pharmacol. 2002 Oct; 42(10):1122-33

j) on 5 December, 2021, Skerritt stated that:

1 the Pfizer Vaccine had been extensively clinically tested;

2 there were no safety problems identified in the clinical trials of the Pfizer Vaccine trials;

3 the children and adults in the clinical trials of the Pfizer Vaccine only suffered adverse effects after injection:

(1) of tiredness, sore arms, headache and similarly minor adverse effects;
(2) which were invariably brief and fairly short-lived;

4 ~~whilst "most kids" got a mild infection from Covid,~~ because about one in 3,000 children developed a multi-system inflammatory condition and "can end up being very sick for months on a risk-benefit balance they should be vaccinated with the Vaccines;

(1) the above statement regarding multi-system inflammatory condition being made in circumstances of the facts known at that time to the Respondents that:

a) case reports of multi-system inflammatory syndrome were submitted following administration of the Vaccines;

b) the European Medicines Agency Pharmacovigilance Risk Assessment Committee (PRAC) had by 28 October, 2021, which was known to Skerritt at that time had confirmed a safety signal in the Vaccines for Multisystem inflammatory syndrome;

5 children and adults taking the Vaccines:

(1) would suffer no serious adverse reactions;

(2) would be at higher risk of injury from Covid than the Vaccines;

(3) would protect children against multi-system inflammatory syndrome.

Particulars

"PRAC recommendations on signals", Adopted at the 25-28 October 2021 PRAC meeting. European Medicines Agency Pharmacovigilance Risk Assessment Committee.

Skerritt expressly stated as follows as reported –

"The head of the TGA, Prof John Skerritt, said the Pfizer vaccine had been "extensively clinically tested" including a trial of 2,500 children aged five to 11.'

'"The response of the body, the immune response, was identical to that in young adults," he said.'

‘“There were … no safety problems identified in those trials. The children had some of the same things that adults get – tiredness, sore arms, headache and so forth – but these tended to be brief and fairly short-lived.”’

‘Skerritt said the children’s Pfizer was the “same vaccine” but “formulated differently for children” – using one-third of an adult dose.’

‘“It will be in a different colour, it will be in a vial that will have an orange cap to distinguish it from the adult ones, which are grey or purple.”’

‘Skerritt said there were 2.3 million Australian children in the five to 11 age group and currently one-fifth of all Covid cases were in the under-12 group. That “may actually be higher for the Omicron variant”, he said.’

‘“Skerritt said while “most kids” got a mild infection from Covid, about one in 3,000 developed a multi-system inflammatory condition and “can end up being very sick for months”’.

https://www.theguardian.com/society/2021/dec/05/australian-children-aged-five-to-11-set-to-receive-pfizer-covid-vaccine-from-mid-january.

k) on 7 December, 2021, Skerritt stated that:

1 myocarditis has a very significant background rate in the community;

(1) the above statement regarding myocarditis being made in circumstances of the facts known at that time to the Respondents that the overall incidence of myocarditis in a population aged 15 years and under was 1.95/100,000 persons as determined by a large, longitudinal population study in 2017 (see particulars);

2 there is no difference in terms of pregnancy outcomes between vaccinated and unvaccinated mothers;

3 that Phase III clinical trials involves a group of people assembled for a period of a couple of months where they look to see whether the Vaccine is causing an antibody response and whether it is preventing against infection.

(1) the above statements regarding clinical trials being made in circumstances of the facts known at that time to the Respondents that:

a) the TGA's own clinical trial handbook states the primary objectives of a Phase III clinical trial are to 'determine the therapeutic effect in patient populations for which the drug is eventually intended' and to 'provide a definitive assessment of risk-benefit balance';

b) the FDA reports that the average duration for Phase III clinical trials is 1 to 4 years;

4 there is no additional risk of adverse pregnancy outcomes following vaccination with the Vaccines;

5 the Vaccines are safe and effective for use during pregnancy;

6 the Vaccines will prevent children infected by Covid from transmitting the virus to other persons;

(1) the above statements regarding transmission of the Virus being made in circumstances of the facts known at that time to the Respondents that:

a) the Vaccines Sponsors did not conduct any clinical trials investigating transmission of the virus;

b) the ability of the Vaccines to prevent transmission was unproven and unknown;

7 the extremely low infection fatality rate of Covid in children ~~for a particular age group is not determinative alone~~ can be overlooked in the risk-benefit ratio of the Vaccines ~~for that particular age group and includes~~ in preference to the propensity to become seriously ill;

(1) the above statement being made in circumstances of the facts known at that time to the Respondents that the Vaccines were also untested and of unknown effect in preventing serious disease, infection, and death;

8 a rate of approximately 3/10,000 children developing a multi-system inflammatory syndrome post Covid infection is significant justification for children aged 5-11 to get vaccinated with the Vaccines

(1) the above statement being made in circumstances of the facts known at that time to the Respondents that:

a) a large scale Israeli study published in the New England Journal of Medicine found vaccination with the Pfizer Vaccine was strongly associated with an elevated risk of:

i) myocarditis (2.7/100,000);

ii) lymphadenopathy (78.4/100,000);

iii) appendicitis (5/100,000); and

iv) herpes zoster infection (15.8/100,00) compared to no vaccination;

(see particulars)

b) the Vaccines will prevent children aged 5-11 from becoming infected with Covid;

i) the above statement being made in circumstances of the facts known at that time to the Respondents that the Vaccines had never been tested for, demonstrated to be, or indicated for the prevention of transmission or infection;

c) Covid infection poses a greater risk to children aged 5-11 than the Vaccines do;

i) statements being made in circumstances of fact known to Skerritt that:

1. at the time the known mean infection fatality rate in children 5-11 years was virtually nil;

2. the WHO background paper for Covid 19 Vaccine assessment at that time stated that the estimated age-specific IFR is very low for children and younger adults (e.g., 0.00002 at age 10;

(see particulars)

Particulars

On whether there should be concern that Pfizer have been granted 55 years by the FDA to release the data from the Vaccine clinical trials "So the FDA has been through all of Pfizer's regional clinical trial data, patient by patient in detail. What we do is look at the aggregated summaries, but we do have a group of international regulators which Australia is vice chair and which the FDA is part of the executive. We've probably had, I don't know if it's 30 or 40 meetings discussing Covid vaccines, I've lost count."

Skerritt expressly stated in respect of the onus of proof in determining if a side effect is due to the vaccine: "It's a rather detailed onus of proof. Firstly, you've got to show that in time it was related to the adverse event. Secondly, you've got to show that there's no other plausible mechanism. Thirdly, identify how it could be medically related. For example, a broken bone had nothing to do with having a vaccination. It would be hard to show that bone spontaneous breakage was, just to use a hypothetical, was plausible. Then we also look at background rates and remember that many things, including myocarditis, have a very significant background rate in the community. There's a number of other measures... observer, suspected...we slice it by the population. We look at the background rates, not just in the whole community but also in the particular age group and gender and even racial cohorts to get together with our colleagues overseas. So it's a detailed analysis, but we don't just do it ourselves. If it's a neurological side effect, we bring in some of Australia's top neurologists. If it's a haematological side effect, as we did for TTS, we bring in some of Australia's top haematologists and so on."

Skerritt expressly stated in respect of whether it is necessary to prove beyond a reasonable doubt or on the balance of probabilities if a side effect is caused by the Vaccine: "So the scheme which you're talking about, and our role is the medical assessment of information provided by the relevant specialist and the treating doctor, is on the balance of probability, there's no other likely cause for that effect. It is different from the broader TGA adverse event scheme, so it is a balance of probability scheme, and that information will, if it isn't already, shortly be made available in detail so that the detailed claims can be prepared."

Skerritt expressly stated in respect of Vaccine safety during pregnancy: "We already have assembled that information. There's about five studies now on pregnancy showing no difference in pregnancy outcomes. Sadly, as we know, quite a significant number of pregnancies, even in apparently healthy mothers, do end in miscarriage. And it's extremely sad for families of those involved. But the key thing is, those studies have shown there is not a difference between the vaccinated group and indeed the unvaccinated group in terms of pregnancy outcomes."

Skerritt expressly stated in respect of Phase III clinical trials:

"I just wanted to correct one thing and comment on another clinical trial. The phase III part of a clinical trial of a medicine or a vaccine does not take seven to ten years. It is a group of people assembled for a period of a couple of months where they look to see whether the vaccine is causing an antibody response and whether it is preventing against infection. And so the actual duration of this trial is not all that different from the normal duration of the trials."

Skerritt expressly stated in respect of the necessity of the Vaccines for 5-11 year olds:

"Firstly, we've had 22,000 cases of Covid in the 5-11 in Australia, and by any measure that's a significant number of cases. As I've said before, we shouldn't just use deaths as a measure. The limitations on those children being able to go to school, the fact that especially in unvaccinated families, there's infection of parents and grandparents. The effects on the mental wellbeing of children who have been infected and therefore have had to stay home and be isolated. And of course the one in 3000, one in 3200 chance, which when there are 22,000 kids, that actually is quite a few kids who develop this multi-system inflammatory syndrome, which the US Centre for Disease Control has shown to be quite serious and lasting for many months. So I reject the assertion that Covid is nothing much for kids and it doesn't matter if they catch it."

The statements were made by Skerritt expressly or by inference in the published Australian Senate Covid Committee discussions - 7 Dec 2021
https://www.youtube.com/watch?v=9Dt597zq1kc&t=17s
"Occurrence and Features of Childhood Myocarditis: A Nationwide Study in Finland", Arola et al, Journal American Health Association, v6(11): 2017 Nov

"Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting", Barda et al, N Engl J Med 2021: 385:1078-1090.

World Health Organization. (2020). Background paper on Covid-19 disease and vaccines: prepared by the Strategic Advisory Group of Experts (SAGE) on immunization working group on COVID-19 vaccines, 22 December

2020. World Health Organization.
https://apps.who.int/iris/handle/10665/338095

l) on 1 March, 2022 Skerritt stated that vaccination of children and booster vaccination against Covid is very important:

1 there is overwhelming evidence that a third dose of vaccination against Covid significantly reduces the risk of serious infection;

2 it is important to have a third dose of the Vaccine even if a person has had a recent infection with the Covid virus;

3 the safety record of the Vaccines is impressive;

(1) the above statements being made in circumstances of the facts known at that time to the Respondents that:

a) at that time, there were 119,208 adverse events reported to DAEN following vaccination with the Vaccines had been reported, 117,006 of which listed one of the Vaccines as the only suspected medicine;

b) AusVaxSafety, unlike DAEN, an active as opposed to passive adverse event reporting system, reported a rate of adverse event associated with the Vaccines of approximately 44%;
(see particulars)

4 ~~the safety record of the vaccines is more impressive for children pre-puberty~~;

5 serious adverse events following vaccination tend to occur 1-2 to 5-6 weeks following vaccination;

6 myocarditis is non-fatal;

7 the risk of death or serious illness from Covid infection is significant in children;

8 children taking the Vaccines would not:

a) be exposed to an unnecessary risk by doing so;

b) be infected with Covid;

c) be hospitalised with Covid;

d) transmit Covid to any other person;

9 people taking a third dose of the Vaccines:

a) would not suffer re-infection by the Covid virus;

b) have a significantly reduced risk of serious infection;

c) would reduce the overall number of Australians contracting Covid;

d) Covid has a high risk of serious injury or death without vaccination;

e) people taking a third dose of the Vaccines after natural infection:

i) gain additional immunity above acquired natural immunity against Covid by doing so;

ii) are not at any additional risk of side effects by doing so;

iii) are at a higher risk of serious infection from Covid if they do not do so as soon as they recover from the infection or within 4 months of recovering;

iv) natural acquired immunity against Covid is inferior to immunity provided by the Vaccines.

v) the above statement being made in circumstances of the facts known at that time to the Respondents that WHO had stated regarding natural immunity on 24 April 2020 that known evidence pointed to most individuals developing strong protective immune responses following natural infection with SARSCoV-2;

10 the risk of Covid infection is higher than the risk of Covid vaccination in children under 12 years of age;

11 the Vaccines side effects by children are only mild;

12 the risk of serious complications from Covid infection in adolescent and young adult males is higher than the risk of myocarditis from the Vaccines;

13 the above statements being made in circumstances of the facts known at that time to the Respondents that:

a) at the time a published study determined the overall incidence of myocarditis after receiving 1 dose of Pfizer Vaccine was 10.69/100,000 for males aged 16-29 years;

b) infection fatality rates from Covid were known to be very low in the younger age groups, having being calculated at: 0.0003% for 0-19 years and 0.003% at 20-29 years as determined by analysing 31 national seroprevalence studies in the pre-Approvals period.

(see particulars)

14 the increased risk of myocarditis following Covid vaccination in adolescents who have reached puberty is acceptable;

15 long-term safety data on Vaccines is not necessary because most serious adverse events occur within six weeks after vaccination;

16 the large number of vaccinations administered globally is evidence of the safety of the Vaccine;

17 there has been no increase in excess deaths or disease globally since the Vaccines were first approved for use in December 2020;

18 it is not possible to obtain long-term safety data of a vaccine without approving the use of, then administering the vaccine to the public;

19 delaying the approval and administration of the Vaccines in order to establish their long-term safety, would have caused more hospitalisations and deaths from COVID.

Particulars

Skerritt expressly stated as follows at a public Press Conference:

“I just want to remind people of the importance of vaccination of children. Because there's been a lot of talk saying, "Well kids don't get very sick with COVID, you know, why are we exposing them unnecessarily?" While the numbers are still being reviewed because of things like Coroner's post-mortems, we believe in Australia there have been at least six deaths of children with COVID. A number more hospitalisations, and now somewhere between 150,000 and 200,000 children under ten have caught COVID in Australia. So that's a very significant impact. And also the impact of transmission to parents and grandparents and so forth.”

“Finally I just want to mention two things. Firstly, the importance of keeping up to date with that third vaccination, particularly with Omicron. And a lot of people sadly in Australia we’ve now had more than 2 million people this year who have caught COVID and again, heading to 2.7 million overall. And we’re concerned that many Australians are not taking up the opportunity to

have that third dose of vaccine despite overwhelming evidence that it does significantly reduce the risk of serious infection."

"The message is, you can have your booster shot or your third shot as we call it, as soon as you recover from COVID. And we certainly encourage people to have it within 4 months of recovering from COVID because any additional immunity you might get from having caught COVID does wear off. So the message is, if you've had COVID, don't lull yourself into a false sense of security. That third dose is important. Have it as soon as you recover."

"Now of course in Australia there's been quite significant experience with 12-17s. We've had over three and a half million doses and of the Pfizer we've already had about 1.1 going to 1.2 million doses in the under 12s. The safety record of both the mRNA vaccines is quite impressive. Of course there's short term reactions and some kids end up having to you know, go to bed early or have a sore arm or a headache, or feel a bit of muscle pain. But the bottom line is that those effects are generally short-term and self-limiting."

"We know that there's been a very rare syndrome called myocarditis, an inflammation of the heart in older teenagers and young adults. Even in the older teenagers and young adults it's quite rare. You know, you're looking at 3, 4, 5, for any age of cases per hundred thousand. And even for boys for the second dose it's 10-13 per hundred thousand so it's still very rare. You've got to be very unlucky. One-in-ten, one-in-twenty thousand if you've presented a different way"

"The really encouraging message is that in Australia, we have no reports, that have been confirmed from our analysis, of myocarditis in children under 12."

"And the Americans who started the rollout of the paediatric vaccines in mid-November [2021], when they did an aggregate analysis of their data, they have had a few reports but it's like one in a million. And we think – the hypothesis is it may be associated with puberty and sex hormones. And so, the safety profile of the vaccines, while impressive overall, is even more impressive for children pre-puberty…We have tremendous experience now both here and globally and we can be very reassured."

Skerritt in response to media question regarding parental concern about lack of long-term safety data: “On longer term safety data, I think it’s important to emphasize two things. Firstly, if rare but serious adverse events occur with vaccines, and this is almost a statement for every single vaccine. They tend to appear within 1-2, to 5-6 weeks after vaccination. That’s different from medicines because remember with a vaccine you have a single one, two or three shots, whereas medicine you take it every day, many of them and it could be a cumulative effect. We now have had vaccinations in this country for over a year. We celebrated the first anniversary of that earlier this week. And we’ve had vaccinations globally since late 2020. And indeed I think we’ve crossed 11 billion shots globally, maybe heading towards 12. That’s one of the largest datasets-to sound like a scientist- on safety that we’ve ever had on any vaccine.”

“We know that there’s [sic] some rare things, like the rare clotting syndrome with AstraZeneca, like the rare, but in Australia certainly and in the US, non-fatal myocarditis syndrome. I think that’s a very commanding dataset when you’ve had more than ten billion doses, heading towards 12 billion doses. So I do push back when people say “Look we need five years of experience” because the other thing, it’s a bit counterintuitive. How do you get five years of experience if you’re not rolling out a vaccine?”

“We would have been in a lot worse place if we’d said “Well we’ve got COVID. We’ve got these vaccines but we’re not going to use them for another few years.”
https://www.youtube.com/watch?v=QePNjVgzYZI

AusVaxSafety Vaccines adverse events data is reported in https://ausvaxsafety.org.au/vaccine-safety-data/covid-19-vaccines

DAEN Vaccines adverse events data is reported in
https://daen.tga.gov.au/medicines-search/

WHO COVID-19 natural immunity Scientific Brief dated 24 April 2020
https://www.who.int/publications/i/item/WHO-2019-nCoV-Sci_Brief-Natural_immunity-2021.1

The known published myocarditis study referred to is:

> "Myocarditis after Covid-19 Vaccination in a Large Health Care Organization", Witberg et al. N Enjl J Med Dec 2021: 385:2132-2139.
> https://pubmed.ncbi.nlm.nih.gov/34614329/

A summary and meta-analysis of many known pre-Approvals seroprevalence studies confirming the true infection fatality rate of Covid known to the Respondents is:

> "Age-stratified infection fatality rate of COVID-19 in the non-elderly informed from pre-vaccination national seroprevalence studies" Pezzullo et al, posted 13 Oct 2022
>
> https://pubmed.ncbi.nlm.nih.gov/36341800/

m) on 1 April, 2022 Skerritt stated that:

1 the lipid nanoparticles in the Vaccines did not require genotoxicity and carcinogenicity studies to be conducted because they were below the internationally recognised thresholds that would require such studies;

(1) the above statements being made in circumstances of the facts known at that time to the Respondents that:

a) pg. 17 of the TGA's own Pfizer Non-Clinical Evaluation Report states that two of the four lipids used in the vaccine are "novel";

b) the WHO guidelines on the nonclinical evaluation of vaccines adjuvants and adjuvanted vaccines states on page 85 that a standard battery of genotoxicity studies is generally recommended for most novel adjuvants that are (or contain) new chemical entities.

(see particulars)

2 the lipid nanoparticles in the Vaccines are distributed throughout the body similar to the lipids from an ingested sausage or steak;

3 the lipid nanoparticles are destroyed from the body rapidly;

(1) the above statements being made in circumstances of the facts known at that time to the Respondents that that:

a) the statement is contrary to the results reported on page 45 of the TGA's own Pfizer Non-Clinical Evaluation Report which disclosed that:

i) the lipids increased steadily in concentration in both the ovaries and testes following vaccination for a period of 48 hours; and

ii) testing was concluded at 48 hours whilst lipid concentrations were increasing and it thereby remained unknown as to the quantum of lipid concentration after that time.

4 there is no evidence that the lipid nanoparticle causes ill effects throughout the body;

5 adverse events are only those that are recognised to be adverse events following assessment of all adverse event reports by global regulators that are then included in the Product Information of the Vaccine;

(1) the above statements being made in circumstances of the facts known at that time to the Respondents that:

a) the provisional approval of the Vaccines and the ongoing Phase III clinical trial required continued

analysis of adverse events following administration to the public;

b) the novel nature of the vaccine precluded the exclusion of unrecognised adverse events from being thoroughly investigated;

c) the statement is contrary to a proper determination of causality of temporally associated reported adverse events to which the Respondents were bound, being:

i) the Naranjo Scale; and

ii) WHO Causality Assessment for Adverse Events.

6 there were not 118,000 known adverse events associated with the mRNA Vaccines that were reported to the TGA at that time;

(1) the above statement being made in circumstances of the facts known at that time to the Respondents that:

a) the DAEN in fact recorded approximately 118,000 adverse events recorded as associated with the mRNA Vaccines;

7 the lipid nanoparticles in the Vaccine are safe for use in all people;

8 the lipid nanoparticles in the Vaccine do not cause any side effects;

9 the lipid nanoparticles in the Vaccine do not pose any greater risk to the body than dietary lipids;

10 all medicines distributed around the body are rapidly broken down;

11 2 million Australian people would have died or been hospitalised if the Vaccines were delayed by 2 years in order to conduct a proper safety review of the Vaccines;

12 the safety risk of the COVID virus to the public was so large that it was not necessary to conduct proper quality assurance on the Vaccines prior to approval;

(1) the above statements being made in circumstances of the facts known at that time to the Respondents that:

a) seroprevalence studies confirmed that across entire populations including the elderly:

i) that the mean infection fatality rate from Covid infection was never higher than:

1. 0.002 across all age groups; and

2. 0.0004 under the age of 70 years old, wherein approximately 89% of the population was known by the Respondents to be below 70 years old;

(see particulars)

b) the claims of enormity of the Covid threat and millions dying from Covid infection were known exponentially inflated falsehoods.

13 modification of the Virus spike protein in the Vaccines did not produce a functional change in the protein, immunogenicity or behaviour of the spike protein;

(1) the above statements being made in circumstances of the facts known at that time to the Respondents that the spike protein as modified in the Vaccines in fact:

a) was modified by the Sponsors for the express purpose of improving its functioning to avoid the innate immune system and increase stability;

b) was produced by the Vaccines in a significantly higher quantity, the limit of which remains unknown, than the Virus;

14 adverse events following vaccination with a Vaccine are only those that are listed within the Product Information for that Vaccine;

(1) the above statement being made in circumstances of the facts known at that time to the Respondents that not every serious adverse event that occurred in the Phase III clinical trials for the Vaccines were included in the Product Information for the Vaccines;

15 a safety signal is not necessarily raised when numerous reports of the same adverse event have been reported to the TGA following vaccination with the Vaccines;

(1) the above statements being made in circumstances of the facts known at that time to the Respondents that:

a) an ongoing Phase III clinical trial of a novel vaccine such as the Vaccines requires additional pharmacovigilance to be conducted in order to:

i) assess the risk of occurrence of rare or delayed onset adverse reactions;

ii) detect occurrence of auto-immune diseases and immune-mediated reactions; and

iii) to investigate clusters of reported adverse events/reactions including investigation as a safety signal numerous

reports of the same adverse event occurring following vaccination with the Vaccines;

b) the TGA Safety Alert Policy to which the TGA was bound expressly states that safety alerts are triggered by any potential safety problem linked to a medicine including:

i) known safety problems;

ii) changes in the reporting pattern of known problems; and

iii) new problems and coincidental events.

Particulars

Skerritt expressly stated as follows as reported –

"So the dose of the lipids in the vaccine is below the threshold that internationally is assessed for genotoxicity and carcinogenicity"

Skerritt expressly stated in respect of the lipid nanoparticles in the vaccines: "And they are distributed throughout arranged parts of the body as are lipids if you have a sausage or a steak for breakfast. And the lipids are hydrolyzed, destroyed by the body fairly rapidly as are dietary lipids."

Skerritt expressly stated in respect of whether the lipid nanoparticle can leave the injection site "They can go around the body but with no evidence of any ill effects."

Skerritt expressly stated in respect of whether the lipid nanoparticles carrying mRNA to the heart could induce the immune system to start attacking heart muscles "There is some evidence that the rare situation of myocarditis, a known adverse effect. Rare but known, does have a potential basis in an immune reaction affecting the

heart. And we do know that any medicine is distributed around the body but then rapidly broken down. So there's still a lot of both fundamental and clinical research going on to look at the mechanism of myocarditis in response to the messenger RNA vaccines. But one of the other questions of course, with anything that is rare is why do those individuals have that event? Why is it more prevalent with particular ages? You know, for example, young children seem to have extremely low cases of myocarditis, there seems to be a peak around in young men and older adolescents. So there might be a testosterone relationship as a male thing. So all that research is actively underway both clinical and-"

Skerritt expressly stated in respect of why this research hadn't been conducted prior to the vaccine approval: "Well senator, if you'd wanted a couple of million people in Australia potentially hospitalised and killed from Covid, you could have had that because this research takes a couple of years to do. In order to understand these things, it would have been another year or two or three until these vaccines would have been released and I think Professor Kelly quite eloquently described the impact of vaccines in this country. And so there is always going to be research on issues that emerge."

Skerritt expressly stated in respect of the separate issues of risk of COVID-19 and risk of COVID-19 vaccines and whether quality assurance needed to be complied with: "No the two are totally connected, Senator."

Skerritt expressly stated in respect of what changes the proline insertions make to the actual spike protein: "We believe there's not a functional change as far as immunogenicity and as far as behaviour."

Skerritt expressly stated in respect of the safety signal that is raised by 118,000 reported adverse events in Australia: "No this is a range of adverse - we've talked before about the difference between an adverse event report and a known adverse event agreed in the product information. There are certainly an order of magnitude fewer

adverse events that are acknowledged in the product information. They are those that are recognised to be adverse events following assessment of all those reports by global regulators. So there's not 118,000 known adverse events to messenger RNA vaccines.
https://www.youtube.com/watch?v=-JJDBfX4U-Q&t=46s

WHO Annex 2 - Guidelines on the nonclinical evaluation of vaccine adjuvants and adjuvanted vaccines - page 85
https://cdn.who.int/media/docs/default-source/biologicals/vaccine-standardization/trs_987_annex2.pdf?sfvrsn=ea91caca_3&download=true

Ioannidis, J "Global perspective of COVID-19 epidemiology for a full-cycle pandemic". European Journal of Clinical Investigation. Dec 2020, Vol 50, Issue 12
https://onlinelibrary.wiley.com/doi/10.1111/eci.13423

ABS – Australian Population by age and sex – national Summary statistics of Australia's population by age and sex – September, 2022
https://www.abs.gov.au/statistics/people/population/national-state-and-territory-population/sep-2022

n) on 16 February, 2023 Skerritt stated that:

1 heart attacks are not an adverse event related to the Vaccines.

(1) the above statements being made in circumstances of the facts known at that time to the Respondents that:

a) it is not appropriate for an ongoing Phase III clinical trial to rule out adverse event reports as causal on the basis that they are not already known adverse events of any of the Vaccines;

b) an ongoing Phase III clinical trial necessitates that all unexpected adverse events be reviewed;

c) the Vaccine Safety Investigation Group (VSIG) guidelines require unexpected serious adverse events to be referred to VSIG for further independent investigation.

2 the TGA was unable to obtain sufficient information on two reported cases of children dying directly following vaccination to assess whether their deaths were related to an adverse event of the Vaccines;

(1) the above statements being made in circumstances of the facts known at that time to the Respondents that:

a) the TGA in the significant majority of cases has not followed-up or sought additional information from injured persons in respect of reported adverse events associated with the Vaccines;

b) the further information being sought by the Respondents in the reported deaths has been for the purposes of seeking to dismiss Vaccines causality:

i) by establishing an alternative plausible causal event;

ii) which the Respondents have never established including in every death dismissed as not having “established causality” with the Vaccines;

c) the temporal association of the death with the Vaccines by all proper standards makes the deaths at least possibly causal:

i) until the Respondents establish an alternative plausible causal event;

ii) which the Respondents failed to establish;

d) the statement misleads the publishee to consider that because the Respondents have not definitively established causality in the deaths, that the deaths are thereby without more, not causal, which is a complete inversion of true and proper causality methodology including the universally recognised:

i) Naranjo Scale;

ii) WHO Causality Assessment for Adverse Events; and

iii) Bradford-Hill Criteria.

3 heart attacks are different to myocardial infarction;

(1) the above statements being made in circumstances of the facts known at that time to the Respondents that heart attack is a commonly used term to describe myocardial infarction, including by medical professionals;

4 the documents on the deaths of the seven year old and nine year old children obtained by a Freedom of Information Request 3727, appearing to show~~ing~~ causality between the children's deaths and vaccination with the Vaccines, did not reasonably indicate on their face an assessment of causality ~~were wrong~~;

5 each of the deaths of the seven and nine year old following vaccination were ~~reviewed by three doctors including a senior doctor and~~ subsequently determined to not be associated with vaccination by the Vaccines;

(1) the above statements being made in circumstances of the facts known at that time to the Respondents that:

a) the documents appeared on their face to indicate a determination of causality;

b) the Respondents ongoing failure or refusal to finally "determine causality":

i) is not and cannot be by any measure described as a determination that the event was not causally related to the Vaccines;

ii) in fact indicates the opposite according to internationally accepted standards of causality – that the deaths were more likely than not causally related to the Vaccines due to the utter absence of any alternative plausible explanation.

iii) the deaths were not properly referred to VSIG for independent determination.

6 myocarditis associated with the Vaccines is much milder than myocarditis after Covid infection or other forms of viral myocarditis;

(1) the above statement being made in circumstances of the facts known at that time to the Respondents that:

a) the ATAGI guideline on myocarditis and pericarditis contradicts this assertion;

b) the TGA produced Australian Product Information for the Comirnaty Original/Omicron BA.1 COVID-19 VACCINE "Tozinameran", released on 1 November, 2022, states that the "Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general";

7 saying myocarditis leads to cardiac arrest is misleading;

(1) the above statements being made in circumstances of the facts known at that time to the Respondents that it is scientifically known and established that:

a) myocarditis can lead to sudden cardiac arrest and death;

b) accounts for approximately 10% of deaths from sudden cardiac death in young individuals aged under 35 years;

(see particulars)

8 the Administrative Appeals Tribunal has confirmed that not publishing the documents in the FOI request 3727 detailing the adverse event reports for the seven and nine year old who died following vaccination with the Vaccines was appropriate;

(1) the above statement being made in circumstances of the facts known at that time to the Respondents that:

a) the Administrative Appeals Tribunal gave no such confirmation and the statement is false;

b) the judicial hearing in fact determined the AAT had no jurisdiction to force the TGA to publish the documents publicly;

c) the AAT at no time drew the conclusion that the TGA not publishing FOI request 3727 was appropriate;

d) the statement misleadingly seeks to support the Respondents' decision to withhold the documents evidencing the Respondents' causality assessments in relation to the reported deaths in young people from the Vaccines from the TGA Public FOI Disclosure Log;

e) the Respondents in fact did withhold those documents from the TGA Public FOI Disclosure Log because:

i) they had determined that disclosure of the documents could undermine public confidence and reduce the willingness of the public to report adverse events to the TGA;

ii) in fact the Respondents unilaterally determined that maintaining public confidence in receiving the Vaccines was a greater priority than disclosing details of causality relating to deaths from the Vaccines in children and young adults.

9 that the TGA did not feel that it is in the public interest for the public to know about deaths of children following vaccination due to a condition of cardiac arrest following vaccination as the condition hadn't already been recognised elsewhere in the world;

(1) the above statement being made in circumstances of the facts known at that time to the Respondents that Cardiac Arrest is in fact reported by Pfizer as an adverse event of special interest following the Pfizer Vaccine as follows:

a) as from 28 February, 2021 in the Pfizer Post-Marketing Data known to the TGA, pg. 30;

b) as from 19 August, 2021 in the Pfizer PSUR at pg. 127, 164, 171, 181, 196, 198, 200, 202, 204, 205.

c) as from 29 January, 2021, cardiac arrest (acute myocardial infarction) being defined as adverse events of special interest in the US Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19, at pg. 3, 5 (Table 1), 12 (Table 3), 15, 21 (Table 4.3), 30.

(see particulars)

10 the spike protein in the Vaccines does not cause myocarditis in children;

(1) the above statement being made in circumstances of the facts known at that time to the Respondents that the aetiology of confirmed myocarditis following vaccination with the Vaccines is presently unknown;

11 since the beginning of the COVID pandemic, more than 10 times as many people have died from paracetamol, as from adverse events due to COVID vaccines;

(1) the above statement being made in circumstances of the facts known at that time to the Respondents that at the time these statements:

a) the total number of reported deaths for all 202 paracetamol containing products dating back to 1 January, 1971 (more than 50 years prior) was 81;
b) the total number of reported deaths for the Vaccines dating back to the date of the first Vaccines being administered on 22 February, 2021 was 978;

12 the Vaccines have an impact on transmission of Covid;

(1) the above statement being made in circumstances of the facts known at that time to the Respondents that:

a) reduction of transmission is not an approved indication of the Vaccines on the Product Information;

b) the effect of the vaccines on transmission of COVID was not investigated by the sponsors;

c) the Respondents were not provided data that showed the Vaccines prevented transmission;

d) the Respondents do not know if the Vaccines prevent transmission of the Virus;

13 the lipid nanoparticles in the Vaccines do not increase in other organs of the body because they get broken up by the body;

(1) the above statement being made in circumstances of the facts known at that time to the Respondents that the metabolic studies conducted on the Vaccines did not demonstrate any breakdown of the lipid nanoparticles to the completion of the animal trials;

14 it is not unusual for a seven or nine year old to suffer a heart attack coincidentally directly following vaccination;

15 it is not uncommon for a seven or nine year old to die of cardiac arrest;

16 every death that occurs as a result of vaccination is announced to the Australian public by the TGA;

17 the deaths of the seven and nine year old following vaccination were not referred by the TGA to another authority for assessment.

(1) the above statement being made in circumstances of the facts known at that time to the Respondents that per the VSIG guideline whilst the Respondents can make a causality assessment:

a) they must refer all unexpected serious adverse events following vaccination to VSIG, who can make an independent causality assessment;

b) VSIG review must be conducted without TGA staff present to avoid conflicts;

18 the word causality next to the word decision on an adverse event report does not indicate causality;

(1) the above statement being made in circumstances of the facts known at that time to the Respondents that the statement is self-evidently contradictory;

19 actuaries have determined the Vaccines are not related to the 16% increase in excess deaths from 1 January, 2022 to 30 September, 2022;

(1) the above statement being made in circumstances of the facts known at that time to the Respondents that the actuaries statements on the excess death figures dated 18 October, 2022, referred to by Skerritt use the Respondents own assertion of only 14 deaths being causally related to the Vaccines as proof that excess deaths are not related to the Vaccines and therefore have not conducted any further, independent analysis as to whether the Vaccines are in fact related to the excess deaths;

20 adverse events other than those listed on the Product Information of the vaccines do not occur;

21 it is not in the public interest to know about rare or new adverse events following vaccination with the Vaccines;

22 paracetamol is more dangerous than the Vaccines;

23 the Vaccines will reduce the transmission of COVID;

24 the lipid nanoparticles do not remain in the body because they are broken down by the body.

Particulars

Skerritt expressly stated as follows as reported –

Skerritt expressly stated in respect of when it first came to the attention of the TGA that two Australian children, one aged seven and one aged nine years of age, died of cardiac arrests directly after receiving a COVID

vaccination: “So these two reports were received in our database of adverse event notifications. Unfortunately, we were unable to get sufficient information on these particular cases to assess them in detail, but the information we did have is that they were associated with heart attack, which is not a known adverse event of any of the COVID vaccines.”

Skerritt expressly stated in respect of whether the known adverse event of myocarditis leads to heart attack: “Some people with myocarditis do have an increased propensity for heart attack, but they are different from a myocardial infarction.”

Skerritt expressly stated in respect of the file notes obtained by Freedom of Information Request 3727 showing causality for both the seven and nine year old who suffered heart attacks shortly after vaccination and died: “No, that is incorrect. If they are as a result of vaccination, we would have put out an announcement. They were not concluded to be associated with it.”

Skerritt expressly stated in respect of whether the deaths of the seven and nine year old children following vaccination with the Vaccine was relayed to ATAGI at any time thereafter: “It's the TGA's responsibility, again using an external vaccine safety investigation group, to determine causality. The external group is when there is questions around the case. As we've indicated in this place before, each of these were looked at by three separate doctors, including a senior doctor, as you'll see from a redaction—the letters 'MO' mean medical officer. This is someone who is trained and registered in Australia. They reviewed each of these. They were not seen as being associated with vaccination. That is incorrect.”

Skerritt expressly stated in respect of information uncovered in Freedom of Information Request 3727 that revealed the TGA had assessed as causally linked to COVID Vaccine deaths that are not included in the 14 acknowledged deaths from the Vaccines: “And it's absolutely false. Go and read the freedom of information and see what it actually says. We have reported every death that has been associated with these vaccines. Why on earth would we hide a seven- and a nine-year-old?”

Skerritt expressly stated in respect of the meaning of the statement “causality” on the FOI reports when others say “awaiting causality”, some

say “not causality”: “Senator, causality is a heading. That is what I was trying to explain. It's the way it's used on the form. You have a decision. Let's use the example that you've quoted at me. I have the form in my hand. It says causality. In the next dot point under causality, it says WHO, unable to be determined, unclassifiable because of a lack of information. Causality is the heading. It's not the conclusion.”

Skerritt expressly stated in respect of the meaning of it actually saying ‘decision, causality’: “It says decisions, dot point 1. I can table this for the chair. I have the document in front of me. It says, 'Decisions, dot point 1, causality, then WHO, unclassifiable, unable to be determined.' That is what it says in black and white.”

Skerritt expressly stated in respect of whether myocarditis leads to cardiac arrest: “Not usually. There are cases where people who have had myocarditis have an increased prevalence of a range of other cardiac conditions. But to say that it leads to cardiac arrest is misleading, especially given that most myocarditis associated with vaccination—indeed, there's a recent publication in a top medical journal by Nordic scientists—is much milder than myocarditis after COVID infection or other forms of viral myocarditis.”

Skerritt expressly stated in respect of whether Professor Skerritt would resolve the issue relating to FOI request 3727 by providing an unredacted copy of the document: “Senator, I believe that we cannot, for reasons of personal privacy. I understand that this issue has been to the Administrative Appeals Tribunal and that the Administrative Appeals Tribunal also confirmed that the documentation released was appropriate.”

Skerritt expressly stated in respect of why all causes of mortality increased by 16% after the pandemic and after mass indiscriminate vaccination: “That figure has been looked at closely by the actuaries. They ascertain about half of it to COVID infection related effects. They ascertain the rest to other effects such as, I think we said earlier this morning, cardiac disease or perhaps oncology if people during the peak of the pandemic didn't go to their GPs early enough for a possible bump and it has turned out to be a stage 4 cancer and, therefore, unfortunately led to death. If you don't have access to those statements from the actuary society, we're happy to provide

them on notice. Actuaries are the professionals who work out the likelihood, probability and causality for things like deaths. They have closely looked at these figures."

Skerritt expressly stated in respect of whether the TGA, through Skerritt, felt any obligation to inform the public after reports of two Australian children aged seven and nine died from cardiac arrest following vaccination with the Vaccines: "We do not feel that it's appropriate to inform the public when we have a report with a condition that exists nowhere else in the world."

Skerritt expressly stated in respect of what causes the myocarditis in children: "It's not the spike protein".

"We have modern medicines, and every medicine has risks as well as benefits. By way of indication: since the beginning of the COVID pandemic, more than 10 times as many people have died from paracetamol, from Panadol, as from adverse events due to COVID vaccines".

"First of all, there are impacts on transmission. The impact on transmission of Omicron is much lower than the impact on transmission of Delta and so forth."
Skerritt expressly stated in respect of the lipid nanoparticles increasing in concentration in organs in the body following vaccination – "these lipids decrease because they get broken up by the body"

Community Affairs Legislation Committee – 16 February, 2023.
Estimates – Health and Aged Care Portfolio.
https://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;adv=yes;orderBy=customrank;page=0;query=community%20affairs%20Dataset:estimate;rec=1;resCount=Default

Pfizer Document 28 February, 2021 - BNT162b2 5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports CONFIDENTIAL 5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021 **("the Pfizer Post-Authorisation Report")**
https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf

PERIODIC SAFETY UPDATE REPORT #1
For ACTIVE SUBSTANCE: COVID-19 mRNA vaccine (nucleoside modified) (BNT162b2). INTERNATIONAL BIRTH DATE (IBD)2 : 19 DECEMBER 2020 EUROPEAN UNION REFERENCE DATE (EURO): 19 DECEMBER 2020 INTERVAL COVERED BY THIS REPORT: 19 DECEMBER 2020 through 18 JUNE 2021 DATE OF THIS REPORT: 19 AUGUST 2021 **("the Pfizer PSUR")**

Vaccine Adverse Event Reporting System (VAERS)
Standard Operating Procedures for COVID-19 (as of 29 January 2021) **("VAERS Definitions Document")**
https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf

Excess Mortality in Australia By Karen Cutter, Jennifer Lang and Richard Lyon
COVID-19 Actuaries Response Group, dated 18 October, 2022, pg. 7.
https://covidactuaries.org/wp-content/uploads/2022/10/ARG-Excess-Mortality-in-Australia-1.pdf

~~213. The Skerritt Misleading Vaccines Statements were:~~

~~a) made publicly on widely available media;~~

~~b) expressly or alternatively, by reasonable inference from the express words spoken;~~

~~c) for the purpose of:~~

~~1 informing the Australian public as to the Vaccines':~~

~~(1) safety;~~

~~(2) efficacy;~~

~~(3) risk-benefit profile;~~

~~2 causing the Australian public to rely upon those statements as true;~~

3 inducing the Australian public to take the Vaccines;

d) in circumstances where in truth the publishee would infer that Skerritt had direct personal knowledge of the veracity of those statements;

e) the statements were:

1 untrue; and

2 misleading to the Australian public;

f) Skerritt knew that the statements were untrue; and

g) further or alternatively, was recklessly indifferent as to the statements veracity or otherwise;

h) without proper evidence to support the assertions;

i) without proper analysis to support the assertions;

j) without reasonable or diligent effort to ascertain true and relevant:

1 data;
2 analysis;
3 conclusion;
4 false interpretation of data.

Particulars

The Skerritt Misleading Vaccines Statements were untrue and known by Skerritt to be untrue in the circumstances of the following factual matters known to Skerritt at the time the Skerritt Misleading Vaccines Statements made:

1. The circumstances pleaded in the Skerritt Misleading Vaccines Statements

~~2. The factual matters going to the conduct, circumstances and knowledge of Skerritt at the time of the Skerritt Misleading Vaccines Statements pleaded at paragraphs 65 to 211 herein.~~

SECRETARY

214. The Secretary made the following public statements expressly or by reasonable inference **("the Secretary Misleading Vaccines Statements")**:

a) on 3 February, 2021 the Secretary stated that:

1 there was no evidence whatsoever that any of the Vaccines:

(1) are dangerous; or

(2) could kill the recipient.

2 the Vaccines are all extremely carefully tested by the TGA;

3 the Vaccines are exponentially more safe and effective than the annual flu vaccines;

4 the risks associated with contracting Covid are exponentially greater than the risks of using the Vaccines;

5 the Vaccines all had or would be subjected to the full regulatory safety and efficacy assessment before approval for use by the public;

6 there is no risk in using the Vaccines;

7 the Vaccines had been or would be subject to the fullest extent of safety and efficacy testing possible before release to the public.

Particulars

ABC Interview

https://www.abc.net.au/7.30/dr-brendan-murphy-answers-questions-about-the/13119036

b) on 7 March, 2021, the Secretary stated that:

1 he has the highest confidence and trust in the Vaccines;

2 the Vaccines are effective;

3 every single Australia should go and be injected with one of the Vaccines as soon as it is possible to do so;

4 the safety and efficacy of the Vaccines are beyond question for use by every single Australian without any other relevant consideration; and

5 the Secretary had personal knowledge of the veracity of these matters.

Particulars

The Secretary expressly stated at a Media Doorstop Interview that:

"I'm really excited to be here to receive this vaccine. I know that people listened to me a lot in the early stages of the pandemic, and I want you to listen to me again when I say that I really, really trust these vaccines – both of them. They both work, and you need to go out there when it's your turn and get them."
https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/doorstop-interview-about-the-vaccine-rollout-and-vaccine-safety.

c) on 10 November, 2022, the Secretary publicly stated that:

1 the spike protein produced by the Vaccines does not cause damage in any location throughout the body;

2 the spike protein produced by the Vaccines does not cause blood

clots;

3 there is no evidence of adverse events caused by the Vaccines;

4 the Vaccines are safe;

5 the Vaccines are effective.

Particulars

Community Affairs Legislation Committee - 10 November, 2022

The Secretary expressly stated in respect of whether the spike protein, which has never been tested, could potentially cause other issues elsewhere in the body, for example blood clots, that:

"If that were the case, Senator, with many billions of doses given, we would have very good evidence of those adverse effects. And we don't have that".

The Secretary expressly stated in respect of whether it is still the department's position that the Covid mRNA Vaccines are safe and effective:

"Yes"

~~215. The Secretary Misleading Vaccines Statements were:~~

~~a) made publicly on widely available media;~~

~~b) expressly or alternatively, by reasonable inference from the express words spoken;~~

~~c) for the purpose of:~~

~~1 informing the Australian public as to the Vaccines':~~

~~(1) safety;~~

(2) efficacy;

(3) risk-benefit profile;

2 causing the Australian public to rely upon those statements as true;

3 inducing the Australian public to take the Vaccines;

d) in circumstances where in truth the publishee would infer that the Secretary had direct personal knowledge of the veracity of those statements;

e) the statements were:

1 untrue; and

2 misleading to the Australian public;

f) the Secretary knew that the statements were untrue; and

g) further or alternatively, was recklessly indifferent as to the statements veracity or otherwise;

h) without proper evidence to support the assertions;

i) without proper analysis to support the assertions;

j) without reasonable or diligent effort to ascertain true and relevant:

1 data;

2 analysis

3 conclusion

4 false interpretation of data.

~~**Particulars**~~

~~The Secretary Misleading Vaccines Statements were untrue and known by the Secretary to be untrue in the circumstances of the following factual matters known to Secretary at the time the Secretary Misleading Vaccines Statements made:~~

~~1. The circumstances pleaded in the Secretary Misleading Vaccines Statements~~

~~2. The factual matters going to the conduct, circumstances and knowledge of the Secretary at the time of the Secretary Misleading Vaccines Statements pleaded at paragraphs 65 to 211 herein.~~

TGA

216. The Respondents made the following public statements through employees and officers of the TGA expressly or by reasonable inference **("the TGA Misleading Vaccines Statements")**:

a) on 27 May, 2021, in a published document entitled "COVID-19 vaccine weekly safety report" on the TGA website that:

1 if a medicine or vaccine is approved for use by the TGA including the Vaccines, it means that the benefits are considered to outweigh its risks, if used as authorised;

2 there are no specific safety concerns from use of the vaccines in older people;

3 there were no new safety signals in relation to COVID-19 vaccines at that time;

4 the Therapeutic Goods Administration (TGA) continues to review data from Australia and overseas relating to the safety and effectiveness of COVID-19 vaccines in older adults;

5 the TGA's monitoring had not detected any new safety signals in relation to COVID-19 vaccines at that time;

6 the TGA reviews all deaths reported after vaccination and monitors for safety signals. Part of this analysis includes comparing expected natural death rates to observed death rates following immunisation. To date, the observed number of deaths reported after vaccination was actually less than the expected number of deaths;

7 at that time, there was no indication that the reported cases of myocarditis and pericarditis were due to the Vaccine.

Particulars

TGA SAFETY REPORT – 27 May, 2021
https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-weekly-safety-report-27-05-2021

b) on 10 September, 2021 in a Media Release by the TGA titled "New restrictions on prescribing Ivermectin for COVID-19" stated:

~~1 Ivermectin does not protect individuals from COVID infection;~~

2 vaccination provides superior protection from COVID infection than Ivermectin;

3 taking Ivermectin for prevention of COVID is dangerous to the public;

4 people who take Ivermectin for prevention of COVID are more likely to not comply with public health directions at that time;

5 people who take Ivermectin for prevention of COVID are less likely to seek medical attention for symptoms of COVID;

6 taking Ivermectin for prevention of COVID increases the spread of COVID throughout the community.

Particulars

In a Media Release published on the TGA website titled "New restrictions on prescribing ivermectin for COVID-19, said: "there are a number of significant public health risks associated with taking ivermectin in an attempt to prevent COVID-19 infection rather than getting vaccinated. Individuals who believe that they are protected from infection by taking ivermectin may choose not to get tested or to seek medical care if they experience symptoms. Doing so has the potential to spread the risk of COVID-19 infection throughout the community.

https://www.tga.gov.au/news/media-releases/new-restrictions-prescribing-ivermectin-covid-19

c) on 16 September, 2021, in a published document entitled "COVID-19 vaccine weekly safety report -16-09-2021" on its website that:

1 vaccination against COVID-19 is the most effective way to reduce deaths and severe illness from infection;

2 being registered for use means that these Vaccines have met the TGA's high standards for quality, safety and effectiveness;

3 importantly, suspected adverse events reported to the TGA are often not caused by the vaccines;

4 the protective benefits of vaccination against COVID-19 far outweighs the potential risks of vaccination;

5 the increase in the number of vaccinated people has increased reporting of fatal events which:

(1) has a coincidental association with vaccination;

(2) does not indicate a link between vaccination and the fatalities reported.

6 review of individual reports and patterns of reporting does not suggest the Vaccines played a role in these deaths;

7 the most authoritative safety information on the COVID-19 vaccines is included in the Product Information (PI) and Consumer Medicine Information (CMI) which can be found on the TGA website;

8 following rigorous investigations by the TGA and other international drug regulators, a clear link between GBS and Vaxzevria (AstraZeneca) had not been established;

9 myocarditis and pericarditis can occur due to other causes, including common viral infections, so it is expected that many reported cases may not be related to vaccination;

10 myocarditis and pericarditis are much more common with COVID-19 infection and damage to the heart is frequently severe after infection;

11 ATAGI have emphasised that the protective benefits of the Pfizer Vaccine greatly outweigh the risk of these rare side effects.

Particulars

COVID-19 vaccine weekly safety report -16-09-2021
https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-weekly-safety-report-16-09-2021

d) on 10 November, 2021:

1 in response to the published factual allegations referred to in the British Medical Journal relating to Pfizer's phase 3 clinical trial of the Pfizer Vaccine that **("the Data Fraud Allegations")**:

(1) data was falsified;

(2) integrity of the data was corrupted;

(3) patients were unblinded in the midst of the trial;

(4) the vaccination staff were inadequately trained;

(5) protocol deviations were not reported;

(6) trial specimens were mis-labelled.

2 through their spokesperson in a published article the Respondents stated that **("the Reported Fraud Response Statements")**:

(1) TGA was seeking additional information from Pfizer in relation to the Data Fraud Allegations;

(2) notwithstanding the Data Fraud Allegations that:

a) the Pfizer Vaccine is highly safe and effective; and

b) Australians should not be concerned about the allegations of fraud and other matters raised in the Data Fraud Allegations;

c) the benefits of the Vaccines are:

i) clear; and

ii) not in dispute;

d) all eligible Australians who are not yet vaccinated should be vaccinated with one of the Vaccines as soon as possible.

e) given that the Data Fraud Allegations only pertain to 2 per cent of the trial population, the overall results are not expected to be impacted;

f) there is no possibility that the alleged fraud in the Data Fraud Allegations was occurring anywhere other than

the extent raised by the Ventavia employee;

g) fraud in the preparation of the clinical trial data of Pfizer upon which the TGA relied raised in the Data Fraud Allegations is not a cause for concern for those having taken or contemplating taking the Vaccines;

h) notwithstanding that the matters raised in the Data Fraud Allegations was still being investigated by the TGA, no person ought to be dissuaded or concerned in respect of taking or having taken any of the Vaccines.

3 the Reported Fraud Response Statements by the Respondents was made in circumstances where in truth:

(1) the Respondents had not received at the time of the statements any information as to the Data Fraud Allegations from Pfizer or the FDA;

(2) the Respondents had not at that time nor at any time since:

a) properly investigated the Data Fraud Allegations;

b) finally determined the veracity of the Data Fraud Allegations;

c) inspected the facility in question or the operations of that facility;

(3) the Data Fraud Allegations were known to have been supported by produced:

a) internal company documents;

b) photos;

c) audio recordings;

d) emails; and

e) the corroborating oral evidence of:

i) a high-level executive at the relevant facility;

ii) another two employees at the facility;

(4) the regulatory body the FDA had not at the time of the TGA's statements (or any time since) inspected the site notwithstanding a complaint having been made in respect of the Data Fraud Allegations over 1 year earlier on 25 September, 2020;

(5) the subsequent trial data including data to which the Data Fraud Allegations related were accepted by the TGA in approving the Pfizer Vaccines.

Particulars

The TGA through its spokesperson made the following express statements as published in the relevant article in news.com.au:

'TGA "Sought additional information from Pfizer."'

'"Australia's medicines regulator has sought additional information from Pfizer after an investigation by the British Medical Journal alleged serious issues with a small number of its vaccine safety trials, including claims of "falsified data" and slowness following up on adverse reactions.'

Spokesperson of the TGA stated:

'The Therapeutic Goods Administration (TGA) has stressed that Pfizer's vaccine is "highly safe and effective", and that Australians "should not be concerned about the issues raised in the article".

"The Pfizer Covid-19 vaccine is highly safe and effective and has been approved for use in nearly 100 countries and also approved by the World Health Organisation," a TGA spokeswoman said.

"Australians who have received the Pfizer vaccine should not be concerned about the issues raised in the BMJ article."

She noted that "the safety and efficacy of the Pfizer Covid-19 vaccine demonstrated in clinical trials has been thoroughly substantiated by real-world use in many millions of people worldwide".

"The benefits of vaccination are clear and not in dispute," she said. "All eligible Australians who are not yet vaccinated are strongly encouraged to get vaccinated as soon as possible."

"TGA has contacted Pfizer to further clarify the issues raised, although given the allegations only pertain to 2 per cent of the trial population, the overall results are not expected to be impacted."'
News.Com.Au Article – 10 November, 2021 - "TGA requests information from Pfizer after medical journal alleges contractor 'falsified' safety data"
https://www.news.com.au/technology/science/human-body/tga-requests-information-from-pfizer-after-medical-journal-alleges-contractor-falsified-safety-data/news-story/342806323e802035bb1d810e561977f4.

British Medical Journal
"BMJ Investigation - Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial".
BMJ 2021; 375 doi: (Published 02 November 2021)
https://www.bmj.com/content/375/bmj.n2635

e) on 5 December, 2021, the Respondents through the TGA website stated that:

1 in making the decision to approve the Pfizer Vaccine, the TGA carefully considered data from clinical trials conducted in the United

States, Finland, Poland and Spain which included participants 5 to 11 years of age and that the study demonstrated effectiveness by showing that the immune response to the vaccine in children was similar to that seen in older age groups;

2 clinical trials showed that the safety profile in children is similar to that seen in adults with the observed side effects being mild;

3 the people of Australia could be confident that the TGA's review process of the Pfizer Vaccine was rigorous and of the highest standard;

4 the decision to provisionally approve the Pfizer Vaccine was informed by expert advice from the Advisory Committee on Vaccines **("the ACV")**;

(1) the above statement being made in circumstances of the facts known at that time to the Respondents that:

a) the ACV was only providing advice to the TGA when asked by the TGA to do so;

b) no advice had been sought from the ACV by the TGA at that time:

i) in respect of the safety of the Pfizer Vaccine for use in the 5-11 years age group;

ii) in respect of adverse events arising by use of the Pfizer Vaccine:

1. causality assessment;

2. safety signals.

iii) not until the 29 September, 2021 did the ACV resolve with the TGA to implement a

pharmacovigilance plan to obtain background safety data and support a focused effort to access/obtain current Australian background rates for reported events wherein such data:

1. was and is essential to assessment of harm to the Australian public;

2. could have been obtained 12 months prior;

3. the TGA's own Safety Monitoring Plan produced in February 2021 had already proposed this measure; and

4. since June 2021 a detailed report reviewing background rates for European countries had already been produced.

Particulars

TGA Website – "COVID-19 vaccine: Pfizer Australia - COMIRNATY (tozinameran) (mRNA)" https://www.tga.gov.au/covid-19-vaccine-pfizer-australia-comirnaty-tozinameran-mrna

"COVID-19 vaccine safety monitoring plan" Australian Government Department of Health / TGA. Dated February, 2021.

"Background rates of Adverse Events of Special Interest for monitoring COVID-19 vaccines" Version 2.0 – dated June 30, 2021. Vaccine Covid-19 Monitoring Readiness; Willame, C.

f) on 27 August, 2021 the Respondents ~~stated~~ through the TGA website stated the following in respect of the Pfizer Vaccine:

1 safe for use by anyone over the age of 5 years;

2 so safe that severe adverse events or death would not occur in use of the Pfizer Vaccine;

3 effective to prevent the recipient of the Pfizer Vaccines from:

(1) being infected with Covid;

(2) suffering ill-effects from Covid.

Particulars

The TGA on its website expressly stated that - “Australians can be confident that the TGA's review process of this vaccine was rigorous and of the highest standard. The decision to provisionally approve the vaccine was also informed by expert advice from the Advisory Committee on Vaccines (ACV), an independent committee with expertise in scientific, medical and clinical fields including consumer representation”. https://www.tga.gov.au/news/media-releases/tga-provisionally-approves-pfizer-covid-19-vaccine

g) on 16 December, 2021, in a published document entitled “COVID-19 vaccine weekly safety report -16-21-2021” the Respondents stated through the TGA website that:

1 myocarditis:

(1) is usually temporary;

(2) from which most people are fully recovered within a few days;

Particulars

COVID-19 vaccine weekly safety report - 16-12-2021
https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-weekly-safety-report-16-12-2021

h) on 16 June, 2022, in a published document entitled "COVID-19 vaccine weekly safety report -16-06-2022" on its website that:

1 the TGA closely reviews all deaths reported in the days and weeks after COVID-19 vaccination;

2 there have been no deaths in children, adolescents or younger adults determined to be linked to COVID-19 vaccination;

3 the risk of myocarditis and other heart effects is much higher after COVID-19 infection than after COVID-19 vaccination;

4 myocarditis cases from the Vaccines:

(1) are often mild;

(2) usually resolve after a few days with treatment and rest;

Particulars

COVID-19 vaccine weekly safety report - 16-06-2022
https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-weekly-safety-report-16-06-2022

i) on 8 November, 2022, the Respondents in a published document entitled "Comirnaty original/Omicron BA.1 COVID-19 Vaccine" stated on the TGA Website that:

1 a booster dose of the Pfizer Bivalent Vaccine prevents COVID infection in individuals 18 years and older;

2 the Pfizer Bivalent Vaccine is safe and effective in individuals 18

years and older;

(1) the above statements were made in circumstances where in truth it was known to the Respondents at that time that:

a) the Pfizer Bivalent Vaccine approval was only based on 4 weeks of data in people aged 55 years and older;

b) there TGA Respondents were provided no efficacy or safety data conducted on people aged under 55 in respect of the Pfizer Bivalent Vaccine prior to approval;

c) the Pfizer Bivalent Vaccine was never tested for, purposed for or proven to prevent transmission of the Virus.

Particulars

The TGA on its website expressly stated that – "Comirnaty original/Omicron BA.1 vaccine has provisional approval for the indication below: As a booster dose for active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 18 years of age and older."

"The decision has been made on the basis of short-term immunogenicity and safety data. Continued approval depends on the evidence of longer term efficacy and safety from ongoing clinical trials and post-market assessment."

j) on 15 December, 2022, in a published document entitled "COVID-19 vaccine weekly safety report -15-12-2022" the Respondents stated through the TGA Website that:

1 most deaths that occur after vaccination are not caused by the

Vaccine;

2 the TGA had identified 14 reports where the cause of death was linked to vaccination from 952 reports received and reviewed;

a) the above statements being made in circumstances where in truth:

i) the TGA in their express wording, had not dismissed the other 938 reported deaths as not caused by the vaccine, rather that they had not been determined to be causally related to the vaccine;

1. the distinction being made possible in circumstances where in truth the TGA had not closed off their investigations for all the reported deaths allowing the continued assertion that they had not been "determined" to be causally related to the vaccines.

3 there have been no deaths in children or adolescents determined to be linked to COVID-19 vaccination;

4 myocarditis is often mild, and cases usually resolve after a few days with treatment and rest.

Particulars

COVID-19 vaccine weekly safety report -15-12-2022
https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-safety-report-15-12-2022

~~217. The TGA Misleading Vaccines Statements were:~~

a) made publicly on widely available media;

b) expressly or alternatively, by reasonable inference from the express words spoken;

c) for the purpose of:

1 informing the Australian public as to the Vaccines':

(1) safety;

(2) efficacy;

(3) risk-benefit profile;

2 causing the Australian public to rely upon those statements as true;

3 inducing the Australian public to take the Vaccines;

d) in circumstances where in truth the publishee would infer that the Respondents had direct personal knowledge of the veracity of those statements;

e) the statements were:

1 untrue; and

2 misleading to the Australian public;

f) the Respondents knew that the statements were untrue; and

g) further or alternatively, were recklessly indifferent as to the statements veracity or otherwise;

h) without proper evidence to support the assertions;

i) without proper analysis to support the assertions;

j) ~~without reasonable or diligent effort to ascertain true and relevant:~~

1 ~~data;~~

2 ~~analysis;~~

3 ~~conclusion;~~

4 ~~false interpretation of data.~~

~~Particulars~~

~~The TGA Misleading Vaccines Statements were untrue and known by the Respondents to be untrue in the circumstances of the following factual matters known to the Respondents at the time the TGA Misleading Vaccines Statements made:~~

~~1.The circumstances pleaded in the TGA Misleading Vaccines Statements.~~

~~2. The factual matters going to the conduct, circumstances and knowledge of Respondents at the time of the TGA Misleading Vaccines Statements pleaded at paragraphs 65 to 211 herein.~~

CHIEF MEDICAL OFFICER

218. The Chief Medical Officer made the following public statements expressly or by reasonable inference **("the Misleading Chief Medical Officer Vaccines Statements")**:

a) on 8 January, 2021, the Chief Medical Officer stated in an interview on ABC Breakfast News:

1 ~~the TGA's Approvals will not be an authority given under emergency use conditions;~~

2 the TGA's Approvals will be a full approval that thoroughly investigates all aspects of the Vaccines, including:

(1) effectiveness of the Vaccines;

(2) the safety profile of the Vaccines;

(3) the quality of the manufacturing of the Vaccines;

(4) side effects of the Vaccines;

3 the Vaccines would be fully assessed in the usual manner prior to approval;

4 vaccine safety was the first priority of the Australian Government.

Particulars

The Chief Medical Officer stated expressly that:

"So, we're in a very enviable position here in Australia. There's very few countries in the world that can afford to wait until full approval is given. At the moment, there is no full approval in the UK, the US, and other parts of the world for this vaccine. What's been given is emergency utilisation authority. That might just sound like a bunch of words, but it's actually really important. The full approval looks at everything - looks at the effectiveness of the vaccine; it looks at the safety profile of the vaccine' it looks at the quality of the manufacturing; and, that's what Australians should expect from any [audio skip] or vaccine that comes into Australia, and that's what we're doing in this case. Safety is our first priority and it then it has to have that tick before we go ahead."
https://www.health.gov.au/news/chief-medical-officer-professor-paul-kellys-interview-on-abc-news-breakfast-on-8-january-2021?language=en

b) on 8 January, 2021 the Chief Medical Officer stated in an interview on ABC

National Radio that:

1 the TGA will expedite the Vaccines approval but will not curtail the rigorous standards of approval in order to do so;

2 the number one priority of the Vaccines approval is to ensure their safety;

3 the TGA will not approve of any vaccine that has not been proven to be completely safe for use on the Australian public;

4 the TGA will guarantee the safety, efficacy and quality of any approved Vaccines.

Particulars

The Chief Medical Officer expressly stated the following:

In respect of how the TGA will give an approval earlier than initially expected: “They will expedite absolutely what they need to do but not cut any corners - number one priority is safety and so that will be done.”

In respect of whether it would be dangerous to bring forward testing of the Vaccine: “So, our regulators are absolutely there to make sure that that is not the case and that it is safe, it's effective and the quality of the vaccination is guaranteed - and that's what they've always been going to do.”
https://www.health.gov.au/news/chief-medical-officer-professor-paul-kellys-interview-on-abc-national-radio-on-8-january-2021?language=en

c) on 13 January, 2021 the Chief Medical Officer stated in an interview on Sky News Live, First Edition, that:

1 the AstraZeneca Vaccine prevents all deaths from Covid;

2 the AstraZeneca Vaccine prevents all severe illness from Covid;

3 the Pfizer Vaccine prevents all deaths from Covid;

4 the Pfizer Vaccine prevents all severe illness from Covid;

5 the only authority and source of reliable information on the safety and efficacy of the Vaccines are the Australian Government and the State and Territory Governments;

6 the medical advice conveyed by the Australian Government to the Australian people throughout the pandemic to date was flawless;

7 the TGA are the only authority who will advise on the safety, quality and efficacy of the Vaccines;

8 the Vaccines can assist to achieve zero community transmission of Covid;

Particulars

The Chief Medical Officer expressly stated the following:

In respect of the AstraZeneca Vaccine – “In terms of preventing death, it works, 100 per cent of the time. In terms of preventing severe illness, it works, 100 per cent of the time. That’s exactly the same as Pfizer on that interim information.”

In respect of whether Professor Kelly was worried about public confidence in the Vaccine given reports of low efficacy “I really call on the Australian public to trust the medical expertise as you've trusted it through the entire pandemic that we've had a for a year now. We haven't let you down. Please listen to the Australian Government and also to the state and territory governments.”

“And just to absolutely say that our TGA, our independent regulator, world-class regulator, will be central to this process and they will be the ones that will advise about those matters of safety, quality and efficacy of all of our vaccines.”

In respect of whether the Australian Government's strategy in dealing with Covid was a suppression strategy: "So, we have the national strategy of suppression leading to no community transmission. I can tell you we'd all be sleeping better at night if there was no community transmission. And that's our aim; that's been our aim for a long time, regardless of what certain people say in certain states, we are very together on that at the national level and that's our strategy. That's what we'll be doing. I'll say this about the vaccine. The vaccine is another tool in that strategy, as were the issues of the- the agreements that were made at National Cabinet with all the state premiers and chief ministers and the Prime Minister in the room making those decisions about strengthening our quarantine, strengthening our international arrivals, the pre-flight testing and so forth of people coming from overseas and the testing of air crew, use of masks on all planes and in all airports."
"The testing, tracing, isolation component is a tool; all of those personal behaviours is a tool; the vaccine is a tool. All of those things are what we need to really protect Australians and we're absolutely committed to continue to do that through 2021."

In respect of whether Professor Kelly was worried about potential misinformation being spread online – "this is the social media pandemic as much as a viral pandemic."

"But I would really say this, that you should consider what the medical advice from those trusted sources is, and that's the one I would really urge you to follow. So, we have- the Australian Government has a presence; the Department of Health has a presence on social media as well as other media channels. All states and territories are also putting out messages. These are the crucial ones to consider to keep us all safe."
https://www.health.gov.au/news/chief-medical-officer-professor-paul-kellys-interview-on-sky-news-live-first-edition-on-13-january-2021

d) on 25 June, 2021 the Chief Medical Officer stated in a radio interview on 3AW that:

1 the Vaccines will protect you against Covid;

2 the Vaccines will prevent community transmission.

Particulars

"So, you know, message to your audience, don't hesitate. If you are eligible to get the vaccine, get that booking and get that jab in your arm. That's the important thing for you, your family and the community."

https://www.health.gov.au/news/chief-medical-officer-professor-paul-kellys-interview-on-3aw-on-25-june-2021?language=en

e) on 7 December, 2021 the Chief Medical Officer stated that:

1 the Vaccine does and can affect transmission of the virus;

2 the Vaccine protects from severe illness from COVID infection;

3 it is a scientific fact that the Vaccines reduce COVID virus transmission;

4 the ability of the Vaccines to prevent transmission has been scientifically proven by the Vaccine manufacturers;

Particulars

"The vaccine does and we know it can affect the transmission. It's not only about the protection from severe illness"

"So Senator, just firstly on the transmission reduction, that's not my opinion, that's the science. There's definitely a decrease in transmission from the virus."
https://www.youtube.com/watch?v=9Dt597zq1kc&t=17s

f) on 10 November,2022 stated in a Senate Committee meeting that the Vaccines were proven scientifically to prevent transmission of the virus.

Particulars

The CHO expressly stated in respect of whether the, according to science, that the Covid Vaccines prevent transmission of the virus:

"That would be my view based on science. There is an effect on transmission".
Community Affairs Legislation Committee
https://colinmendelsohn.com.au/wp-content/uploads/2022/11/Hansard.-Community-Affairs-Legislation-Committee-Skerritt-p54-57-60-62-10Nov2022.pdf

~~219. The Misleading Chief Medical Officer Vaccines Statements were:~~

~~a) made publicly on widely available media;~~

~~b) expressly or alternatively, by reasonable inference from the express words spoken;~~

~~c) for the purpose of:~~

~~1 informing the Australian public as to the Vaccines':~~

~~(1) safety;~~

~~(2) efficacy;~~

~~(3) risk-benefit profile;~~

~~2 causing the Australian public to rely upon those statements as true;~~

~~3 inducing the Australian public to take the Vaccines;~~

d) in circumstances where in truth the publishee would infer that the Chief Medical Officer had direct personal knowledge of the veracity of those statements;

e) the statements were:

1 untrue; and

2 misleading to the Australian public;

f) the Chief Medical Officer was recklessly indifferent as to the statements veracity or otherwise;

g) without proper evidence to support the assertions;

h) without proper analysis to support the assertions;

i) without reasonable or diligent effort to ascertain true and relevant:

1 data;

2 analysis;

3 conclusion;

4 false interpretation of data.

Particulars

The Chief Medical Officer Misleading Vaccines Statements were untrue and known by the Chief Medical Officer to be untrue in the circumstances of the following factual matters known to the Chief Medical Officer at the time of the Chief Medical Officer Misleading Vaccines Statements were made:

1. The circumstances pleaded in the Chief Medical

~~Officer Misleading Statements.~~

~~2. The factual matters going to the conduct, circumstances and knowledge of Respondents at the time of the Chief Medical Officer Misleading Vaccines Statements pleaded at paragraphs 65 to 211 herein.~~

FORMER MINISTER FOR HEALTH AND AGED CARE, GREG HUNT

220. The then Minister for Health and Aged Care, Hunt, stated the following on 7 March, 2021 expressly or by reasonable inference that **("the Ministers Misleading Vaccines Statement")**:

a) there was no evidence that the Vaccines are harmful in pregnancy;

b) there was no need to be concerned if a person is pregnant and has taken or intends to take the Vaccines;

c) any statements to the contrary are merely conspiracy theories worthy of rejection;

d) taking the Vaccines are entirely safe for pregnant recipients and their unborn child;

e) there is no evidence in existence that the Vaccines are harmful to pregnant recipients and their unborn child.

Particulars

Hunt stated the following expressly in the public interview:

"Certainly, I absolutely agree with what Ms Gillard said. There is a very good set of advice on the health.gov.au website. There's trusted advice. There's information that is being sent out to all general practitioners about the vaccine. Trust the advice that's official. There is a lot of misinformation out there. It is simply untrue. Many of the anti-vaxxer conspiracy theories that are out there, you

just need to ignore them and get the best advice that you can find. So go to the trusted sources. Just in terms of pregnancy, I think, as Ms Gillard said, there is no evidence that these vaccines are harmful in pregnancy. So, if someone has a vaccine and turns out to be pregnant, we don't need to worry. But we also don't know for sure. We don't have enough data to say that they're absolutely safe in pregnancy. There's no reason why they wouldn't be safe in pregnancy, but we're recommending that people who are pregnant should discuss vaccination with their doctor before they consider it. Just look at the risks versus the benefits."

https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/doorstop-interview-about-the-vaccine-rollout-and-vaccine-safety.

~~221. The Ministers Misleading Vaccines Statements were:~~

~~a) made publicly on widely available media;~~

~~b) expressly or alternatively, by reasonable inference from the express words spoken;~~

~~c) for the purpose of:~~

~~1 informing the Australian public as to the Vaccines':~~

~~(1) safety;~~

~~(2) efficacy;~~

~~(3) risk-benefit profile;~~

~~2 causing the Australian public to rely upon those statements as true;~~

~~3 inducing the Australian public to take the Vaccines;~~

~~d) in circumstances where in truth the publishee would infer that Hunt had direct personal knowledge of the veracity of those statements;~~

e) the statements were:

1 untrue; and

2 misleading to the Australian public;

f) Hunt was recklessly indifferent as to the statements veracity or otherwise;

g) without proper evidence to support the assertions;

h) without proper analysis to support the assertions;

i) without reasonable or diligent effort to ascertain true and relevant:

1 data;
2 analysis
3 conclusion
4 false interpretation of data;

Particulars

The Minister Misleading Vaccines Statement was untrue and known by Hunt to be untrue in the circumstances of the following factual matters known to the Hunt at the time he Minister Misleading Vaccines Statements made:

1. The circumstances pleaded in the Minister Misleading Vaccines Statements;

2. The factual matters going to the conduct, circumstances and knowledge of Hunt at the time of the Minister Misleading Vaccines Statements pleaded at paragraphs 65 to 211 herein

THE DEPARTMENT

222. The Respondents through the Department stated expressly or by reasonable inference that **("the Department Misleading Vaccines Statements"):**

a) the Department stated on 8 November, 2021 by publishing the document "Guidance on Myocarditis and Pericarditis after mRNA COVID-19 Vaccines" **("the Myocarditis Concerns Guidance Document")** in the context of the admission in the document that "there are currently limited available data on the long-term outcomes of people who have had myocarditis and/or pericarditis after an mRNA COVID-19 vaccine" that:

1 short to medium term follow-up data in respect of the outcomes of those who suffer from myocarditis and/or pericarditis after an mRNA COVID-19 vaccine is reassuring for those considering taking or having taken the Vaccines;

2 most people who have had myocarditis and/or pericarditis due to other causes recover completely and have no ongoing impairment of cardiac function for which the data suggest this is likely for cases associated with mRNA COVID-19 vaccination, based upon the study "Tunuguntla H, et al, 'Acute Myocarditis and Pericarditis in Children' Ped. Rev. 2019; 40(1):14-25" **("the Cited Myocarditis Study")**;

3 that even if the Vaccines recipient might suffer myocarditis or pericarditis as an effect of the Vaccines, that in all likelihood the person would recover completely with no ongoing impairment of cardiac function;

4 the above statements made in circumstances where in truth the Respondents knew that:

(1) the Cited Myocarditis Study in fact states expressly, contrary to the Department's statements, that:

a) the myocarditis disease process can rapidly become life-threatening;

b) myocarditis can cause sudden cardiac death, with no symptoms until death;

c) in the study of 171 paediatric patients with myocarditis, 13% died or underwent cardiac transplant during their initial hospitalization;

d) for those with an underlying etiology of myocarditis, the incidence of transplant or death at 5 years after diagnosis was 27%;

e) myocarditis can also lead to the development of a chronic dilated cardiomyopathy (DCM), which is the leading cause of pediatric heart transplant in children older than 1 year;

f) in a large cohort of paediatric patients with DCM from the Paediatric Cardiomyopathy Registry, myocarditis was the most common known cause of DCM;

g) of children with a known cause for DCM, up to 46% have been reported to be due to myocarditis;

h) 50% of those with a DCM without known myocarditis had died or undergone cardiac transplant by 5 years after diagnosis;

i) the prognosis for individuals with myocarditis is as variable as the clinical presentation wherein:

    i) patients with acute myocarditis and normal cardiac function have a good prognosis overall, with a high likelihood for spontaneous recovery;

    ii) those with fulminant viral myocarditis are more likely to have recovery if adequately supported with medications or MCS

during the initial phase;

iii) those with giant cell myocarditis have a poor prognosis in both children and adults, with median survival of less than 6 months without cardiac transplant.

j) when evaluated from a sudden death perspective, myocarditis accounts for approximately 5% to 6% of sudden deaths in young athletes in the United States;

k) myocarditis can result in life-threatening arrhythmias and conduction abnormalities, including variable degrees of:

i) atrioventricular block;

ii) ventricular fibrillation/flutter; or

iii) ventricular tachycardia.

(2) despite the prolific and free availability of studies regarding the dangers of pericarditis and myocarditis, the Department selected the Cited Myocarditis Study as a supporting citation which:

a) was only viewable by registration and payment of a $25 USD fee;

b) consequently and obviously certain to be substantially limited in those viewing the study in its full form.

(3) the Myocarditis Concerns Guidance Document was purposed:

a) for use by medical practitioners;

b) to reassure and represent to medical practitioners and their patients that:

i) regulators were carefully monitoring for these events relating to myocarditis and pericarditis;

ii) myocarditis and pericarditis after taking the Vaccines was in most cases:

1. of minimal or no concern;

2. attended only by extremely rare instances of any long term sequalae.

(4) the Respondents were entirely unaware as to:

a) the long-term outcomes of people who have had myocarditis and/or pericarditis after the Vaccines;

b) the underlying aetiology of people who have had myocarditis and/or pericarditis after the Vaccines and therefore:

i) the short or long term prognosis of people who have had myocarditis and/or pericarditis after the Vaccines; and

ii) the true risk to those who take the Vaccines of death or serious short or long term injury.

(5) myocarditis and pericarditis following injection with the mRNA based Vaccines:

a) were reasonably postulated at that time to be occurring as a result of:

i) toxic or inflammatory effects of the nano lipid delivery system used in the

Vaccines; and

ii) an auto-immune response to the autologous spike protein production in those Vaccines;

b) possessed a large number of histological correlates with a variety of possible inflammatory and white blood cell infiltrates into the myocardium.

(6) the European Medicines Agency Pharmacovigilance Risk Assessment Committee (PRAC) had by 28 October, 2021, which was known to the Respondents at that time:

a) confirmed a safety signal in the Vaccines for myocarditis and pericarditis, as well as capillary leak syndrome in the Moderna Vaccine;

b) recommended changes to the Product Information to reflect this in the Moderna Vaccine and the Pfizer Vaccine;

c) stated that any cardiac arrest or death occurring in young people must constitute a safety signal;

(see particulars)

(7) it was a well-established and easily accessible scientific fact based upon extensive empirical historical data that **("Established Scientific Facts of Myocarditis")**:

a) myocarditis and pericarditis are in every instance serious and life-threatening conditions;

b) neither prognosis nor treatment can be determined without a histological based understanding of the underlying pathophysiological processes;

c) following myocarditis there is:

i) generally across all aetiologies 30-40 % chance of progression to death or cardiac failure within 5 years;

ii) some aetiologies attended by a 25% survival rate within a 6 month period;

iii) at least 50% of patients develop cardiomyopathy in the long term;

iv) a one-year mortality rate for acute myocarditis generally of 20% which increases to 56% on four-year follow-up;

v) discernible changes to a patients ECG results are rare;

vi) assessment requires a minimum of an MRI to confirm the diagnosis;

vii) proper treatment can only be guided by the result of a myocardial biopsy;

viii) outcomes of acute myocarditis are often life threatening;

ix) the risk of sudden cardiac death in patients with acute myocarditis is not always associated with the severity of myocardial inflammation and can persist after the acute phase of myocarditis is resolved;

x) acute myocarditis can also present as sudden cardiac death, accounting for approximately 10% of deaths from

sudden cardiac death in young individuals aged under 35 years;

xi) life-threatening bradyarrhythmia and tachyarrhythmia can occur at any stage of the disease and lead to sudden cardiac death.

(see particulars)

Particulars

the Myocarditis Concerns Guidance Document was published on the Department's website as from 8 November, 2021, expressly stating that:

"Early suspicion for and recognition of signs and symptoms, particularly of myocarditis, are important because the disease process can rapidly become life-threatening….. When evaluated from a sudden death perspective, myocarditis accounts for approximately 5% to 6% of sudden deaths in young athletes in the United States. Myocarditis can also lead to the development of chronic dilated cardiomyopathy (DCM), which is the leading cause of pediatric heart transplant in children older than 1 year. Of children with a known cause for DCM, up to 46% have been reported to be due to myocarditis. Myocarditis can result in life-threatening arrhythmias and conduction abnormalities, including variable degrees of atrioventricular block, ventricular fibrillation/flutter, or ventricular tachycardia. Myocarditis can cause sudden cardiac death, with no symptoms until death.

The prognosis for individuals with myocarditis is as variable as the clinical presentation. Patients with acute myocarditis and normal cardiac function have a good prognosis overall, with a high likelihood for spontaneous recovery. Those with fulminant viral myocarditis are more likely to have recovery if adequately supported with medications or MCS during the initial phase. Giant cell myocarditis has a poor prognosis in both children and adults, with median survival of less than 6 months without cardiac transplant.

In a study of a multicentre cohort of 171 paediatric patients with myocarditis, 13% died or underwent cardiac transplant during their initial hospitalization.

In a large cohort of paediatric patients with DCM from the Paediatric Cardiomyopathy Registry, myocarditis was the most common known cause of DCM. For those with an underlying etiology of myocarditis, freedom from transplant or death at 5 years after diagnosis was 73%.

In contrast, 50% of those with a DCM without known myocarditis had died or undergone cardiac transplant by 5 years after diagnosis.

https://www.health.gov.au/sites/default/files/documents/2021/12/covid-19-vaccination-guidance-on-myocarditis-and-pericarditis-after-mrna-covid-19-vaccines_0.pdf

The Cited Myocarditis Study is available at https://publications.aap.org/pediatricsinreview/article-abstract/40/1/14/35218/Acute-Myocarditis-and-Pericarditis-in-Children?redirectedFrom=fulltext and only available after payment of $25 USD to view.

“PRAC recommendations on signals”, Adopted at the 25-28 October 2021 PRAC meeting. European Medicines Agency Pharmacovigilance Risk Assessment Committee.

The Established Scientific Facts of Myocarditis known to the Respondents at the time are evident in, *inter alia*, the following published studies:

Al-Akchar M, Shams P, Kiel J. Acute Myocarditis. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; Update: July, 2021. https://www.ncbi.nlm.nih.gov/books/NBK441847/;

Tschöpe C, Ammirati E, Bozkurt B, et al. Myocarditis and inflammatory cardiomyopathy: current evidence and future

directions. Nat Rev Cardiol; Oct 2021;18(3):169-193. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7548534/

b) the Department stated on 23 December, 2021 by publishing the document "Pfizer COVID-19 vaccine for children aged 5 to 11: information for parents and guardians" on 23 December 2021 stated that:

1 as at that time, no specific safety concerns have been identified in the 5 – 11 year old age group in the use of the Pfizer Child Vaccine;

2 that the Pfizer Child Vaccine would prevent transmission of Covid by recipients;

3 that the Pfizer Child Vaccine would prevent infection of Covid in recipients;

4 the benefits of taking the Pfizer Child Vaccine outweigh the risk; and

5 the rate and severity of myocarditis in children is expected to be lower in children aged 5 – 11 than that in adolescents, and more mild;

6 the risks of injury in failing to vaccinate children with the Pfizer Child Vaccine are considerable and in need of mitigation;

7 the risk of injury by injecting them with the Pfizer Child Vaccine are almost nil;

8 myocarditis is a non-serious condition that generally people recover from fully;

9 the Department had independently ascertained the veracity of these matters;

10 such statement made in circumstances where in truth it was known to the Respondents at that time that:

(1) there was no evidence in existence at that time or since to

support the asserted expectations;

(2) the precise opposite of that expectation was at that time and since supported by scientific evidence;

(3) the document does not inform of the known fact that the underlying pathophysiology as a consequence of injection with the Vaccines is unknown;

(4) the fact that a proportion of people reported to have myocarditis associated with the Vaccines have been reported to have died or to remain injured.

Particulars

The Department published in the document entitled “Pfizer COVID-19 vaccine for children aged 5 to 11: information for parents and guardians” express statements that:

“In the United States, vaccination of children aged 5 to 11 years with the Pfizer COVID-19 vaccine started on 4 November 2021. As at 9 December 2021, more than 5 million children in this age group have received at least one dose and more than 2 million have received both doses of the Pfizer COVID-19 vaccine. No specific safety concerns have been identified in this age group in this large, real-world population, where the number of children vaccinated is already greater than the approximately 2.3 million children aged 5–11 years in Australia.

In the United States, almost 6,000 cases have been reported of a rare but serious condition associated with COVID-19 called paediatric inflammatory multisystem syndrome temporally 2 associated with SARS-CoV-2 (PIMS-TS). This is also known as multisystem inflammatory syndrome in children (MIS-C). Most children with PIMS-TS/MIS-C need to be treated in hospital and a small proportion of children with PIMS-TS/MIS-C have died. Most people who contracted PIMS-TS/MIS-C were aged between 5 and 11 years.

Children can transmit the virus to others, including older family members who are at higher risk of becoming seriously ill. Infected children often miss out on school and other activities. When children are vaccinated, the risk that they will become infected and spread COVID-19 to family members, friends and others around them is reduced. Reducing the spread of COVID-19 may help to minimise school closures and other disruptions to extra-curricular and social activities which significantly impact on the wellbeing of children and their families. Getting your child vaccinated will also help with the return to normal activities without disruptions, like needing to isolate after contact with someone with COVID-19, and will support the safe enjoyment of other activities, like overseas travel. Protection against COVID-19 starts from about 2 to 3 weeks after the first dose. While one dose may give some protection, it may only last for the short term. Two doses will give improved protection;

The rate and severity of myocarditis in children is expected to be lower than that in adolescents, and more mild. Myocarditis is more commonly seen in males under 30 years of age after the second dose. Most people who have had these conditions after their vaccine have recovered fully. The clinical trial in children aged 5 to 11 years did not have enough participants to assess rates of myocarditis or pericarditis following vaccination with the Pfizer COVID-19 vaccine, but no specific safety concerns have been identified so far from millions of doses of this vaccine administered overseas to children aged 5 to 11 years. The benefits of vaccination outweigh this very rare risk, and vaccination is still recommended for all eligible age groups. The Therapeutic Goods Administration (TGA) assesses all vaccines in Australia. For a vaccine to be approved, the TGA must assess that it is safe, effective and manufactured to a very high quality standard. A description of the process for approval of COVID-19 vaccines is available at: www.tga.gov.au."

https://www.health.gov.au/resources/publications/covid-19-vaccine-information-and-consent-form-for-parents-and-guardians-of-children-aged-5-to-11-years.

c) In publishing the document “Clinical recommendations for COVID-19 vaccines” on 12 December, 2022, the Department stated that:

1 there is substantial data on the safe use of the original Pfizer Vaccine during pregnancy;

2 there are no theoretical safety concerns relating to the use of the Novavax Vaccine during pregnancy;

3 the AstraZeneca vaccine is not preferred in pregnancy but it can be used during pregnancy;

4 there are no theoretical safety concerns relating to the use of the bivalent booster Vaccines during pregnancy;

5 vaccination following infection enhances natural acquired immunity;

6 all available Vaccines are safe for use during pregnancy;

7 there is no additional risk to the unborn child or mother if a COVID vaccine is used during pregnancy;

8 vaccination provides superior protection against COVID infection than natural acquired immunity;

9 the above statements were made in circumstances where in truth it was known to the Respondents at that time that:

(1) there was no evidence in existence to support the contention that the mRNA Vaccines were safe for use in pregnancy;

(2) there was substantial nonclinical evidence known to the Respondents that the mRNA Vaccines were not safe for use in pregnancy;

(3) there were no references in the document to evidence supporting the safety of the mRNA Vaccines;

(4) the references at the end of the document relate to combination vaccination with different products/booster doses;

(5) the document at no point discloses the known and evident risks in pregnancy known to the Respondents being:

a) foetal demise;

b) miscarriage;

c) spontaneous abortion;

d) foetal malformation; or

e) transmission of spike protein through breastmilk.

Particulars

The Department published in the document entitled “Clinical recommendations for COVID-19 vaccines” express statements that:

“Pfizer original ≥12 years formulation (purple cap) is the recommended vaccines for primary course vaccination in pregnancy. There are substantial data on its safe use in pregnancy.” “Novavax can also be used for a primary course in pregnancy. There are no immunogenicity or safety data for this vaccine in pregnancy but there are no theoretical safety concerns.”

“AstraZeneca is not preferred in pregnancy. Pregnant women who have already received a first dose of AstraZeneca can receive Pfizer original ≥12 years formulation (purple cap), AstraZeneca, or Novavax for their second dose.”

“For booster doses, refer to booster vaccine preference recommendations below. Although bivalent booster vaccines have not been studied in pregnant women, there are no theoretical concerns regarding their safety, and they can be offered to pregnant women who are due for a booster dose.”

"Vaccination is likely to enhance the protection induced by infection. The interval between infection and vaccination enhances the protection from vaccination by further boosting the immune response, including immune memory response, generated following infection."
https://www.health.gov.au/our-work/covid-19-vaccines/advice-for-providers/clinical-guidance/clinical-recommendations

PUBLIC MESSAGE

223. The ~~misleading~~ statements pleaded at paragraphs 212, 214, 216, 218, 220 and ~~to~~ 222 herein **("the Misleading Vaccines Statements")**:

a) individually and in confluence represented to the Australian population (including the Group Members) either expressly or impliedly that **("the Misleading Public Message ~~Representations~~")**:

1 the Vaccines were unquestionably safe;

2 the Vaccines were so safe that anything other than the most mild of side effects almost never occurred;

3 the Vaccines were completely or almost completely effective to:

(1) prevent infection from the Virus;

(2) prevent transmission of the Virus;

(3) prevent serious Covid;

(4) prevent death from Covid;

4 prior the Approvals, the Vaccines had been subjected to:

(1) the most rigorous assessment for safety and efficacy possible;

(2) an assessment procedure equivalent to that applied all other

approved therapeutic products in Australia.

5 that nothing known by the Respondents in respect of testing prior to the Approvals or known data in respect of safety of efficacy of the Vaccines were of any concern;

6 that if people did not take the Vaccines they would be at a high risk of dying or becoming seriously ill;

7 that for everyone in Australia the risks of serious illness and death from not taking the Vaccines were significantly higher than the risks of injury from taking the Vaccines;

8 that taking the Vaccines was essential to protect others from Covid;

9 that nothing in the known data in respect of post-Approvals side effects from the Vaccines was of any material concern to the Australian public;

10 that public reporting and statements of the Respondents pre-Approvals and post-Approvals in respect of the safety, efficacy and risk-benefit profile of the Vaccines discloses to the Australian public the most accurate and comprehensively evident representation of those matters.

~~b) were materially false or misleading at the relevant time;~~

~~c) were made without scientific, logical or proper evidentiary basis for the propositions which they contained;~~

d) contained the Misleading Public Message ~~propositions they contained were~~ which was misleading because in truth, it was contrary to the balance of data and evidences in the possession of, known to, or reasonably available to the persons who made them and authorised them, being the Respondents and those acting under their direction and authority;

e) were made for the ~~sole~~ purposes of inducing the Australian population to receive one or more of the Vaccines:

1 in the greatest numbers possible;

2 with the minimal hesitation possible; and

3 with the minimal delay possible.

f) were made with the expectation and intention that the Australian Public would rely upon the truth of the Misleading Public Message ~~Representations~~ in deciding whether or not to receive one or more of the Vaccines;

g) were made in the circumstances of the following knowledge and conduct, where having occurred at the relevant point in time:

1 the Known Serious Vaccines Risks And Conduct - Pre-Approvals;

2 the Known Serious Vaccines Risks And Conduct - Post-Approvals; and

3 the knowledge and conduct pleaded and particularised in the Misleading Statements.

~~h) were made by the Respondents and those under their direction and authority in the circumstances:~~

~~1 with knowledge of:~~

~~(1) their substantive falsity or alternatively misleading nature; and/or~~

~~(2) the lack of scientific, logical or evidentiary basis for propositions which they contained;~~

~~2 further or alternatively, reckless indifference as to whether they were:~~

~~(1) true or not;~~

~~(2) supported by scientific, logical or evidentiary basis for~~

~~propositions which they contained.~~

i) were made in circumstances such that no reasonable person acting carefully, reasonably, skillfully, and in good faith would otherwise have made them.

Particulars

The Misleading Public Message arising from the Misleading Vaccines Statements was misleading by reason of the knowledge of the Respondents and acts and omissions undertaken as pleaded in the:

the Known Serious Vaccines Risks And Conduct - Pre-Approvals;

the Known Serious Vaccines Risks And Conduct - Post-Approvals;

the knowledge and conduct pleaded in the Misleading Vaccines Statements pleaded at paragraphs 212, 214, 216, 218, 220 and 222 herein.

NEGLIGENCE CLAIM

KNOWLEDGE AND ACTIONS OF THE RESPONDENTS IN PURPORTED CONDUCT UNDER THE ACT

224. The Respondents at all relevant times as pleaded prior to the Approvals possessed the knowledge and undertook the actions pleaded at paragraphs 65 to 130 herein **("the Known Serious Vaccines Risks And Conduct - Pre-Approvals")**:

a) in respect of the knowledge, such knowledge being obtained in the course of the Respondents:

1 purportedly acting in accordance with, pursuant to, and under the powers provided to them under the Act;

2 determining whether to grant the Approvals;

b) in respect of actions, such actions being undertaken in the course of the Respondents:

1 purportedly acting in accordance with, pursuant to, and under the powers provided to them under the Act;

2 determining whether to grant the Approvals.

225. The Respondents at all relevant times as pleaded after the Approvals possessed the knowledge and undertook the actions pleaded at paragraphs 131 to 211 herein **("the Known Serious Vaccines Risks And Conduct - Post-Approvals")**:

a) in respect of the knowledge, such knowledge being obtained and in the course of the Respondents:

1 purportedly acting in accordance with, pursuant to, and under the powers provided to them under the Act;

2 determining whether to maintain the Approvals.

b) in respect of actions, such actions being undertaken in the course of the Respondents:

1 purportedly acting in accordance with, pursuant to, and under the powers provided to them under the Act;

2 determining whether to maintain the Approvals.

~~226. The Respondents and those under their authority and direction at all relevant times in making the Misleading Vaccines Statements:~~

~~a) in respect of the knowledge, those statements were made in each instance in the circumstances of the matters known to the maker of the statement at the relevant time being:~~

~~1 the Known Serious Vaccines Risks And Conduct - Pre-Approvals;~~

2 the Known Serious Vaccines Risks And Conduct - Post-Approvals;

3 the knowledge where pleaded in the Misleading Vaccines Statements;

b) in respect of actions, each statement was made in the course of the maker of the statement purportedly acting in accordance with, pursuant to, and under the powers provided to them under the Act;

c) were in every case:

1 made publicly on widely available media;

2 expressly or alternatively, by reasonable inference from the express words spoken;

3 for the purpose of:

(1) conveying the assertions to the Australian public (including the Group Members) that the Vaccines were:

a) safe;

b) effective;

c) possessing of a positive risk-benefit profile;

d) absolutely essential for their safety and health.

(2) causing the Australian public to rely upon those statements as true;

(3) inducing the Australian public (including the Group Members) to take the Vaccines;

(4) causing the highest possible degree of adoption by the Australian public of the Vaccines.

d) in circumstances where the Australian public would reasonably infer that the maker of the statement had direct personal knowledge of the truth of those statements;

e) the statements were:

1 untrue; and

2 further or in the alternative, misleading to the Australian public (including the Group Members);

f) the maker of the statement knew that the statements were:

1 untrue; and

2 further or in the alternative, misleading to the Australian public (including the Group Members);

g) further or alternatively, the maker of the statement was recklessly indifferent as to the statements truth or otherwise;

h) the maker of the statements knew that the statements would be widely republished, and in fact were, to most or all of the Australian public;

i) made without proper evidence to support the assertions;

j) made without proper analysis to support the assertions;

k) made without reasonable or diligent effort to ascertain true and relevant:

1 data;

2 analysis;

3 conclusions;

4 interpretation of data.

CONTROL OF THERAPEUTIC GOODS AND STATEMENTS

227. By reason of the factual matters pleaded at 10 to 18 and 25 to 56 (inclusive) herein, the Respondents whether through the TGA or otherwise were at all material times **("the Respondents Control of Therapeutic Goods in Australia")**:

a) were in a position to control, and did control absolutely, whether or not a therapeutic good in Australia (including the Vaccines) could be lawfully or otherwise authorised for use in the general Australian public (including the Group Members) in Australia (including in the Approvals) and if so authorised:

1 under what conditions; and

2 for what period of time.

b) were in a position to control and did control absolutely, direct, lawful and practical access to the Vaccines by the Australian public (including the Group Members) by:

1 the Approvals;

2 the Continuing Approvals.

c) were in a position to, and did control and direct absolutely all statements to the Australian public (including the Group Members) by the Respondents themselves or any other officer of the TGA as to:

1 the Vaccines':

(1) safety;

(2) efficacy;

(3) risk-benefit profile;

(4) necessity for use by the Australian public (including the Group Members);

2 any other matter relating to the Approvals, the Continuing Approvals and the Vaccines.

d) were in a position to control and did control absolutely whether a therapeutic good in Australia (including the Vaccines) could be withdrawn from lawful or otherwise use by the general Australian public (including the Group Members) in Australia (including in the Approvals and the Continuing Approvals);

e) in determining whether or not to lawfully or otherwise authorise (including in the Approvals and Continuing Approvals) for use by the general Australian public (including the Group Members) a therapeutic good in Australia (including the Vaccines), were in a position to control and did control absolutely:

1 the information and data to which they would and did have regard or otherwise;

2 the procedure by which they would make any such determinations.

228. The Respondents Control of Therapeutic Goods in Australia were:

a) generally known by the Group Members and the Australian Public;

b) promoted publicly by the TGA and the Respondents.

KNOWLEDGE OF THE GROUP MEMBERS RELIANCE

229. By reason of the Respondents Control of Therapeutic Goods in Australia and the public knowledge of that fact, the Respondents knew and the Australian public (including the Group Members) did in fact, reasonably expected and relied upon the fact that the Respondents in performing their functions regarding the Approvals, the Continuing Approvals, and the Misleading Public Message ~~Vaccines Statements~~ would **("the Public's Reasonable Expectation and Reliance")**:

a) do so in accordance with and adherence to:

1 the Act and Regulations;

2 the TGA Policies;

3 good practice;

4 would in all the circumstances do so:

(1) with reasonable care;

(2) in good faith; and

(3) in fulfilment of the objects of the Act.

b) as regards statements in the Misleading Public Message ~~Vaccines Statements~~ by the Respondents (or on their behalf) were obliged to and would be accepted by the Australian public including the Group Members as true and accurate representations of those matters;

c) be relied upon to act in accordance with those reasonable expectations by the Australian public (including the Group Members) in determining whether to accept and use any authorised therapeutic product in Australia (including the Vaccines).

PUBLIC EXPECTATION OF RESPONDENTS TECHNICAL SKILL IN APPROVALS

230. The Respondents knew at all material times that they, those acting on their authority, and the TGA were invested with powers, discretions and functions **("the Public Expectation of Skill")**:

a) in a highly technical and complex area of national health care;

b) pursuant to which it was reasonably expected that in the exercise of such powers discretions and functions including the Approvals :

1 would be in fact:

(1) undertaken by, and understood by the Australian public (including the Group Members) to be undertaken by professionally qualified persons, having skill, experience and the necessary expertise in their areas of work;

(2) thereby necessarily giving such actions and omissions (including the Authorisation Functions and the Public Statements Functions) exceptional force and authority.

c) in the exercise of which were responsible for administering the Act according to its provisions;

d) in such an important, sensitive, and publicly known function, that would be reasonably expected and accepted by the Australian population (including the Group Members) to be:

1 undertaken:

(1) with reasonable care, professionally and in good faith;

(2) in adherence to and compliance with:

a) empowering legislation including the Act and the Regulations;

b) publicly declared policy including the TGA Policies.

2 thereby relied upon as such in the exercise of their functions as such including:

(1) the Approvals;

(2) the Continuing Approvals;

(3) the Misleading Public Message. ~~Vaccines Statements~~

231. The Respondents and the Australian public knew in fact, that the Respondents and

those acting under authority through Act and Regulations were **("the Known Gravity of the Approvals")**:

a) invested with the power, functions and discretion relating to the approval of therapeutic goods in Australia;

b) thereby in the conduct of those functions undertaken in respect of the Approvals and the Continuing Approvals ~~and the Misleading Vaccines Statements~~ would:

1 be significant and material to the Australian population (including the Group Members);

2 expose the Australian population (including the Group Members) to a deleterious and extreme risk of harm if those functions and powers were exercised:

(1) without reasonable care;

(2) extraneous to power;

(3) for improper purpose; and/or

(4) with known or reckless indifference to:

a) the statutory power or otherwise to undertake those functions;

b) resultant injury or damage to the Group Members which may arise;

c) the misleading or false nature of statements made.

KNOWLEDGE OF VULNERABILITY OF AUSTRALIAN PUBLIC TO TGA ACTIONS

232. By reason of the matters pleaded at paragraphs 10 to 231 (inclusive) herein, the Respondents knew or ought reasonably to have known that any decision, act or omission undertaken by them or those under their authority and direction in respect

of or ancillary to the Approvals and the Continuing Approvals ~~or the Misleading Vaccines Statements~~ would **("the Known Vulnerability of the Australian Public")**:

a) directly affect whether or not the Australian population (including the Group Members) had lawful access to any or all of the Vaccines;

b) directly affect whether or not the Australian population (including the Group Members) were injected with any or all of the Vaccines;

c) directly affect whether or not the Vaccines being injected by the Australian Population once approved were in truth:

1 safe for their intended use;

2 effective for their intended use;

3 possessive of a positive risk-benefit profile.

d) directly affect the health and well-being of those injected with the Vaccines;

e) directly affect the likelihood of serious personal injury and harm to those injected with the Vaccines.

FORESEEABILITY OF RISK AND HARM

233. In the premises, it was reasonably foreseeable that **("the Foreseeability of Risk and Harm")**:

a) the Group Members would in respect of the Misleading Public Message ~~Vaccines Statements~~:

1 rely upon and act upon the Misleading Vaccines Statements;

2 apprehend and believe the Misleading Public Message ~~Representations~~;

3 determine thereby to take one or more of the Vaccines.

b) in respect of the Approvals and the Continuing Approvals cause:

1 to make available access to the Vaccines by the Group Members for use not otherwise available;

2 the Group Members to use the Vaccines which would not otherwise have occurred;

3 the Group Members to suffer injury, loss and damage;

4 pervasive and serious negative consequences upon the health and well-being of the Australian population (including the Group Members).

c) that when exercising or purporting to exercise powers, functions and discretions under the Act including in the Approvals, the Continuing Approvals, and the Misleading Public Message ~~Vaccines Statements~~ where not undertaken carefully, reasonably, skillfully and in good faith, such acts or omissions carried the high probability and likelihood that those consequently injected with the Vaccines (including the Group Members) would suffer:

(1) serious or catastrophic personal injuries;

(2) loss and damage.

RESPONDENTS' DUTY TO THE GROUP MEMBERS

234. By reason of the factual matters and the circumstances of the relationship between the Respondents and the Group Members pleaded herein, the Respondents were under a duty to the Group Members to act carefully, reasonably, skillfully and in good faith when exercising or purporting to exercise powers, functions and discretions under the Act **("the Respondents Duty")**.

RESPONDENTS CONDUCT – NEGLIGENCE AND BREACH OF DUTY IN APPROVALS

235. In the circumstances of and by reason of the acts, omissions and knowledge of the

Respondents in connection with the granting of the Approvals purportedly pursuant to the Act pleaded in the Known Serious Vaccines Risks And Conduct - Pre-Approvals, the Approvals were undertaken **("the Reckless Failures - Approvals")**:

a) in breach of the following Statutory Obligations:

1 the TGA's Statutory Purpose;

2 the Register's Statutory Purpose;

3 the Provisional Determination Statutory Criteria;

4 the Provisional Registration Statutory Standard;

5 the Statutory Requirement to Seek Gene Technology Regulator Advice;

6 the Statutory Requirement to Consider Gene Technology Regulator Advice;

7 the Statutory Lapsing Application Where Misleading;

b) in breach of the following TGA Policies:

1 the TGA Vaccine Regulation Policy;

2 the TGA Provisional Approval Policy;

3 the TGA Safety Covid Information Policy;

4 the TGA Covid Vaccine Approvals Policy;

5 the TGA Covid Vaccine Evidence Policy;

6 First In Human Medicine Policy;

7 Pharmacovigilance in Vaccine Approvals Policy;

8 Clinical Trials Oversight Policy; and

9 Guideline on Clinical Evaluation of New Vaccines.

c) such that at that time of the Approvals the Vaccines were in fact:

1 not safe for their intended purpose;

2 not effective for their intended purpose;

3 not possessing of a positive risk-benefit profile;

d) such that at the time of the Approvals the Vaccines were not demonstrated by the evidence known to the Respondents and reasonably available evidence globally to be reasonably or otherwise:

1 safe for their intended purpose;

2 effective for their intended purpose;

3 possessing of a positive risk-benefit profile.

e) such that at the time of the Approvals the data and evidence known to the Respondents and reasonably available evidence globally obviously demonstrated that the Vaccines were in truth:

1 unsafe for their intended use;

2 ineffective for their intended use;

3 possessive of a grossly negative risk-benefit profile.

f) such that at the time of the Approvals the Respondents did with knowledge or reckless indifference as to any obligation not to:

1 fail or refuse to consider or alternatively properly consider prior to the

Approvals the known evidence and reasonably available evidence relevant to the Vaccines':

(1) safety;

(2) efficacy;

(3) risk-benefit profile;

(4) necessity;

2 fail or refuse to establish, satisfactorily establish, or alternatively reasonably establish the Vaccines':

(1) safety;

(2) efficacy; or

(3) benefits as exceeding their risks:

a) substantially;

b) significantly; or

c) at all.

3 ignore or dismiss the scientifically and reasonably established facts at the time of the respective Approvals that obviously demonstrated:

(1) in respect of the safety of each the Vaccines for their intended purpose:

a) the Vaccines were not safe;

b) further or in the alternative, that the Vaccines' safety was not established.

(2) in respect of the efficacy of each the Vaccines for their intended

purpose:

a) the Vaccines were not effective;

b) further or in the alternative, that the Vaccines' efficacy was not established.

(3) in respect of the risk-benefit profile of each the Vaccines for their intended purpose:

a) the risks of the Vaccines exceeded their benefit;

b) further or in the alternative, it was not established that the Vaccines' benefit exceeded their risks.

4 ignore or dismiss entirely any scientific and logical analysis and quantification of the risk associated with natural Covid infection in the Australian population such that the Respondents at no time properly engaged in a logical or scientifically based:

(1) risk-benefit analysis of the Vaccines;

(2) analysis of the need for the Vaccines in the Australian population:

a) generally;

b) in certain age sectors of the population;

c) in the sectors of the population already possessing antibodies acquired through natural immunity;

d) sectors of the population that were at elevated risk from serious adverse reactions arising from the Vaccines' unique composition.

g) with the knowledge of the Respondents prior to and at the time of the Approvals that:

1 the studies undertaken by the Sponsors and data provided to the Respondents in respect of the Approvals disclosed that:

(1) no clinical testing or data establishing in any of the Vaccines the effect of:

a) prevention of transmission of the Virus;

b) prevention of infection with the Virus;

c) prevention of serious illness from Covid;

d) prevention of hospitalisation from Covid;

e) prevention of death from Covid;

f) use of the Vaccines in those for whom use was intended being the Untested Groups, including in:

i) pregnant women;

ii) immunocompromised people;

iii) people with certain pre-existing health conditions;

iv) people receiving other vaccines concurrently;

v) people with natural immunity resultant from prior infection with the Virus;

g) long-term efficacy;

h) genotoxicity;

i) carcinogenicity;

j) long-term safety.

k) extraordinary and unacceptable risks associated with the Vaccines being:

i) risks of serious adverse events;

ii) risk of death;

iii) unquantified and known risk of incorporation of the mRNA in the mRNA Vaccines into the human genome with the potential to cause intergenerational effects;

iv) risk of carcinogenicity;

v) risk of extreme and unquantified proliferation of the spike protein in the human body with the mRNA Vaccines;

vi) known and unquantified distribution and concentration of the Vaccines' lipid nanoparticle in the entire human body including the human organs for an untested and unquantified period;

vii) risk of Vaccine Associated Enhanced Disease;

viii) risk of use in pregnancy.

(2) there were such deficiencies in the scope and nature of the evidence provided by the Sponsors in support of the Applications so as to render a determination of safety, efficacy and positive risk-benefit in the Vaccines impossible;

(3) there were known factual matters which provided the

Respondents a reasonable basis to doubt the accuracy and quality of the data provided by the Sponsors;

(4) they did not at any time receive the patient-level data in respect of the Vaccines Clinical Trials such that:

a) the Respondents relied wholly upon the Sponsors' summaries and characterisations of the actual trial data without further investigation by the Respondents;

b) the Respondents were deprived of the possibility to apply rigorous analysis to the data upon which they relied in granting the Approvals;

c) risk-benefit analysis in respect of the stratification of risk by age and other sectors could not be accurately performed in the circumstances where Covid was known to disproportionately affect the elderly and the risks from Covid infection was negligible in the under 50 years sector of the population.

2 despite those deficiencies pleaded herein known to the Respondents, the Respondents proceeded to grant the Approvals:

(1) without any requirement by the Respondents for substantial provision of further studies or data from the Sponsors:

a) to remedy the deficiencies prior to the Approvals;

b) that would or did in fact remedy those deficiencies;

(2) by generally seeking and accepting an explanation from the Sponsor as to those deficiencies which were invariably accepted by the Respondents in lieu of any further data;

3 no special consideration or application was given to the substantially heightened risks of injury and harm associated with the known:

(1) first ever in-human use and unknown effect of mRNA technologies in the mRNA Vaccines;

(2) the novel use of lipid nanoparticles in the Vaccines;

(3) the known fact that coronaviruses had never before been the subject of mass vaccination;

(4) the intention that and subsequent fact that the Vaccines were to be used on a mass scale to the Australian population;

(5) the reduction of the time taken for analysis and testing of the Vaccines to a fraction of that established historically and scientifically as appropriate for such analysis;

4 the Respondents had proceeded to the Approvals:

(1) with no proper or reasonable evidentiary or logical basis to reasonably determine the Vaccines to be safe, effective and possessing a positive risk-benefit profile;

(2) having denied, ignored, or dismissed the evident substantial risks of the Vaccines obviously disclosed to the Respondents through the received data and scientifically known and reasonably available evidence;

(3) having accepted numerous unfounded explanations from the Sponsors as to why the data provided was deficient;

(4) where in truth possessing no statutory power to do so and acting extraneously to any power granted them under the Act because contrary to the express provisions of the Act and its stated purpose:

a) the data obtained by and/or reasonably available to the Respondents demonstrated that the Vaccines were in truth:

i) unsafe for their intended use;

ii) ineffective for their intended use;

iii) possessive of a grossly negative risk-benefit profile.

b) further or in the alternative, the data obtained by and/or reasonably available to the Respondents at no time demonstrated that the Vaccines were in truth:

i) safe for their intended use;

ii) effective for their intended use;

iii) possessive of a positive risk-benefit profile.

(5) doing so in the circumstances of the above knowledge, knowingly or alternatively with reckless indifference as to:

a) whether they possessed the statutory power to grant the Approval;

b) whether the Vaccines were in truth and fact:

i) safe;

ii) effective;

iii) displaying a benefit substantially greater than their known risks;

iv) necessary;

c) whether the Vaccines were able or likely to cause harm to those whom would receive the Vaccines in circumstances where the Vaccines were intended for

use by:

i) almost the entire Australian Population;

ii) almost entirely healthy persons.

h) in aggravating circumstances, contemporaneously with the Misleading Public Message ~~Vaccines Statements~~ (where made before the respective Approvals) such that at the time of the Approvals the Australian public had:

1 been materially misled by the Respondents or those under their direction and authority as to the Vaccines' truly known or actual:

(1) safety for intended use;

(2) efficacy for intended use;

(3) risk-benefit profile;

(4) necessity.

2 trusted and relied upon the Misleading Public Message ~~Representations~~.

i) *in toto*, in circumstances so unreasonable that no reasonable person in the place of the Respondents acting carefully, reasonably, skillfully, and in good faith would have:

1 conducted themselves in the same manner as the Respondents, specifically the Reckless Failures - Approvals in the circumstances of the Known Serious Vaccines Risks And Conduct - Pre-Approvals when considering granting the Approvals;

2 made the decision to grant the Approvals in the circumstances of the Known Serious Vaccines Risks And Conduct - Pre-Approvals; or

3 in deed granted the Approvals.

Particulars

The particulars of the known facts manifesting the Reckless Failures - Approvals are contained in the factual matters pleaded herein in the Known Serious Vaccines Risks And Conduct - Pre-Approvals.

BREACH OF DUTY – APPROVALS

236. By reason of the acts and omissions of the Respondents in the Reckless Failures - Approvals, the Approvals were **("the Approvals Breach")**:

a) in breach of the Respondents Duty;

b) acts of gross negligence;

c) undertaken with knowledge of, or alternatively reckless indifference as to, the evident facts that the Approvals were undertaken:

1 in breach of Approvals Duty;

2 extraneous to any power under the Act, or otherwise, provided to the Respondents;

3 likely to cause harm.

d) not undertaken thereby in good faith.

RESPONDENTS CONDUCT – NEGLIGENCE AND BREACH OF DUTY IN CONTINUING APPROVALS

237. In the circumstances of and by reason of the acts, omissions and knowledge of the Respondents in connection with the granting of the Continuing Approvals purportedly pursuant to the Act since the time of the Approvals pleaded in the Known Serious Vaccines Risks And Conduct – Post-Approvals, the Continuing Approvals were and continue to be undertaken **("the Reckless Failures - Continuing Approvals")**:

a) in the known circumstances of:

1 the acts, omissions and knowledge of the Respondents in the:

(1) Known Serious Vaccines Risks And Conduct - Pre-Approvals;

(2) Known Serious Vaccines Risks And Conduct – Post-Approvals;

2 the knowledge of the grossly negligent and reckless acts and omissions of the Respondents undertaken in the Reckless Failures - Approvals by which the Approvals were already granted;

3 the consequent knowledge thereby that:

(1) the Approvals ought not to have been granted at that time or at all;

(2) the Continuing Approvals ongoing subsequent to the negligently and recklessly granted Approvals;

b) in breach of the following Statutory Obligations:

1 the TGA's Statutory Purpose;

2 the Register's Statutory Purpose;

3 the Provisional Determination Statutory Criteria;

4 the Provisional Registration Statutory Standard;

5 in breach of the balance of the above provisions, the failure to appropriately invoke the following statutory powers:

(1) the Statutory Revocation of Provisional Approval;

(2) the TGA Power to Obtain Documents;

(3) the TGA Power to Obtain Information;

(4) the Statutory Power to Suspend or Cancel by application of the appropriate Statutory Cancellation Standard;

c) in breach of the following TGA Policies:

1 the TGA Vaccine Regulation Policy;

2 the Adverse Events Identification;

3 the TGA Adverse Events Reporting Policy;

4 the TGA Provisional Approval Policy;

5 the TGA Safety Monitoring Policy;

6 the TGA AEFI Reporting Policy;

7 the TGA Safety Alert Policy;

8 the TGA Safety Covid Vaccines Information Policy;

9 the TGA Sponsors Pharmacovigilance Policy;

10 the TGA Sponsors Pharmacovigilance Policy 2;

11 the TGA Covid Vaccine Approvals Policy;

12 the TGA Covid Vaccine Evidence Policy;

13 the National Vaccines Adverse Events Reporting Procedure;

14 the EMA Pharmacovigilance Practice Policy;

15 First In Human Medicine Policy;

16 Pharmacovigilance in Vaccine Approvals Policy;

d) such that at all times since the Approvals in undertaking the Continuing Approvals the Vaccines were in fact:

1 not safe for their intended purpose;

2 not effective for their intended purpose;

3 not possessing of a positive risk-benefit profile;

e) such that at all times since the Approvals in undertaking the Continuing Approvals, the Vaccines were not demonstrated by the evidence known to the Respondents and reasonably available evidence globally to be reasonably or otherwise:

1 safe for their intended purpose;

2 effective for their intended purpose;

3 possessing of a positive risk-benefit profile.

f) such that at all times since the Approvals in undertaking the Continuing Approvals, the data and evidence known to the Respondents and reasonably available evidence globally obviously demonstrated that the Vaccines were in truth:

1 unsafe for their intended use;

2 ineffective for their intended use;

3 possessive of a grossly negative risk-benefit profile.

g) such that at all times since the Approvals in undertaking the Continuing Approvals, the Respondents did with knowledge or reckless indifference as to any obligation not to:

1 fail or refuse to consider or alternatively properly consider subsequent to the Approvals the known evidence and reasonably available evidence relevant to the Vaccines':

(1) safety;

(2) efficacy;

(3) risk-benefit profile;

(4) necessity;

2 fail or refuse to establish, satisfactorily establish, or alternatively reasonably establish the Vaccines':

(1) safety;

(2) efficacy; or

(3) benefits as exceeding their risks:

a) substantially;

b) significantly; or

c) at all.

3 ignore or dismiss the scientifically and reasonably established facts at all times since the Approvals that obviously demonstrate:

(1) in respect of the safety of each the Vaccines for their intended purpose:

a) the Vaccines were not safe;

b) further or in the alternative, that the Vaccines' safety was not established.

(2) in respect of the efficacy of each the Vaccines for their intended purpose:

a) the Vaccines were not effective;

b) further or in the alternative, that the Vaccines' efficacy was not established.

(3) in respect of the risk-benefit profile of each the Vaccines for their intended purpose:

a) the risks of the Vaccines exceeded their benefit;

b) further or in the alternative, it was not established that the Vaccines' benefit exceeded their risks.

4 ignore or dismiss entirely any scientific and logical analysis and quantification of the risk associated with natural Covid infection in the Australian population such that the Respondents at no time since the Approvals have properly engaged in a logical or scientifically based:

(1) risk-benefit analysis of the Vaccines;

(2) analysis of the need for the Vaccines in the Australian population:

a) generally;

b) in certain age sectors of the population;

c) in the sectors of the population already possessing antibodies acquired through natural immunity;

d) sectors of the population that were at elevated risk from serious adverse reactions arising from the Vaccines' unique composition.

h) with the knowledge of the Respondents in undertaking the Continuing Approvals, subsequent to the time of the Approvals that:

1 the studies undertaken by the Sponsors and data provided to the

Respondents before and subsequent to the Approvals disclosing that:

(1) no clinical testing or data establishing in any of the Vaccines the effect of:

a) prevention of transmission of the Virus;

b) prevention of infection with the Virus;

c) prevention of serious illness from Covid;

d) prevention of hospitalisation from Covid;

e) prevention of death from Covid;

f) use of the Vaccines in those for whom use was intended being the Untested Groups, including in:

i) pregnant women;

ii) immunocompromised people;

iii) people with certain pre-existing health conditions;

iv) people receiving other vaccines concurrently;

v) people with natural immunity resultant from prior infection with the Virus;

g) long-term efficacy;

h) genotoxicity;

i) carcinogenicity;

j) long-term safety.

k) extraordinary and unacceptable risks associated with the Vaccines being:

i) risks of serious adverse events;

ii) risk of death;

iii) unquantified and known risk of incorporation of the mRNA in the mRNA Vaccines into the human genome with the potential to cause intergenerational effects;

iv) risk of carcinogenicity;

v) risk of extreme and unquantified proliferation of the spike protein in the human body with the mRNA Vaccines;

vi) known and unquantified distribution and concentration of the Vaccines' lipid nanoparticle in the entire human body including the human organs for an untested and unquantified period;

vii) risk of Vaccine Associated Enhanced Disease;

viii) risk of use in pregnancy.

(2) there were such deficiencies in the scope and nature of the evidence provided by the Sponsors in support of and subsequent to the Applications so as to render a determination of safety, efficacy and positive risk-benefit in the Vaccines impossible;

(3) there were known factual matters which provided the

Respondents a reasonable basis to doubt the accuracy and quality of the data provided by the Sponsors prior and subsequent to the Applications;

(4) they did not at any time receive the patient-level data in respect of the Vaccines Clinical Trials before or subsequent to the Approvals such that:

a) the Respondents relied wholly upon the Sponsors' summaries and characterisations of the actual trial data without further investigation by the Respondents;

b) the Respondents were deprived of the possibility to apply rigorous analysis to the data upon which they relied in the Continuing Approvals;

c) risk-benefit analysis in respect of the stratification of risk by age and other sectors could not be accurately performed in the circumstances where Covid was known to disproportionately affect the elderly and the risks from Covid infection was negligible in the under 50 years sector of the population.

2 despite those deficiencies pleaded herein known to the Respondents, the Respondents proceeded to grant the Approvals:

(1) without any requirement by the Respondents for substantial provision of further studies or data from the Sponsors:

a) to remedy the deficiencies prior to the Approvals;

b) that would or did in fact remedy those deficiencies;

(2) by generally seeking and accepting an explanation from the Sponsor as to those deficiencies which were invariably accepted by the Respondents in lieu of any further data;

3 no special consideration or application was or has been given from

prior or subsequent to the Approvals given to the substantially heightened risks of injury and harm associated with the known:

(1) first ever in-human use and unknown effect of mRNA technologies in the mRNA Vaccines;

(2) the novel use of lipid nanoparticles in the Vaccines;

(3) the known fact that coronaviruses had never before been the subject of mass vaccination;

(4) the intention that and subsequent fact that the Vaccines were to be used on a mass scale to the Australian population;

(5) the reduction of the time taken for analysis and testing of the Vaccines to a fraction of that established historically and scientifically as appropriate for such analysis;

4 the Respondents at all times since the Approvals in undertaking the Continuing Approvals have done so:

(1) with no proper or reasonable evidentiary or logical basis to reasonably determine the Vaccines to be safe, effective and possessing a positive risk-benefit profile;

(2) having denied, ignored, or dismissed the evident substantial risks of the Vaccines obviously disclosed to the Respondents through the received data and scientifically known and reasonably available evidence;

(3) having accepted numerous unfounded explanations from the Sponsors as to why the data provided was deficient;

(4) where in truth possessing no statutory power to do so and acting extraneously to any power granted them under the Act because contrary to the express provisions of the Act and its stated purpose:

a) the data having been obtained by and/or reasonably available to the Respondents demonstrates to the Respondents reasonably that the Vaccines are and were at all times since the Approvals in truth:

i) unsafe for their intended use;

ii) ineffective for their intended use;

iii) possessive of a grossly negative risk-benefit profile.

b) further or in the alternative, the data obtained by and/or reasonably available to the Respondents at no time demonstrated that the Vaccines are and were at all times since the Approvals in truth:

i) safe for their intended use;

ii) effective for their intended use;

iii) possessive of a positive risk-benefit profile.

(5) doing so in the circumstances of the above knowledge since the Approvals, knowingly or alternatively with reckless indifference as to:

a) whether they possessed the statutory power to grant the Continuing Approvals;

b) whether the Vaccines were in truth and fact:

i) safe;

ii) effective;

iii) displaying a benefit substantially greater

than their known risks;

iv) necessary;

c) whether the Vaccines were able or likely to cause harm to those whom would receive the Vaccines in circumstances where the Vaccines were intended for use by:

i) almost the entire Australian Population;

ii) almost entirely healthy persons.

i) since the Approvals in undertaking the Continuing Approvals the Respondents have known the following:

1 that there was from that time and since a known proliferation of never-before seen volume and rate of adverse events reporting in respect of the Vaccines both in Australia and internationally;

2 that the Respondents have on an ongoing basis since that time engaged in denial of the known causality of reported adverse events arising in connection with the Vaccines by adopting a measure of causality:

(1) in abrogation of TGA Policies in respect of causation determination;

(2) unknown to the internationally accepted standards of adverse event causality assessment including:

a) Bradford-Hill Analysis;

b) WHO-UMC Standard;

c) the Naranjo Scale.

(3) adopting an erroneous standard for causality predicated upon the false presumption that causality, even where temporally associated with the Vaccines and reported to the DAEN:

a) is at best unlikely or lower;

b) unless and until the Respondents are satisfied by further data establishing positive causality in the mind of the Respondents;

(4) wherein the Respondents, despite positive obligations to do so, has advanced upon this false presumption of causality so as to deny the vast number of adverse events and deaths reported as temporally associated with the Vaccines by:

a) failing or refusing to conduct any or minimal further investigation in respect of those known adverse events and deaths;

b) where conducting any investigation, leaving open for prolonged and continuing periods any purported investigations of causality such that the Respondents continue to assert that causality has still not been established;

3 that each of the Vaccines represents an evident and known risk of death, serious illness or serious injury, the scope of which:

(1) based upon the evidence already before or reasonably available to the Respondents, has not been fully disclosed to the Australian public;

(2) vastly exceeded from the time of the Approvals, any benefits of the Vaccines;

(3) made manifest the obligation upon the Respondents under the Statutory Cancellation Standard and the Policies and Statutory Requirements relevant to the Approvals pleaded herein:

a) to withdraw the Approval of each of the Vaccines;

b) pursuant to the Statutory Power to Suspend or Cancel by application;

c) from the time of the Approvals, and at all times subsequent to the date of the Approvals.

j) that the Respondents since the time of Approvals, have failed or refused to identify or regard based upon the known post-Approval data the evident facts that the Vaccines are in truth:

1 not safe;

2 not effective;

3 not possessing a positive risk-benefit profile;

k) the Respondents, despite the ongoing safety surveillance data obtained and/or reasonably available to the Respondents after the time of the Approvals demonstrating the extraordinary risks and negative risk-benefit profile data of the Vaccines, continued to engage in the Continuing Approvals since that time despite these issues being made manifest in:

1 the proportional reporting ratios in respect of almost all manner of adverse reactions related to the Vaccines demonstrating the occurrence of adverse events at a rate exponentially higher than:

(1) similarly classified vaccines historically;

(2) the point at which the Respondents had previously declared to be a cause for safety concern;

2 the unprecedented proliferation of the rate of adverse event reporting temporally associated with the Vaccines as compared to historical data uniformly dismissed by the Respondents as of no concern on the erroneous bases that:

(1) the data is purportedly in line with “background rates” of illness and death;

(2) the reported deaths and events not being causally established by the Respondents based upon erroneous causality assessment or alternatively failures or delays in causality assessments by TGA Respondents;

(3) despite the extreme proportional reporting ratios displayed in the reporting of the Vaccines’ adverse events since the Approvals;

3 since the time of the Approvals, the increasingly evident negative risk-benefit profile of the Vaccines such that the risks associated with the Vaccines are based upon the known Approvals data and post-Approvals data are significantly higher than the benefits in circumstances where:

(1) the Respondents possess and possessed no power to approve or maintain approval of the Vaccines in those circumstances:

a) under the Act;

b) at all.

(2) the TGA Policies requiring that the Respondents would only approve and maintain upon the Register therapeutic products that display a risk – benefit profile precisely in the inverse: where the benefit significantly exceeds the risks;

l) that despite the obligation to do so pursuant to the TGA Policies, failed to issue safety alerts arising from the known data to the Australian public such that:

1 the Australian public has been underinformed or misinformed as to the true extent of safety issues and risks surrounding the Vaccines;

2 the Respondents continue to allow the Continuing Approvals upon

the basis that the Vaccines are still evidently safe;

m) from the time of the Approvals, based upon the data known and reasonably available to the Respondents including post-Approvals surveillance data the following have been made evident to the Respondents:

1 that since that time the Vaccines were not demonstrated by the evidence known to the Respondents and reasonably available evidence globally to be reasonably or otherwise:

(1) safe for their intended purpose;

(2) effective for their intended purpose;

(3) possessing of a positive risk-benefit profile.

2 that since that time the data and evidence known to the Respondents and reasonably available evidence globally obviously demonstrated that the Vaccines were in truth:

(1) unsafe for their intended use;

(2) ineffective for their intended use;

(3) possessive of a grossly negative risk-benefit profile.

3 that since that time the Respondents knew and in fact did:

(1) fail or refuse to consider or properly consider the known evidence and reasonably available evidence relevant to the Vaccines':

a) safety;

b) efficacy;

c) risk-benefit profile;

d) ongoing necessity;

(2) fail or refuse to establish the Vaccines, satisfactorily, reasonably or otherwise:

a) safety;

b) efficacy; or

c) benefits as exceeding their risks;

i) substantially;

ii) significantly; or

iii) at all.

(3) ignored or dismissed the scientifically and reasonably established facts since that time which obviously demonstrated:

a) in respect of the safety of each the Vaccines for their intended purpose:

i) the Vaccines were not safe;

ii) further or in the alternative, that the Vaccines' safety was not established.

b) in respect of the efficacy of each the Vaccines for their intended purpose:

i) the Vaccines were not effective;

ii) further or in the alternative, that the Vaccines' efficacy was not established.

c) in respect of the risk-benefit profile of each the Vaccines for their intended purpose:

i) the risk of the Vaccines exceeded their benefit;

ii) further or in the alternative, it was not established that the Vaccines' benefit exceeded their risks.

(4) ignored or dismissed entirely since that period any scientific and logical analysis and quantification of the risk associated with natural Covid infection in the Australian population such that the Respondents have not properly engaged in a logical or scientifically based:

a) risk-benefit analysis of the Vaccines;

b) analysis of the need for the Vaccines in the Australian population:

i) generally;

ii) in certain age sectors of the population;

iii) in the sectors of the population already possessing antibodies acquired through natural immunity;

iv) in sectors of the population that were at elevated risk from serious adverse reactions arising from the Vaccines' unique composition.

n) since the time of the Approvals, the Respondents knew that the studies undertaken by the Sponsors and further surveillance data provided to the Respondents disclosed subsequently to the Approvals that:

1 the testing and ongoing data does not establish in any of the Vaccines the effect of:

(1) prevention of transmission of the Virus;

(2) prevention of infection with the Virus;

(3) prevention of serious illness from Covid;

(4) prevention of hospitalisation from Covid;

(5) prevention of death from Covid;

(6) safety, efficacy, or positive risk-benefit in use of the Vaccines in those for whom use was intended including in:

a) pregnant women;

b) immunocompromised people;

c) people with certain pre-existing health conditions;

d) people receiving other vaccines concurrently;

e) people with natural immunity resultant from prior infection with the Virus;

f) long-term efficacy;

g) long-term safety.

2 there were extraordinary and unacceptable risks associated with the Vaccines being:

(1) risks of serious adverse events;

(2) risk of death;

3 the Vaccines displayed an exponentially negative risk-benefit profile for:

(1) the entire population of Australia;

(2) further or in the alternative, those person under 70 years of age;

4 that the Vaccines:

(1) are not safe for their intended use;

(2) are not effective for their intended use;

(3) possess significantly higher risk than benefit:

a) in all recipients of the Vaccines;

b) further or in the alternative, recipients under the age of 70 years.

o) despite these significant known risks and issues associated with the Vaccines made evident to the Respondents from the time of the Approvals, the Respondents continued to engage in the Continuing Approvals, without any proper or reasonable evidentiary or logical basis by continuing to:

1 determine that the Vaccines are safe, effective and possessing a positive risk-benefit profile;

2 deny, ignore, or dismiss the evident substantial risks of the Vaccines obviously disclosed to the Respondents through the received data, surveillance data, and scientifically known and reasonably available evidence;

3 possess no statutory power to engage in the Continuing Approvals and continuing thereby to act extraneously to any power granted them under the Act because contrary to the express provisions of the Act and its stated purpose, from the time of the Approvals:

(1) the data obtained by and known to the Respondents demonstrated that the Vaccines were in truth:

a) unsafe for their intended use;

b) ineffective for their intended use;

c) possessive of a grossly negative risk-benefit profile.

(2) further or in the alternative, the data obtained by and known to the Respondents at no time demonstrated that the Vaccines were:

a) safe for their intended use;

b) effective for their intended use;

c) possessive of a positive risk-benefit profile.

4 continuing from the time of the Approvals, to do so in the circumstances of the above knowledge, knowingly or alternatively with reckless indifference as to the evident facts that:

(1) the Respondents possess or possessed no statutory power to continue to engage in the Continuing Approvals;

(2) the Vaccines were in truth and fact:

a) not safe;

b) not effective;

c) not displaying a benefit substantially greater than their known risks;

d) not necessary;

(3) the Vaccines were able or likely to cause harm to those whom would receive the Vaccines in circumstances where the Vaccines were intended for:

a) almost the entire Australian Population;

b) almost entirely healthy persons.

p) in aggravating circumstances, contemporaneously with the Misleading Public Message ~~Vaccines Statements~~ such that subsequent to the Approvals the Australian public had:

1 been materially misled by the Respondents or those under their direction and authority as to the Vaccines' truly known or actual:

(1) safety for intended use;

(2) efficacy for intended use;

(3) risk-benefit profile;

(4) necessity.

2 trusted and relied upon the Misleading Representations.

q) *in toto*, in the circumstances, acting in the Continuing Approvals in a manner so unreasonable that no reasonable person in the place of the Respondents acting carefully, reasonably, skillfully, and in good faith would otherwise have:

1 conducted themselves in the same manner as the Respondents, specifically the Reckless Failures - Continuing Approvals, in the circumstances of the:

(1) Known Serious Vaccines Risks And Conduct - Approvals;

(2) Known Serious Vaccines Risks And Conduct - Continuing Approvals;

(3) the Reckless Failures - Approvals; and

(4) the Reckless Failures - Continuing Approvals;

2 made the decision to undertake the Continuing Approvals in the above circumstances;

3 in deed undertook the Continuing Approvals .

Particulars

The particulars of the known facts manifesting the Reckless Failures - Continuing Approvals are contained in the factual matters pleaded herein in the:

Known Serious Vaccines Risks And Conduct - Pre-Approvals;

Known Serious Vaccines Risks And Conduct - Post-Approvals;

Reckless Failures -Approvals.

BREACH OF DUTY – CONTINUING APPROVALS

238. By reason of the acts and omissions of the Respondents in the Reckless Failures - Approvals, the Continuing Approvals were **("the Continuing Approvals Breach")**:

a) in breach of the Respondents Duty;

b) acts of gross negligence;

c) undertaken with knowledge of, or alternatively reckless indifference as to, the evident facts that the Continuing Approvals were undertaken:

1 in breach of the Respondents Duty;

2 extraneous to any power under the Act, or otherwise, provided to the Respondents;

3 likely to cause harm;

4 not undertaken thereby in good faith.

239. But for one or more of the Approvals Breach and the Continuing Approvals Breach **("the Breaches")**, the Group Members would not have:

a) had access to the Vaccines;

b) received one or more of the Vaccines;

c) consequently suffered injury, loss and damage.

240. By reason of one or more of the Breaches, the Group Members:

a) had access to the Vaccines;

b) received one or more of the Vaccines;

c) consequently suffered loss or damage.

Particulars

The loss and damage to Mr Rose is the Rose Damages.
The loss and damage to Mr O'Gradie is the O'Gradie Damages.
The loss and damage to Mr Derose is the Derose Damages.

Particulars of each of the other Group Members' loss and damage may be provided after the trial of common issues but is expected to include:

1. personal injury;
2. health care expenses;
3. other out of pocket expenses;
4. economic loss;
5. the need for gratuitous and in addition, or alternatively, commercial care; and
6. non-economic loss.

PART N - MISFEASANCE CLAIM

PUBLIC OFFICERS

241. The Public Officers were at all material times:

a) employed by the Commonwealth;

b) acting for an on behalf of the Commonwealth;

c) in their respective positions:

1 holding public office;

2 discharging a public duty.

242. Whilst acting to administer the Act and the Regulations, the Public officers were exercising:

a) the executive power of the Commonwealth;

b) maintaining and executing a law of the Commonwealth.

243. The Public Officers in undertaking the Approvals and the Ongoing Approvals were each purportedly discharging a public duty in administering the Act and associated legislative instruments in exercising powers, functions and discretions under those instruments including to **("the Relevant Public Duties")**:

a) undertake all matters connected with the consideration of and granting of approvals for registration of therapeutic goods in Australia relevantly including:

b) maintain the Vaccines upon the Register subsequent to the Approvals;

c) undertake matters connected with the ongoing monitoring, assessment and pharmacovigilance after the Approvals in respect of the Vaccines;

d) make public statements in respect of those matters.

244. The powers to perform the Relevant Public Duties were at all material times conferred on the Public Officers by means of:

a) direct or delegation of a statutory power under the Act;

b) designation as an authorised person for the purpose of express powers under the Act;

c) the Commonwealth acting through the Department giving full allowance to TGA and the Public Officers to exercise the executive power of the Commonwealth under section 61 of the Constitution in the maintenance and execution of the Act; and/or

d) further and without limiting the above, the Commonwealth, so acting, giving full allowance to the Public Officers to determine when to exercise informal powers instead of, or in addition to, formal powers conferred under the Act;

245. By reason of the matters pleaded herein, when purporting to administer the Act, including by exercising any of the Relevant Public Duties purportedly pursuant to powers under the Act, each of the Public Officers:

a) were at all material times public officers exercising the executive power of the Commonwealth;

b) owed a duty to exercise the powers for the public good and not for any ulterior purpose;

c) owed that duty to the Group Members as members of the public in respect of which the Act operates.

MISFEASANCE IN PUBLIC OFFICE

246. The Public Officers engaged in the acts and omissions:

a) being **("the Misfeasance")**:

1 the Approvals; and

2 the Continuing Approvals;

3 ~~the Misleading Vaccines Statements~~;

b) with the knowledge, and in the circumstances of the following matters pleaded herein **("the Misfeasance Circumstances")**:

1 the Known Serious Vaccines Risks And Conduct - Approvals;

2 the Known Serious Vaccines Risks And Conduct – Continuing Approvals;

3 the Reckless Failures – Approvals;

4 the Reckless Failures – Continuing Approvals;

5 the Misleading Public Message; ~~Vaccines Statements~~

6 the Breaches;

247. The Misfeasance, to the extent that it was undertaken by the Public Officers as pleaded herein:

a) were exercises of power undertaken purportedly pursuant to a power:

1 incident to their office;

2 arising under the Act or associated legislative instruments;

b) were:

1 undertaken extraneous to and in excess of any powers provided for under the Act or at all;

2 thereby invalid exercises of power;

c) were in the circumstances and at all times likely to cause harm to the Group Members;

d) were undertaken with:

1 knowledge of the Public Officers that such conduct and purported exercise of power was:

(1) extraneous to and in excess of any powers provided for under the Act or at all;

(2) likely in the circumstances to cause harm to the Group Members.

2 further or in the alternative, reckless indifference by the Public Officers as to whether such conduct and purported exercise of power was:

(1) extraneous to and in excess of any powers provided for under the Act or at all;

(2) likely in the circumstances to cause harm to the Group Members.

Particulars

The known requisite knowledge or alternatively reckless indifference alleged in respect of the Public Officers arises upon the facts of knowledge held and acts of the Respondents undertaken in the Misfeasance Circumstances.

e) caused:

1 harm to the Group Members;

2 the harm to the Applicants pleaded herein.

Particulars of Damages

The loss and damage to Mr Rose is the Rose Damages.
The loss and damage to Mr O'Gradie is the O'Gradie Damages.
The loss and damage to Mr Derose is the Derose Damages.

Particulars of each of the other Group Members' loss and damage may be provided after the trial of common issues but is expected to include:

personal injury;
health care expenses;
other out of pocket expenses;
economic loss;
the need for gratuitous and in addition, or alternatively, commercial care; and
non-economic loss.

BREACH OF STATUTORY DUTY

248. In the premises of the factual and legal matters pleaded herein, the Respondents breached their statutory duty arising under the Act.

VICARIOUS LIABILITY OF THE COMMONWEALTH

249. The Commonwealth is vicariously liable for the any and all tortious actions by the Public Officers in this proceeding pleaded herein because those actions:

a) were undertaken in the purported administration of the Act;

b) the Commonwealth through the Department gave full allowance to the Public Officers, the TGA and to its various senior officers, to make decisions in respect of the execution and maintenance of the Act subject to the general direction of the Commonwealth;

c) the executive power of the Commonwealth under s. 61 of the Constitution was exercised by the TGA in general and the Public Officers in particular so far as it concerned the execution and maintenance of the Act;

d) by way of appointment to their positions, the Public Officers had actual *de*

facto authority to make decisions concerning the execution and maintenance of the Act on behalf of the Commonwealth;

e) by conferring the office and title on each of the Public Officers and permitting them to hold themselves out as such and/or holding senior positions within the TGA and the Department, bodies in turn held out as being responsible for the administering of the Act:

1 the Commonwealth clothed each of the Public Officers with authority:

(1) to act and speak for and on behalf of the Commonwealth in respect to matters concerning the Act; and

(2) thereby to act as representative of the Commonwealth; and

2 the Public Officers were thereby relevantly "officers of the Commonwealth" for the purposes of s. 75(v) of the Constitution;

f) the tortious acts alleged against the Public Officers in this proceeding occurred in all instances and at all material times within the scope of the authority alleged above;

g) further, or in the alternative, the Applicants:

1 will contend that in all of the circumstances pleaded and particularised herein, the conduct of the Public Officers was the conduct of the Commonwealth;

2 will rely on:

(1) s. 61 and s. 64 of the Constitution;

(2) s. 56 and s. 64 of the *Judiciary Act 1903* (Cth)*;* and

(3) the unwritten law of vicarious liability.

250. In the premises each of the said actions was done so as to render the Commonwealth liable in law for the actions of the Public Officers and any and all

unidentified officers of the TGA.

FORESEEABILITY AND CAUSATION

251. The Commonwealth of Australia and the Public Officers:

a) knew that the Misfeasance was likely to cause loss and damage to the Group Members;

b) further or in the alternative, were recklessly indifferent to the fact that the Misfeasance was likely to cause loss and damage to the Group Members.

252. The Commonwealth of Australia and the Public Officers:

a) knew that the Misfeasance were made in the absence of power to do so:

1 under the Act; or

2 at all.

b) further or in the alternative, were recklessly indifferent to the fact that the Misfeasance were made in the absence of power to do so:

1 under the Act; or

2 at all.

253. But for one or more of the acts or omissions constituting the Misfeasance, the Group Members would not have suffered:

a) personal injuries;

b) loss and damage.

254. But for the conduct of the Commonwealth of Australia and the Public Officers, the Applicants would not have suffered these losses and is entitled to claim each loss, including the loss reflective of the Applicants' loss, against the Commonwealth of Australia for the conduct of the Public Officers in engaging in misfeasance in public

office.

255. The Commonwealth of Australia is liable for any damages, including exemplary damages, that would be awarded in favour of the Applicants as against the Public Officers for their conduct as pleaded in this proceeding.

DAMAGES

256. By reason of the above matters, the Applicants have suffered loss and damage.

257. The Applicants on their own behalf and on behalf of other Group Members, claim relief as follows from each of the Respondents:

a) Damages;

b) Interest in pursuant to s. 51A and s. 52 of the *Federal Court of Australia Act 1976* (Cth);

c) Costs.

PART O - PARTICULARS OF LOSS AND DAMAGE

1. As to Mr Rose - the Rose Injuries;

2. As to Mr Derose - the Derose Injuries;

3. As to Mr O'Gradie - the O'Gradie Injuries;

4. As to all of the Applicants:

a. Health care expenses.

b. Additional out of pocket expenses.

c. Economic loss.

d. The need for gratuitous care and additionally or alternatively, commercial care.

e. Non-economic loss.

f. Additional particulars may be provided following the service of evidence.

Date: 26 April, 2023

Signed by Natalie Strijland

Lawyer for the Applicant

This pleading was prepared by J.M. Manner of Counsel.

Certificate of Lawyer

I, Natalie Strijland, certify to the Court that, in relation to the statement of claim filed on behalf of the Applicant, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 26 April, 2023

Signed by Natalie Strijland
Lawyer for the Applicant