To the Attorney General of Australia,

I am an Australian Citizen, living in Melbourne Victoria, who seeks protection under my absolute and non-derogable right under article 4(2) of the ICCPR **freedom from medical or scientific experimentation without consent (art 7)** (which, as stated in the Australian Government Attorney General's Department) cannot be suspended **even in a state of emergency**.

I do not consent to be involved in a COVID-19 vaccination program which involves the use of a vaccine that are still experimental and have not been approved.
I am being coerced, manipulated and discriminated against for my decision to not be involved and I ask for your immediate intervention and protection on my behalf.

I am willing to purchase and take a regular rapid antigen test as a less restrictive alternative and ask that you act on my behalf to make this option, and any other reasonable less restrictive option, available to me **immediately** in a way that allows me to not be discriminated against.
I would also like your advice on

1. How I can challenge my right to not be discriminated against when accessing services
2. How I can get a vaccination exemption until the vaccines are not experimental
3. How I can get my doctor to support me in postponing a vaccination requirement until the vaccines are no longer experimental
4. How I can choose the vaccine that has shown the most clinical efficacy and least adverse effects
5. How I can hold my government to account as they are not abiding by a non-derogable right under article 4(2) of the ICCPR **freedom from medical or scientific experimentation without consent (art 7, freedom from punishment, freedom of thought, conscience and religion**.

I would also ask you to protect my right to

1. **'Freedom from … punishment'** as I am being excluded from work and services because of my choice to not consent to an experimental vaccine.
2. **'Freedom of thought, conscience and religion'**
    a. I have been thoroughly looking at the science behind the vaccines and am well informed with international statistics. My understanding cautions me to wait for further information.
    b. I recently learned that the Pfizer vaccine includes human embryo cells (which Pfizer has not been willing to publicise) and this goes against my conscience.
    c. And finally, I learned that Moderna has suspended using the vaccine for 12–17-year-old due to health concerns and even though they are saying this based on adverse events the Australian Government continues to allow Moderna vaccines for young people AGAINST adverse reactions data.

For further information I have include, below information that has helped me to understand my rights and the reason why I contacted you and I have highlighted the areas that stand out most to me.

Yours Sincerely,

Sourced from Deputy Lyndall Dean Fair Work Commission Decision 2021

Vaccinations should be voluntary

a. Unlike many other vaccinations such as those used to stop the spread of tetanus, yellow fever and smallpox, COVID vaccinations are not designed to stop COVID. They are designed to reduce the symptoms of the virus, however a fully vaccinated person can contract and transmit COVID.

b. The science is clear in that COVID is less serious for those who are young and otherwise healthy compared to those who are elderly and/or who have co-morbidities. In other words, the risk of COVID is far greater for those who are elderly or have co-morbidities. Around 87% of those who have died with COVID in Australia are over 80 years old and had other pre-existing illnesses listed on their death certificates.

c. The World Health Organisation has stated that most people diagnosed with COVID will recover without the need for any medical treatment.

d. The vaccines are only provisionally approved for use in Australia and are accordingly still part of a clinical trial 20.

e. There are side effects to the COVID vaccines that are now known. That side effects exist is not a conspiracy theory.

f. The long-term effects of the COVID vaccines are unknown, and this is recognised by the Therapeutic Goods Administration (TGA) in Australia.

Consent is required for participation in clinical trials

[114] Consent is required for all participation in a clinical trial. Consent is necessary because people have a fundamental right to bodily integrity, that being autonomy and self-determination over their own body without unconsented physical intrusion. Voluntary consent for any medical treatment has been a fundamental part of the laws of Australia and internationally for decades.
It is legally, ethically and morally wrong to coerce a person to participate in a clinical trial.

[115] Coercion is not consent. Coercion is the practice of persuading someone to do something using force or threats. Some have suggested that there is no coercion in threatening a person with dismissal and withdrawing their ability to participate in society if that person does not have the COVID vaccine. However, nothing could be further from the truth.

[116] All COVID vaccines in Australia are only provisionally approved, and as such remain part of a clinical trial 21. This is not part of a conspiracy theory. It is a fact easily verifiable from the website of the TGA, Australia's regulatory authority responsible for assessing and registering/approving all COVID vaccines before they can be used in Australia.

[117] The requirement for consent in this context is not new and should never be controversial. The Nuremburg Code (the Code), formulated in 1947 in response to Nazi doctors performing medical experiments on people during WWII, is one of the most important documents in the history of the ethics of medical research.

[118] The first principle of the Code is that "The voluntary consent of the human subject is absolutely essential". The Code goes on to say that "This means that the person involved should have legal

capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision...."

[119] Informed and freely given consent is at the heart of the Code and is rightly viewed as a protection of a person's human rights.

[120] The United Nations, including through the *Universal Declaration of Human Rights*, first proclaimed in 1948, has long recognised the right to bodily integrity.

[121] The Declaration of Helsinki (the Declaration), made in 1964 by the World Medical Association, is also a statement of ethical principles for medical research involving human subjects. Under the heading of "Informed Consent", the Declaration starts with the acknowledgement that "Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary".

[122] Australia is a party to the seven core international human rights treaties, including the *International Covenant on Civil and Political Rights*.

[123] The *Australian Human Right Commission Act 1986 (Cth)* gives effect to Australia's obligations under the *International Covenant on Civil and Political Rights*, which provides in Article 7 that "...no one shall be subjected without his free consent to medical or scientific experimentation".

[124] In 1984, the American Association for the International Commission of Jurists (AAICJ) held an international colloquium in Siracusa, Italy, which was co-sponsored by the International Commission of Jurists. The focus of the colloquium was the limitation and derogation provisions of the *International Covenant on Civil and Political Rights*, and the outcome is a document that is referred to as the *Siracusa Principles* 22.

[125] The introductory note to the Siracusa Principles commences in the following terms:

> "It has long been observed by the American Association for the International Commission of Jurists (AAICJ) that one of the main instruments employed by governments to repress and deny the fundamental rights and freedoms of peoples has been the illegal and unwarranted Declaration of Martial Law or a State of Emergency. Very often these measures are taken under the pretext of the existence of a "public emergency which threatens the life of a nation" or "threats to national security".
>
> The abuse of applicable provisions allowing governments to limit or derogate from certain rights contained in the International Covenant on Civil and Political Rights has resulted in the need for a closer examination of the conditions and grounds for permissible limitations and derogations in order to achieve an effective implementation of the rule of law. The United Nations General Assembly has frequently emphasised the importance of a uniform interpretation of limitations on rights enunciated in the Covenant."

[126] Paragraph 58 of the Siracusa Principles under the heading of Non-Derogable Rights provides:

> **No state party shall, even in time of emergency threatening the life of the nation, derogate from the Covenant's guarantees** of the right to life; freedom from torture, cruel, inhuman or degrading treatment or punishment, **and from medical or scientific experimentation without free consent**; freedom from slavery or involuntary servitude; the right not be be imprisoned for contractual debt; the right not to be convicted or sentenced to a heavier penalty by virtue of retroactive

criminal legislation; the right to recognition as a person before the law; and freedom of thought, conscience and religion. **These rights are not derogable under any conditions even for the asserted purpose of preserving the life of the nation**. (emphasis added)

[127] This is consistent with Article 4 of the *International Covenant on Civil and Political Rights.*

[128] Australia's *National Statement on Ethical Conduct in Human Research* 23 confirms that consent is a fundamental requirement for participation in any clinical trial, and that "no person should be subject to coercion or pressure in deciding whether to participate" in a clinical trial. Further, the Australian Government's *Consumer Guide to Clinical Trials*24 also confirms that participation in a clinical trial is voluntary, and states "it is important that you never feel forced to take part in a trial".

[129] Freely given consent to any medical treatment, particularly in the context of a clinical trial, is not optional. Coercion is completely incompatible with consent, and denying a person the ability to work and participate in society if the person does not have a COVID vaccine will unquestionably breach this fundamental and internationally recognised human right.

Can COVID vaccinations be mandated by employers on health and safety grounds?

[130] The short answer to this question, in almost every case, is no.

[131] The fundamental starting point here is the answer to the question – what is the risk? All risk controls are (or should be) designed to address an identified risk. The risk needs to be a real risk and not a perceived risk. The real risk for employers is that a person who has COVID will spread COVID to others within the workplace.

[132] The risk of spreading COVID only arises with a person who *has* COVID. This should be apparent and obvious. There is no risk associated with a person who is unvaccinated and does not have COVID, notwithstanding the misleading statements by politicians that the unvaccinated are a significant threat to the vaccinated, supposedly justifying "locking out the unvaccinated from society" and denying them the ability to work.

[133] The primary duty of care for employers under health and safety law requires the employer to ensure health and safety so far as is reasonably practicable by eliminating risks to health and safety, and if this is not reasonably practicable, risks must be minimised so far as is reasonably practicable.

[134] There is nothing controversial in stating that vaccines do not *eliminate* the risk of COVID, given that those who are vaccinated can catch and transmit COVID. By way of one example, a report issued by the Centres for Disease Control and Prevention (CDC) in the United States on 6 August 2021 25 looked at an outbreak of COVID in Massachusetts during July 2021. Of the 469 COVID cases identified, 74% were fully vaccinated. Of this group, 79% were symptomatic. In total, 5 people required hospitalisation and of these, 4 were fully vaccinated. This is not an anomaly – the data from many countries and other parts of the United States provides a similar picture, although obtaining similar data from the United States will now be problematic given the decision by the CDC on 1 May 2021 to cease monitoring and recording breakthrough case information unless the person is hospitalised or dies. What is clear, however, is that the vaccine is not an effective control measure to deal with transmission of COVID by itself.

[135] In order for an employer to meet its duties under health and safety laws, it will need to minimise the risk of exposure to COVID in the workplace, which will require employers to apply all *reasonably practicable* COVID control measures.

[136] As noted earlier, Safe Work Australia, in relation to whether employers need to include mandatory vaccination as a control measure to comply with WHS duties, has advised that "it is unlikely that a requirement for workers to be vaccinated will be 'reasonably practicable'".

[137] The Safe Work Australia website also includes the following advice to employers:

> "Employers have a duty under the model Work Health and Safety (WHS) laws to eliminate, or if that is not reasonably practicable, minimise the risk of exposure to COVID-19 in the workplace.
>
> ..... However, while this is a decision you will need to make taking into account your workplace, **most employers will not need to make vaccination mandatory to comply with the model WHS laws**.
>
> A safe and effective vaccine is only one part of keeping the Australian community safe and healthy. To meet your duties under the model WHS laws and minimise the risk of exposure to COVID-19 in your workplace, you must continue to apply all reasonably practicable COVID-19 control measures including physical distancing, good hygiene and regular cleaning and maintenance and ensuring your workers do not attend work if they are unwell." 26

[138] It is very clear that a range of control measures will need to be implemented by employers to meet their health and safety obligations. In addition to the measures noted above, controls (based on a proper assessment of the risk in a particular workplace) might include appropriate air ventilation and filters, personal protective equipment including masks, staggered meal breaks, increased use of outdoor areas etc. The simple act of requiring people to stay at home if unwell and symptomatic will no doubt have a significant impact on the spread of all coronaviruses (whether a cold, flu or COVID).

[139] Critically, there is another alternative to vaccines to assist employers in meeting their WHS obligations, that being testing. Given there is no doubt that those who are fully vaccinated can catch and transmit the virus, testing (whether rapid antigen or otherwise) will provide employers with a level of comfort that a worker does not have COVID and therefore will not transmit COVID to others (that being the risk that is to be managed) in the workplace.

[140] Testing is now widely used around the world as a risk control for the spread of COVID. There is absolutely no reason why it cannot be widely used in Australia.

[141] Testing is arguably a better control measure compared to vaccines in meeting health and safety obligations.

[142] Vaccines have not been broadly mandated on health and safety grounds in most countries. For example, despite what has been reported in Australia, most of the European Union (EU) and the Scandinavian countries have not actually mandated vaccinations for travel purposes. EU citizens can travel freely now if any one of three options are satisfied, that being a vaccine, a negative COVID test, or evidence of having recently recovered from COVID (in recognition of the natural immunity that comes with having recovered from having COVID). The EU have provided these options so that people who are not vaccinated will not be discriminated against when travelling across the EU. In other words, all those who are not vaccinated can get tested for COVID and travel freely 27.

[143] In a scientific brief prepared by the World Health Organisation (WHO) dated 10 May 2021 on COVID natural immunity, the WHO found that "within four weeks following infection, 90-99% of individuals infected with [COVID] virus develop detectable neutralising antibodies....". Further, "available scientific data suggests that in most people immune responses remain robust and

protective against reinfection for at least 6-8 months after infection (the longest follow up with strong scientific evidence is currently approximately 8 months)".

[144] The science is clear that those who have recovered from COVID have at least the same level of protection from COVID as a person who has been vaccinated. There can be absolutely no legitimate basis, then, for mandating vaccination for this group of people.

[145] In short, there is no justifiable basis for employers to mandate COVID vaccinations to meet their health and safety obligations when other options are available to appropriately manage the risk.

[146] Finally, it should be clearly understood that employers who mandate vaccinations will be liable for any adverse reactions their workers may experience, given this is a foreseeable outcome for some people.

Use of Public Health Orders to mandate vaccinations

[152] The Australian Health Protection Principal Committee (AHPPC) is Australia's key decision making body for heath emergencies and public health emergency management. It has issued a number of public statements on minimising the potential risk of COVID 28, the purpose of which is to provide advice on the appropriate management of COVID in certain industries or occupation groups.

[153] A statement on COVID vaccination requirements for aged care workers it issued on 4 June 2021 29 commences with the following:

> "AHPPC **does not** recommend compulsory COVID-19 vaccines for aged care workers" (emphasis added)

[154] Notwithstanding this advice, a PHO has been made mandating COVID vaccinations for aged care workers.

[155] The AHPPC statement on minimising the potential risk of COVID transmission in schools, made on 26 July 2021, does not recommend compulsory COVID vaccines for school staff either.

161] The Great Barrington Declaration (GB Declaration) 31, a statement by infectious disease epidemiologists and public health scientists, recommended an approach called Focused Protection. The GB Declaration includes the following:

> "Current lockdown policies are producing devastating effects on short and long-term public health. The results (to name a few) include lower childhood vaccination rates, worsening cardiovascular disease outcomes, fewer cancer screenings and deteriorating mental health – leading to greater excess mortality in years to come, with the working class and younger members of society carrying the heaviest burden. Keeping students out of school is a grave injustice.
>
> ….We know that vulnerability to death from COVID-19 is more than a thousand-fold higher in the old and infirm than the young. Indeed, for children, COVID-19 is less dangerous than many other harms, including influenza.
>
> As immunity builds in the population, the risk of infection to all – including the vulnerable – falls. We know that all populations will eventually reach herd immunity – i.e. the point at which the rate of new infections is stable – **and that this can be assisted by (but is not dependent upon) a**

vaccine. Our goal should therefore be to minimize mortality and social harm until we reach herd immunity.

The most compassionate approach that balances the risks and benefits of reaching herd immunity, is to allow those who are at minimal risk of death to live their lives normally to build up immunity to the virus through natural infection, while better protecting those who are at highest risk. We call this Focused Protection.

Adopting measures to protect the vulnerable should be the central aim of public health responses to COVID-19. By way of example, nursing homes should use staff with acquired immunity and perform frequent testing of other staff and all visitors. Staff rotation should be minimized. Retired people living at home should have groceries and other essentials delivered to their home. When possible, they should meet family members outside rather than inside. A comprehensive and detailed list of measures, including approaches to multi-generational households, can be implemented, and is well within the scope and capability of public health professionals.

Those who are not vulnerable should immediately be allowed to resume life as normal. Simple hygiene measures, such as hand washing and staying home when sick should be practiced by everyone to reduce the herd immunity threshold. Schools and universities should be open for in-person teaching. Extracurricular activities, such as sports, should be resumed. Young low-risk adults should work normally, rather than from home. Restaurants and other businesses should open. Arts, music, sport and other cultural activities should resume. People who are more at risk may participate if they wish, while society as a whole enjoys the protection conferred upon the vulnerable by those who have built up herd immunity." (emphasis added)

[162] The authors and first signatories to the GB Declaration were Dr. Martin Kulldorff, professor of medicine at Harvard University, a biostatistician, and epidemiologist with expertise in detecting and monitoring infectious disease outbreaks and vaccine safety evaluations, Dr. Sunetra Gupta, professor at Oxford University, an epidemiologist with expertise in immunology, vaccine development, and mathematical modelling of infectious diseases, and Dr. Jay Bhattacharya, professor at Stanford University Medical School, a physician, epidemiologist, health economist, and public health policy expert focusing on infectious diseases and vulnerable populations.

[163] The qualifications held by the list of 44 co-signatories to the GB Declaration is impressive 32, and since the GB Declaration was first made, over 860,000 scientists and health professionals have signed the GB Declaration.

[164] It should be abundantly clear that there are other, far less restrictive and less intrusive ways in which we can ensure public health and appropriately address the risk of COVID without resorting to the extreme measures currently in place.

[165] In an article published by Monash University's Castan Centre for Human Rights Law, the author, Professor the Hon Kevin Bell AM QC 33, considered the COVID guidance issued by the United Nations Office of the High Commissioner for Human Rights for introducing COVID response measures consistent with human rights. He provided the following summary:

- "Governments have to take difficult decisions in response to COVID-19. International law allows emergency measures in response to significant threats – but measures that restrict human rights should be proportionate to the evaluated risk, necessary and applied in a non-discriminatory way. This means having a specific focus and duration, and taking the least intrusive approach possible to protect public health.

- With regard to COVID-19, emergency powers must only be used for legitimate public health goals, not used as a basis to quash dissent, silence the work of human rights defenders or journalists, deny other human rights or take any other steps that are not strictly necessary to address the health situation.
- Governments should inform the affected population of what the emergency measures are, where they apply and for how long they are intended to remain in effect, and should update this information regularly and make it widely available.
- As soon as feasible, it will be important for Governments to ensure a return to life as normal and not use emergency powers to indefinitely regulate day-to-day life, recognising that the response must match the needs of different phases of the crisis".

[166] In an article recently published by two Senior Lecturers from the Faculty of Law at Monash University entitled "*Wars, Pandemics and Emergencies What can history tell us about executive power and surveillance in times of Crisis?*" 34, the authors concluded that "in an emergency, we must be particularly vigilant to protect civil liberties and human rights against incursions that are more than the absolute minimum necessary to combat the crisis....."

[167] The Australian Financial Review, in an article published on 8 September 2021 entitled "*The 17,000 flu linked deaths no one is talking about*" 35, notes that modelling by the Doherty Institute says about 600 people die each year of influenza and there are about 200,000 cases annually, but in 2019, influenza and pneumonia were the underlying cause of 4124 deaths in Australia. While the vast majority of these deaths are people over the age of 80, there is an annual average of 5 infants under the age of one, 13 children aged 1-14, and 48 people aged 25-44 that died of flu or pneumonia in 2019.

[168] The article goes on to note that about 17,385 people died *with* flu and pneumonia in 2019, where flu and pneumonia was either the underlying cause or an associate cause of death, according to the Australian Bureau of Statistics. In Sweden, doctors in one county analysed all their COVID deaths and found that COVID was the chief underlying cause of death in only 15% of cases. In 70% of cases COVID was an associated cause of death, and in the remaining 15% of cases it was irrelevant.

[169] To put all of this further in perspective, Australia is ranked 118th in the world for COVID deaths. Broadly speaking, Australia has had around 56,000 cases of COVID with around 1,000 deaths. Of the deaths in Australia, only 1% were under the age of 50. In the same time period as the 1,000 COVID deaths, around 200,000 Australians have died for other reasons, including around 70,000 from cancer, 19,000 from heart disease, 17,000 from respiratory illnesses (not COVID), 13,000 from strokes and 4,500 from suicide.

[170] Each and every single day, around 8,000 children die around the world from starvation, which of course is completely preventable.

[171] As at 2019, there were 4,344 paedophiles in NSW on the Child Protection Register. There are no blanket rules which prevent these people from working or participating in society, nor do they have to declare that they are paedophiles before entering a business or a school.

[172] The initial predictions of a 60% infection rate from COVID with a 1% death rate thankfully did not materialise. It is now time to ask whether the 'cure' is proportionate to the risk, and the answer should be a resounding no. When deciding now what is actually reasonable, necessary and proportionate in terms of any response to COVID, governments and employers should actively avoid

the hysteria and fear-mongering that is now so prevalent in the public discourse, and which will cloud rational, fact based decision making.

[173] In summary, the powers to make PHOs cannot lawfully be used in a way that is punitive, and human rights are not suspended during states of emergency or disaster. The current PHOs have moved well past the minimum necessary to achieve public health aims, and into the realm of depravation. It is not proportionate, reasonable or necessary to "lock out" those who are unvaccinated and remove their ability to work or otherwise contribute to society. PHOs, by their nature, are designed and intended for short term use in the event of an emergency or crisis. They are not intended to be an ongoing vehicle to enforce significant depravations of our civil liberties. The COVID pandemic started over 20 months ago. The time is fast approaching where the reliance on PHO's will no longer be justified on public health grounds, particularly where there is such a significant intrusion on individual liberties.

Disability Discrimination

[174] It is highly likely that the dismissal of an employee who fails to have the COVID vaccine will breach the *Disability Discrimination Act 1992* (DD Act). The DD Act makes it unlawful to discriminate against a person, including in employment and in accessing services, because of a disability.

[175] The definition of disability in s.4 of the DD Act includes "the presence in the body of organisms capable of causing disease or illness". It includes a disability that presently exists, or previously existed but no longer exists, or may exist in the future, or is imputed to a person.

[176] The Explanatory Memorandum to the DD Act discusses the definition of disability as being:

> "…intended to include physical, sensory, intellectual and psychiatric impairment, mental illness or disorder, and provisions relating to the presence in the body of organisms capable of causing disease. These provisions have broad application, for example, they are intended to ensure that persons with HIV/AIDS come within the definition of disability for the purposes of this Bill."

[177] As a recent article has highlighted, 36 gay men were the prime target for protection under this part of the definition of disability because of a perception they were at a greater risk from HIV. In this situation the DD Act works to prohibit all types of discrimination not only against gay men but everyone who may in future be infected with HIV. The author notes that "for the same legal reason that a publican cannot say 'gay men are not allowed into my pub because they might be infected with HIV', a publican also cannot say 'unvaccinated people are not allowed into my pub because they might be infected with measles. Nor is it valid for a State or Territory to pass a law to that effect – the Act binds them too."

[178] Section 48 of the DD Act provides an exemption for discrimination that is necessary to protect public health where a person's disability is an infectious disease, however being unvaccinated is not an infectious disease. What logically follows is that an employer who dismisses a person because they do not have a COVID vaccine will breach the DD Act.

Final comments

[179] Research in the context of COVID-19 has shown that many who are 'vaccine-hesitant' are well educated, work in the health care industry and have questions about how effective the vaccines are in stopping transmission, whether they are safe to take during pregnancy, or if they affect fertility. 37 A far safer and more democratic approach to addressing vaccine hesitancy, and therefore increasing

voluntary vaccination uptake, lies in better education, addressing specific and often legitimate concerns that people may hold, and promoting genuine informed consent. It does not lie in censoring differing opinions or removing rights and civil liberties that are fundamental in a democratic nation. It certainly does not lie in the use of highly coercive, undemocratic and unethical mandates.

[180] The statements by politicians that those who are not vaccinated are a threat to public health and should be "locked out of society" and denied the ability to work are not measures to protect public health. They are not about public health and not justified because they do not address the actual risk of COVID. These measures can only be about punishing those who choose not to be vaccinated. If the purpose of the PHOs is genuinely to reduce the spread of COVID, there is no basis for locking out people who do not have COVID, which is easily established by a rapid antigen test. Conversely, a vaccinated person who contracts COVID should be required to isolate until such time as they have recovered.

[181] Blanket rules, such as mandating vaccinations for everyone across a whole profession or industry regardless of the actual risk, fail the tests of proportionality, necessity and reasonableness. It is more than the absolute minimum necessary to combat the crisis and cannot be justified on health grounds. It is a lazy and fundamentally flawed approach to risk management and should be soundly rejected by courts when challenged.

[182] All Australians should vigorously oppose the introduction of a system of medical apartheid and segregation in Australia. It is an abhorrent concept and is morally and ethically wrong, and the anthesis of our democratic way of life and everything we value.

[183] Australians should also vigorously oppose the ongoing censorship of any views that question the current policies regarding COVID. Science is no longer science if it a person is not allowed to question it.

[184] Finally, all Australians, including those who hold or are suspected of holding "anti-vaccination sentiments", are entitled to the protection of our laws, including the protections afforded by the Fair Work Act. In this regard, one can only hope that the Majority Decision is recognised as an anomaly and not followed by others.

VICE PRESIDENT

Appearances:

Mr *J Pearce* of counsel for the Appellant.

Mr *R Reitano* of counsel for the Respondent.

Hearing details:

2021.

Sydney (via video-link):

29 June.

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VRBPAC Briefing Document

Vaccines and Related Biological Products Advisory Committee Meeting December 17, 2020 FDA Briefing Document Moderna COVID-19 Vaccine

8.3 Known Risks The vaccine elicited increased local and systemic adverse reactions as compared to those in the placebo arm, usually lasting a few days.

The most common solicited adverse reactions were pain at injection site (91.6%), fatigue (68.5%), headache (63.0%), muscle pain (59.6%), joint pain (44.8%), and chills (43.4%).

Adverse reactions characterized as reactogenicity were generally mild to moderate; 0.2% to 9.7% of these events were reported as severe, with severe solicited adverse reactions being more frequent after dose 2 than after dose 1 and generally less frequent in older adults (≥65 years of age) as compared to younger participants.

Among reported unsolicited adverse events, lymphadenopathy occurred much more frequently in the vaccine group than the placebo group and is plausibly related to vaccination. The number of participants reporting hypersensitivity-related adverse events was numerically higher in the vaccine group compared with the placebo group (258 events in 233 participants [1.5%] vs. 185 events in 166 participants [1.1%]). There were no anaphylactic or severe hypersensitivity reactions with close temporal relation to the vaccine.

Serious adverse events, while uncommon (1.0% in both treatment groups), represented medical events that occur in the general population at similar frequency as observed in the study. Of the 7 SAEs in the mRNA-1273 group that were considered as related by the investigator, FDA considered 3 as related: intractable nausea and vomiting (n=1), facial swelling (n=2).

For the serious adverse events of rheumatoid arthritis, peripheral edema/dyspnea with exertion, and autonomic dysfunction, a possibility of vaccine contribution cannot be excluded.

For the event of B-cell lymphoma, an alternative etiology is more likely.

An SAE of Bell's palsy occurred in a vaccine recipient, for which a causal relationship to vaccination cannot be concluded at this time.

No specific safety concerns were identified in subgroup analyses by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection.

8.4 Unknown Risks/Data Gaps Safety in certain subpopulations

There are currently insufficient data to make conclusions about the safety of the vaccine in subpopulations such as children less than 18 years of age, pregnant and lactating individuals, and immunocompromised individuals. FDA review of a combined developmental and perinatal/postnatal reproductive toxicity study of mRNA-1273 in female rats concluded that mRNA1273 given prior to mating and during gestation periods at dose of 100 µg did not have any effects on female reproduction, fetal/embryonal development, or postnatal developmental except for skeletal variations which are common and typically resolve postnatally without intervention Adverse reactions that are very uncommon or that require longer follow-up to be detected

Following authorization of the vaccine, use in large numbers of individuals may reveal additional, potentially less frequent and/or more serious adverse events not detected in the trial safety population of approximately 30,000 participants over the period of follow-up at this time.

Active and passive safety surveillance will continue during the post-authorization period to detect new safety signals.

51 Moderna COVID-19 Vaccine VRBPAC Briefing Document

Although the safety database revealed an imbalance of cases of Bell's palsy (3 in the vaccine group and 1 in the placebo group), causal relationship is less certain because the number of cases was small and not more frequent than expected in the general population. Further signal detection efforts for these adverse events will be informative with more widespread use of the vaccine.

Vaccine-enhanced disease

Available data do not indicate a risk of vaccine-enhanced disease, and conversely suggest effectiveness against severe disease within the available follow-up period. However, risk of vaccine-enhanced disease over time, potentially associated with waning immunity, remains unknown and needs to be evaluated further in ongoing clinical trials and in observational studies that could be conducted following authorization and/or licensure.

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Among reported unsolicited adverse events, lymphadenopathy occurred much more frequently in the vaccine group than the placebo group and is plausibly related to vaccination. The number of participants reporting hypersensitivity-related adverse events was numerically higher in the vaccine group compared with the placebo group (258 events in 233 participants [1.5%] vs. 185 events in 166 participants [1.1%]). There were no anaphylactic or severe hypersensitivity reactions with close temporal relation to the vaccine.
Serious adverse events, while uncommon (1.0% in both treatment groups), represented medical events that occur in the general population at similar frequency as observed in the study. Of the 7 SAEs in the mRNA-1273 group that were considered as related by the investigator, FDA considered 3 as related: intractable nausea and vomiting (n=1), facial swelling (n=2).
For the serious adverse events of rheumatoid arthritis, peripheral edema/dyspnea with exertion, and autonomic dysfunction, a possibility of vaccine contribution cannot be excluded.
For the event of B-cell lymphoma, an alternative etiology is more likely.
An SAE of Bell's palsy occurred in a vaccine recipient, for which a causal relationship to vaccination cannot be concluded at this time.
No specific safety concerns were identified in subgroup analyses by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection.
8.4 Unknown Risks/Data Gaps Safety in certain subpopulations
There are currently insufficient data to make conclusions about the safety of the vaccine in subpopulations such as children less than 18 years of age, pregnant and lactating individuals, and immunocompromised individuals. FDA review of a combined developmental and perinatal/postnatal reproductive toxicity study of mRNA-1273 in female rats concluded that mRNA1273 given prior to mating and during gestation periods at dose of 100 µg did not have any effects on female reproduction, fetal/embryonal development, or postnatal developmental except for skeletal variations which are common and typically resolve postnatally without intervention Adverse reactions that are very uncommon or that require longer follow-up to be detected

Following authorization of the vaccine, use in large numbers of individuals may reveal additional, potentially less frequent and/or more serious adverse events not detected in the trial safety population of approximately 30,000 participants over the period of follow-up at this time.
Active and passive safety surveillance will continue during the post-authorization period to detect new safety signals.
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Although the safety database revealed an imbalance of cases of Bell's palsy (3 in the vaccine group and 1 in the placebo group), causal relationship is less certain because the number of cases was small and not more frequent than expected in the general population. Further signal detection efforts for these adverse events will be informative with more widespread use of the vaccine.
Vaccine-enhanced disease
Available data do not indicate a risk of vaccine-enhanced disease, and conversely suggest effectiveness against severe disease within the available follow-up period. However, risk of vaccine-enhanced disease over time, potentially associated with waning immunity, remains unknown and needs to be evaluated further in ongoing clinical trials and in observational studies that could be conducted following authorization and/or licensure.