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Submission to the Education and Employment Committee

COVID-19 Vaccination Status (Prevention of Discrimination) Bill 2022 and the Fair Work Amendment (Prohibiting COVID-19 Vaccine Discrimination) Bill 2023

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Introduction

Reasons and evidence for amendments of the COVID-19 Vaccination Status (Prevention of Discrimination) Bill 2022 and the Fair Work Amendment (Prohibiting COVID-19 Vaccine Discrimination) Bill 2023

The Australian Medical Professionals' Society (AMPS) is a community of medical and allied health professionals whose principal purpose is to protect and promote the interests of our members and their patients, and to support the best possible health outcomes for all Australians. AMPS members strongly value medical ethics, health of their patients, and wellbeing of the community. AMPS welcomes the opportunity to provide feedback to the Senate Standing Committees on Education and Employment in relation to the COVID-19 Vaccination Status (Prevention of Discrimination) Bill 2022 and the Fair Work Amendment (Prohibiting COVID-19 Vaccine Discrimination) Bill 2023 bills on behalf of our membership.

AMPS welcomes the intent of these bills which second reading speeches indicate is aimed at prioritising the individual's human rights before the interests of the state with the goal of defending and protecting individuals' human and workers' rights. The intention is good; however, the drafting of these bills appears to allow broad discrimination by vaccination status through the exclusion of all Commonwealth, State and Territory employees, all frontline health and care workers and anyone deemed by an employer to require vaccinations as inherent for their employment. It is difficult to understand how these bills would affect vaccine health mandates and directives for AMPS members now or in future.

This submission provides a brief overview of the professional medical views of AMPS members as well as a brief review of the publicly available government data that conflicts with statements and documentation used to Mandate COVID-19 vaccines. Directives were issued using secret health advice that was in contradiction to many public health principles, medical ethics, well-researched pandemic plans and government reports. Health practitioners were censored by regulators from open scientific discourse. Australian workers were denied proper consultation and a full, transparent, evidence-based risk assessment. This caused harm socially, economically, physically and psychologically. These were unreasonable, unscientific, unjust directives.

The vaccines were never tested for any alleged effectiveness in stopping transmission of Covid-19 from person to person. Any efficacy wanes quickly. Revelation of these facts demonstrates that the control measure fails to accomplish the goal of stopping the spread of Covid-19. Health Directives and orders were justified on the grounds of stopping or reducing community spread or transmission; there was no available evidence then or now that showed the vaccines could achieve such a goal. We consequently believe it is reasonable to demand health professionals have access to the health advice that forms the basis of what the government or an employer deems "a reasonable and justified requirement of the job." Government data indicate very few health care employees meet the current definition of fully vaccinated.

AMPS asserts there was ample evidence available at the time mandates were legislated to clearly indicate the risk of harm to employees from these unsafe and ineffective control measures. Now, there is even more such evidence available. Health care workers should not be excluded from the anti-discrimination bill and any medical procedure deemed an inherent requirement for employment through the Fair Work Act must be fully approved and proven beyond reasonable doubt

safe and effective.

Mechanisms for challenge must be available to employees for any mandate or policy directive deemed an inherent requirement of employment. Medical professionals must be permitted to openly debate the scientific and medical basis, through transparent consultation. Extensive risk assessments must be provided that thoroughly scrutinise best evidence regarding transmission, safety, efficacy, and collateral effects.

Our health professionals are our front line during any health crisis, and risking their health by excluding them from this anti-discrimination bill and allowing caveats of "inherent requirement" in the absence of defined protections is itself a public health risk. Any therapeutic worthy of inherent status needs to be fully approved; transparent, accountable consultation should be part of the process and free from censorship.

Health authorities must justify their position in the public forum. Here, an entire population is being denied bodily autonomy through threats to their livelihood, introduced to coerce them to submit to injecting a provisional product that does not accomplish its stated goal. No exclusions to anti-discrimination law or claims of an inherent requirement should be considered ethically or legally reasonable in these circumstances.

AMPS professional medical opinion on mandates

AMPS has been established as a platform of advocacy for medical professionals in this country. We advocate–policies and practices which support the health and safety of the Australian public and which are consistent with the Good Medical Practice Code of Conduct. The Code sets out professional obligations to ensure patient care is our highest priority. Doctors are obliged to act honestly, ethically and in a trustworthy manner. Public trust in medical professionals is a bedrock of public health. Australians expect their doctors to act competently, providing advice openly and with full disclosure, and to display qualities of integrity, truthfulness, dependability and compassion.

It is our belief that to meet our Code of Conduct obligations, we must advocate safe evidence-based public health policy that always adheres to principles of informed consent, medical ethics, the precautionary principle and clinical trial guidelines provided by the Therapeutic Goods Administration (TGA)[1] involving any investigational product for our members and the Australian community.

AMPS surveyed our professional medical membership to seek their views on the bills before the Education and Employment committee in regard to COVID-19 vaccine mandate policies:

- 100% believe it necessary that AMPS as an association of health professionals with extensive medical and scientific expertise contribute to these critical public health discussions.
- 100% do not support mandates and believe they are discriminatory.
- 100% believe there was no evidence the COVID-19 vaccines ever prevented transmission of SARS-CoV-2 nor did they believe there was sufficient evidence to demonstrate safety and efficacy and therefore there was no justification for mandates.

[1] https://www.tga.gov.au/clinical-trials

- 99% do not believe there was sufficient scientific evidence demonstrating a greater benefit than risk for provisionally-approved COVID-19 vaccine mandates?
- 100% said there was not appropriate consultation with employees regarding COVID-19 mandate policies
- 100% believe the vaccine mandates have resulted in harm to Australians
- 98% believe it was inappropriate that health advice supporting mandates was and remains secret.
- 99% believe government and private sector employers should allow open debate on the scientific evidence supporting any vaccine mandates. Evidence on safety and efficacy must be proved beyond reasonable doubt.
- 99% believe COVID-19 vaccine mandates are contributing to critical workforce shortages and exacerbate public health pressures.

The vast majority of respondents feel a great many employment laws, Commonwealth laws, human rights laws, medical ethics and international agreements have been and continue to be breached, putting the health and wellbeing of the Australian workforce and population at large at risk.

Further, there should be no ongoing discrimination or "consequences for failure to comply" for those who chose not to receive the provisionally-approved COVID-19 vaccines. Disciplinary measures, such as reduction in pay as reported in Queensland,[2] for "failure to comply with a health directive" are in bad faith and an unjust punishment. Punishing people further who have already lost careers and livelihood for failing to comply with a control measure that could not achieve its approved goal demonstrates a reckless disregard for the welfare of Australians.

Recommendation: Drop all mandates and stop all provisionally-approved COVID-19 vaccines pending a full independent investigation with access to all raw data. Frontline health or care workers or employees of the Commonwealth, State or Territory governments should not be discriminated against on the basis of their COVID-19 vaccine status. There is no reasonable, rational basis for the mandate when medical and political authorities acknowledge the vaccines fail to accomplish its stated goal of stopping or measurably reducing the spread of SARS-CoV-2 from person to person.

Unreasonable to mandate a novel provisional therapeutic as an inherent requirement that fails to accomplish its stated goal

According to government documents, COVID-19 vaccine mandates were justified as a reasonable and lawful direction to minimise transmission of SARS-CoV-2 to protect the public and to protect the health and safety of people at a place of work. However, there was never any evidence the available therapeutics would have any measurable effect on transmission. The TGA Australian Public Health Assessment reports, Advisory Committee on Vaccines and the FDA all establish that the vaccines had not been tested for transmission, with the Pfizer data indicating the absolute risk reduction for their mRNA injection was less than 1%. (This is covered in more detail below.)

[2] https://7news.com.au/lifestyle/health-wellbeing/queensland-teachers-school-workers-not-vaccinated-for-covid-19-to-suffer-pay-reduction-c-7978663

The novel mRNA and DNA COVID-19 vaccinations were only provisionally approved at the time mandates were enforced. From the available government health directive policy documentation it is not obvious that the potential health harms to practitioners were risk assessed. If a control measure cannot fulfil its stated goal and has known and unknown potential harms there can be no rationale for mandates and the measure must be reviewed.

There was no evidence the vaccines stopped transmission at the time mandates were legislated. Government TGA AusPAR reports confirm that the vaccine had no data "to show efficacy against asymptomatic infection and viral transmission[3]". There was no evidence that coercively enforced provisional vaccines could achieve the indication for which they were approved, stopping or reducing the spread. Trial and real-world data show these provisionally approved vaccines do not prevent the spread of COVID-19[4]. There are no reasonable exclusions from anti-discrimination or fair work legislation that justify coercing employees to inject and be injected with an investigational product, bearing known and unknown harms, that fails to fulfil its stated goal.

Any public health order or health directive must provide mechanisms that allow for open, transparent and accountable consultation without any threat of severe censure and reprisal.

Data limitations

In addition to the unknown longer-term safety and unknown duration of vaccine protection, there are other limitations with the submitted data. The following questions have not yet been addressed:

- Vaccine efficacy against asymptomatic infection and viral transmission.
- The concomitant use of this vaccine with other vaccines.
- Vaccine data in pregnant women and lactating mothers.
- Vaccine efficacy and safety in immunocompromised individuals.
- Vaccine efficacy and safety in paediatric subjects (< 16 years old).
- A correlate of protection has yet to be established. The vaccine immunogenicity cannot be considered and used as the surrogate for vaccine protective efficacy at this stage.

The committee needs to seriously consider the dearth of information that was available on transmission, efficacy and safety. Not only were the vaccines never tested for transmission before, but in regard to immunogenicity the FDA specifically reminded "the public and health care providers that results from currently authorized SARS-CoV-2 antibody tests should not be used to evaluate a person's level of immunity or protection from COVID-19 at any time, and especially after the person received a COVID-19 vaccination.[5]"

As an association of highly qualified medical professionals we cannot comprehend that there was no full scientific risk-versus-benefit analysis that was undertaken prior to mandating these provisionally-approved novel lipid nanoparticle synthetic mRNA and DNA vaccines. These were vaccines that immunologists, scientists and the government's own reports all made clear would not

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[3] https://www.tga.gov.au/sites/default/files/auspar-bnt162b2-mrna-210125.pdf
[4] https://www.opastpublishers.com/open-access-articles/covid19-vaccinesan-australian-review.pdf
[5] https://www.fda.gov/medical-devices/safety-communications/antibody-testing-not-currently-recommended-assess-immunity-after-covid-19-vaccination-fda-safety

work to prevent transmission and therefore the spread of COVID-19. There can be no justification on any reasonable and lawful grounds to coercively mandate a therapeutic that fails to accomplish its stated goal of stopping the spread.

Recommendation: Drop all mandates and stop all provisionally approved COVID-19 vaccines pending a full independent investigation with access to all raw data. Frontline health or care workers or employees of the Commonwealth, State or Territory governments should not be discriminated against on the basis of their COVID-19 vaccine status. There is no reasonable rational basis for COVID-19 vaccine mandates/directives to be considered an inherent requirement when medical and political authorities acknowledge the vaccines fail to accomplish its stated goal of stopping or measurably reducing the spread of SARS-CoV-2 from person to person.

Transmission reduction threshold not met

Real-world data clearly demonstrate that currently available spike-protein-based COVID-19 vaccines do not materially prevent transmission nor do they provide neutralising immunity against incubation of SARS-CoV-2 to transferable viral loads. The onus upon all employers demanding workers receive COVID-19 vaccinations has been to demonstrate proof of the claim that these particular vaccinations reduce transmission; to date this onus has not been met. Counterintuitive trends in infection risk are also now evident, which require more explanation below.

It is currently unsubstantiated that these vaccines conform to the indication outlined in the Australian Public Assessment Reports (AusPAR), for which they were provisionally approved on preliminary (incomplete) data. In January 2021, Comirnaty [BNT162b2 (mRNA)] COVID-19 vaccine received provisional approval from the TGA for the following indication:[6]

> "Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 16 years of age and older."

Crucially, the January 2021 report stated there was missing information on "vaccine efficacy against asymptomatic infection and viral transmission." The lack of evidence for transmission had already been publicly stated on the FDA website in December 2020, where it was outlined via a media release when issuing the Emergency Use Authorisation.

> "At this time, data are not available to make a determination about how long the vaccine will provide protection, nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person."[7]

The fact that the Pfizer vaccine was never tested for transmission was confirmed and circulated widely recently when a recording of Pfizer representative Janine Small answering questions in the EU Parliament went viral.[8] In July 2022, a mere six months into mandates here, the Department

[6] Australian Public Assessment Report for BNT162b2 (mRNA), Therapeutic Goods Administration, published January 2021.
[7] FDA News Release, FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine, U.S. Food & Drug Administration, Published 11 December 2020.
[8] Pfizer did not know whether Covid vaccine stopped transmission before rollout, executive admits, Frank Chung, News.com.au, Published 13 October 2022.

of Health Chief Medical Officer Professor Paul Kelly stated that "[these] vaccines do not stop the transmission of this virus,"[9] with boosters now being recommended every three to four months.[10]

The failure to prevent transmission of respiratory viruses through systemic vaccination has been discussed by prominent immunologists such as Emeritus Professor Robert Clancy AM, who states "there is no significant effect on virus spread because [the COVID-19 vaccine] doesn't stimulate mucosal immunity."[11] Professor Clancy also raised concerns about the effects of repeated dosing, in conjunction with acquired COVID-19 infections, activating T reg cells, resulting specifically in *suppressing immunity* to COVID-19 infection - i.e. "reverse immunity". This results in what is now understood to be negative vaccine efficacy, with studies finding the multi-vaccinated are more likely to get COVID-19 than less-vaccinated comparison groups after waning of vaccine induced antibodies.

Recommendation: Drop all mandates and stop all provisionally approved COVID-19 vaccines pending a full independent investigation with access to all raw data, which access is currently denied. Frontline health or care workers or employees of the Commonwealth, State or Territory governments should not be discriminated against on the basis of their COVID-19 vaccine status. There is no reasonable rational basis for the mandate when medical and political authorities acknowledge the vaccines fail to accomplish its stated goal of stopping or measurably reducing the spread of SARS-CoV-2 from person to person.

COVID-19 provisionally-approved vaccine safety

For governments to mandate a pharmaceutical product to employees to protect the health and safety of people at their place of work the control measure, in this case COVID-19 vaccines, would need to be proved safe for this to be a reasonable act. It is especially important when for working-age people SARS-CoV-2 poses minimal risk with COVID infection fatality risk (IFR) being greatly stratified according to age. Professor Ioannidis et al[12] found that across "31 national seroprevalence studies in the pre-vaccination era…breakdown by age group found that the average IFR was 0.0003% at 0-19 years, 0.003% at 20-29 years, 0.011% at 30-39 years, 0.035% at 40-49 years, 0.129% at 50-59 years, and 0.501% at 60-69 years." The risk to healthy working age people from COVID-19 is low to extremely low and consequently the safety risks from the control measures, namely mandatory vaccines, need to be carefully analysed.

If the vaccines are not safe they would be inconsistent with workplace health and safety legislation and could not be considered an inherent requirement, nor could there be anti-discrimination exclusions based on occupation or place of employment.

Pfizer, Moderna, Astrazeneca, and NovaVax each use technology that has not been previously

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[9] Press Conference with Chief Medical Officer Paul Kelly and Minister Mark Butler on Tuesday 19 July 2022, Department of Health and Aged Care, Australian Government.
[10] COVID-19 booster vaccine advice, Department of Health and Aged Care, Australian Government, published 13 December 2022.
[11] The Problem with the COVID Narrative, Robert Clancy, Quadrant Online, published 16 November 2022.
[12] https://www.medrxiv.org/content/10.1101/2022.10.11.22280963v1.full

used at a population level prior to their provisional approval,[13] and there is extremely limited published literature about the use of the technology in human vivo prior to December 2020. A brief look at the government's own reports as well as the European Medicine Agency assessment and the Pfizer court-ordered released documents demonstrates serious safety concerns with these provisionally-approved vaccines. A risk assessment would have shown that the provisionally-approved (experimental as they were still a clinical trial) DNA (later removed for safety concerns) synthetic LNP mRNA Pfizer and Moderna vaccines had not been proved safe with serious data limitations, were missing information and had no long-term safety data.

The mandated products are certainly experimental, and undergo continued post-marketing surveillance and reporting obligations with high rates of new pathophysiological mechanisms, adverse events, and immune-phenomena being discovered to this day. Former Health Minister Greg Hunt confirmed classification when he referred to the vaccination program in February 2021 as "the largest clinical trial, the largest global vaccination trial ever."[14]

In January 2021 the AusPAR stated the Pfizer Comirnaty vaccine is to be included in the Black Triangle Scheme on account of its only having provisional approval.[15] The experimental nature of these new medicines means greater pharmacovigilance is required as outlined in the *National Statement on Ethical Conduct in Human Research*[16]. "The black triangle reminds health professionals and consumers to report suspected adverse events related to new medicines."

The Pfizer, Moderna, and AstraZeneca vaccines utilise genetic technologies that manipulate natural human protein synthesis to produce novel spike protein within the cell. NovaVax, Pfizer, and Moderna use new and proprietary Lipid Nanotechnology to deliver their payloads; NovaVax directly delivers novel spike protein.

It is therefore unsurprising that new phenomena and risks are being debated, and it is imperative on those in positions of authority to courageously and openly analyse risks involved. Any mandated pharmaceutical must be proved safe, be fully approved, have a thorough and conclusive risk assessment, fulfil the goal for which it is approved and be transparently open to public consultation by employees and medical and scientific professionals.

Recommendation: Drop all mandates and stop all provisionally approved COVID-19 vaccines pending a full independent investigation with access to all raw data. Frontline health or care workers or employees of the Commonwealth, State or Territory governments should not be discriminated against on the basis of their COVID-19 vaccine status. There is no reasonable rational basis for COVID-19 vaccine mandates/directives to be considered an inherent requirement when medical and political authorities acknowledge the vaccines fail to accomplish its stated goal of stopping or measurably reducing the spread of SARS-CoV-2 from person to person.

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[13] COVID-19 vaccine provisional determinations, Therapeutic Goods Administration, Australian Government, updated 13 December 2022.
[14] Minister Hunt: Interview with David Speers on ABC Insiders on the COVID-19 vaccine rollout, Department of Health and Aged Care, 21 February 2021.
[15] The Black Triangle Scheme, Therapeutics Goods Administration, Australian Government.
[16] National Statement on Ethical Conduct in Human Research, National Statement in accordance with the National Health and Medical Research Council Act 1992, Australian Research Council, Australian Government.

The novel spike protein is unsafe

Much to the surprise of our medical communities during 2021, the spike protein is highly cytotoxic. Cardiologists and clinicians now state that novel spike protein is dangerous to use as an immunising agent. In fact, the spike protein fulfils the essential criteria for the definition of a toxin, having harmful effects, known mechanism(s) of action, concentration and dose-dependence and specificity. In animal models, even the cleaved S1 subunit of the spike protein alone has been found to induce tissue damage and acute lung damage.[17] The harmful effects of novel spike protein are being investigated, and it is already acknowledged that heart damage is an adverse event following vaccination. Only recently have FDA sponsored scientists discovered a statistically significant safety signal for pulmonary embolisms, Disseminated Intravascular Coagulation, and Acute Myocardial Infarction from receipt of Comirnaty (Pfizer) vaccination in the studied group (aged >65 years). It is an association only now formally referred to the FDA for further investigation.[18] It is not clear whether the link from this study is due to novel spike protein or some other factor. However, it is precautionary.

Biodistribution and persistence of the mandated products' payloads and the resultant distribution of novel spike protein throughout the body are mostly unknown.[19] The nonclinical report from the TGA only described up to two days of bioaccumulation, even though the study ran for nine days, and showed increasing accumulation in the blood and organs (this report details many uncertainties and gaps in assurances yet unfilled).[20]

Risk-reduction, efficacy and consent

The Emergency Use Authorisation (EUA) of the Pfizer-BioNTech Covid-19 Vaccine/BNT 162b2 was granted on the efficacy data of 170 patients[21]. The TGA should have been concerned that major disqualifying protocol deviations were identified in the 170 patients upon which the EUA was granted. These protocol deviations raise serious concerns about the legitimacy of the clinical trial and the scientific norms and ethical principles upon which good medical practice is founded. Pfizer gained provisional approval for their COVID-19 injection following a mere two-month trial, claiming 95% efficacy for the prevention of coronavirus disease.[22][23] Many Australians lost their jobs for not taking an investigational product that was promoted and mandated using potentially false and misleading claims. AMPS must bring to your attention the misleading nature of the efficacy claim as it was based

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[17] Biancatelli et. al., The SARS-CoV-2 spike protein subunit S1 induces COVID-19-like acute lung injury in K18-hACE2 transgenic mice and barrier dysfunction in human endothelial cells, *American Journal of Physiology Lung Cellular and Molecular Physiology,* published 22 June 2021 <10.1152/ajplung.00223.2021>.

[18] Wong et. al., Surveillance of COVID-19 vaccine safety among elderly persons aged 65 years and older, *Vaccine*, published 1 December 2022.

[19] Malhotra, Curing the pandemic of misinformation on COVID-19 mRNA vaccine through real evidence-based medicine - Part 1, *Journal of Insulin Resistance,* published 26 September 2022 <https://doi.org/10.4102/jir.v5i1.71>.

[20] Nonclinical Evaluation report: BNT162b2 [mRNA] COVID-19 vaccine (COMIRNATYtm), Therapeutic Goods Administration, Department of Health, Published January 2021 - released by FOIA in 2022.

[21]https://dailyclout.io/report-41-the-170-clinical-trial-participants-who-changed-the-world-pfizer-ignored-protocol-deviations-to-obtain-emergency-use-authorization-for-its-covid-19-mrna-vaccine/

[22]https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19

[23] Deplanque & Launay, Efficacy of COVID-19 vaccines: From clinical trials to real life, *Therapies,* published July-August 2021. <https://doi.org/10.1016/j.therap.2021.05.004>

on relative risk reduction, not absolute risk reduction, it also does not hold up to scrutiny. The absolute risk reduction against symptomatic disease for Comirnaty during the Phase 3 trial was less than 1%, and there was no statistical benefit against transmission, hospitalisation, and or death.

Transparent evidence-based communication of risk and benefit of any therapeutic or treatment is a critical ethical imperative for informed consent. The Academy of Medical Royal Colleges made clear the importance of understanding the difference between relative and absolute risk reduction in a 2015 BMJ article, to protect against patient manipulation.[24]

Additionally, any efficacy of the Pfizer vaccine after the implementation of the December 2021 mandates is questionable following revelations from the CEO of Pfizer in January 2021 that the first two jabs provide 'limited protection, if any' against Omicron.[25]

Recommendation: Drop all mandates and stop all provisionally approved COVID-19 vaccines pending a full independent investigation with access to all raw data. Frontline health or care workers or employees of the Commonwealth, State or Territory governments should not be discriminated against on the basis of their COVID-19 vaccine status. There is no reasonable rational basis for COVID-19 vaccine mandates/directives to be considered an inherent requirement when medical and political authorities acknowledge the vaccines fail to accomplish its stated goal of stopping or measurably reducing the spread of SARS-CoV-2 from person to person.

Mandated medicines are provisionally approved

It is also worth noting that amendments were made to the Therapeutic Goods Regulation Act on 23 July 2021 that reduce the safety and efficacy requirements for any therapeutic that is being assessed for "the treatment or prevention of the disease known as coronavirus disease (COVID-19)." This change meant for any therapeutic against COVID-19, including COVID-19 vaccines; the following regulation no longer applies:

> (b) either:
>
> (i) no therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods); or
>
> (ii) if one or more therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods) – 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;

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[24] Malhotra A, Maughan D, Ansell J, et al. Choosing Wisely in the UK: The Academy of Medical Royal Colleges' initiative to reduce the harms of too much medicine. *British Medical Journal*, published 2015. https://doi.org/10.1136/bmj.h2308

[25] Frank Chung, Pfizer boss says two doses provide 'limited protection, if any' against Omicron, published 12 January 2022.

(c) there is preliminary clinical data demonstrating that the medicine is likely to provide a major therapeutic advance;

The TGA is now only legislatively required to classify the disease known as novel coronavirus disease (COVID-19) as, "of a life-threatening or seriously debilitating condition" to grant provisional approval for its use.[26] Government statistics on the morbidity and mortality of COVID-19 for healthy people make this classification questionable from the very beginning.

Manufacturers also have six years to provide the government with safety and efficacy data on these provisionally-approved vaccines. This reduction in safety and efficacy requirements for any treatment for COVID-19 as well as the lack of long-term safety data outlined in the AusPAR does raise questions about the substance of campaign-inspired claims by the Qld Government that "The COVID-19 vaccine is safe, effective and free."[27] There are no conclusive data or evidence to support such a claim and it is therefore misleading.

Furthermore, an assessment report from the European Medicines Agency from February 2021[28] for the Pfizer vaccine highlighted a lack of safety evidence for the Pfizer BioNTech vaccines[29]. There were no safety pharmacology studies conducted with BNT162b2, no genotoxicity nor carcinogenicity studies provided, toxicology and reproductive toxicity assessment was based on rat animal testing. "The Applicant refers to that (s*ic*) they are not considered necessary according to the WHO guideline (WHO, 2005)."[30] Senate Estimate questioning of the TGA has also revealed no genotoxicity testing has been undertaken in Australia, elements of vaccine contents remain commercial in confidence and the spike protein produced as a result of the vaccines has a different genomic sequence to that of the virus.[31] The obvious lack of safety and efficacy data for these mandated injectables demonstrates the fact they only received provisional approval.

Quality assurance

There are also concerns about manufacturing and quality assurance of the mRNA integrity which may explain the wide variation in adverse events reported by batch number as demonstrated on the website called, *How bad is my batch*?, and also in government FOIA documents.[32]

Quality assurance concerns were raised in a BMJ article in March 2021 in response to The EMA COVID-19 data leak, and the issues around mRNA instability. The investigation found "a significant difference in % RNA integrity/truncated species" between the clinical batches and

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[26] See reg 10L and sub-reg 10L(2) of the *Therapeutic Goods Regulation 1990* (Cth).
[27] COVID-19 vaccine overview, Queensland Government, updated 10 May 2022.
[28] Assessment Report Comirnaty, EMA/707383/2020, Committee for Medicinal Products for Human Use, European Medicines Agency, dated 19 February 2021.
[29] Hernândez et. al., Safety of COVID-19 vaccines administered in the EU: Should we be concerned?, *Toxicology Reports*, published 20 April 2021.
[30] Assessment Report Comirnaty, EMA/707383/2020, Committee for Medicinal Products for Human Use, European Medicines Agency, dated 19 February 2021.
[31] Senate Estimates Questions and the TGA answers, Gerard Rennick, Australian Senate, Published 3 May 2022 & Additionally published 4 April 2022.
[32] How Bad Is My Batch Website, Craig Paardekooper, 2022.

proposed commercial batches—from around 78% to 55%. The root cause was unknown and the effect of this loss of RNA integrity on safety and efficacy of the vaccine was "yet to be defined."[33]

Safety Regarding Pregnancy

Advisory Committee on Vaccines Meeting 18 Minutes from January 2021 accessed through FOI document that pregnant women are not included in any study[34]. This lack of information in regard to pregnancy was highlighted in an article from the National Institute of Health website titled, *COVID UPDATE: What is the truth*. The author states:

> "It should be noted that no studies were ever done on several critical aspects of this type of vaccine… They have never been properly tested for safety during any stage of pregnancy… No follow-up studies have been done on the babies of vaccinated women… There are no long-term studies on the children of vaccinated pregnant women after their birth (especially as neurodevelopmental milestones occur)."[35]

The AusPAR outlines that in the pregnancy category these…

> "…Drugs 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 have not shown evidence of an increased occurrence of fetal damage. The use of any medicine during pregnancy requires careful consideration of both risks and benefits by the treating health professional."

Although the EMA and our AusPAR outline there is missing information on the safety of these genetic vaccines in pregnant and breastfeeding women, the Australian Technical Advisory Group on Immunisation (ATAGI) states, "Pregnancy is not a valid reason for exemption in the absence of any of the criteria listed above."[36] This may lead to discrimination in the workplace and potentially to further injury. No employer should ever be able to mandate a control measure that so blatantly breaches medical ethical principles.

For a thorough review of cutting-edge up-to-date information on the COVID-19 vaccinations and a comprehensive analysis of associated Adverse Events, please view, *"The Time of COVID"* report which can be found on the AMPS website.[37] Following extensive research AMPS supports the conclusions reached by Dr Aseem Malhotra in his peer-reviewed journal article titled, *Curing the pandemic of misinformation on COVID-19 mRNA vaccines through real evidence-based medicine - Part 2*:

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[33] The EMA covid-19 data leak, and what it tells us about mRNA instability, Serena Tinari, *British Medical Journal,* published 10 March 2021.
[34] https://www.tga.gov.au/sites/default/files/2023-03/foi-4093-01.pdf
[35] Russell Blaylock, COVID UPDATE: What is the truth?, *Surgical Neurology International,* published 22 April 2022.
[36] ATAGI expanded guidance on acute major medical conditions that warrant a temporary medical exemption relevant for COVID-19 vaccines, Australian Technical Advisory Group on Immunisation, Australian Government, updated August 2022.
[37] The Time of Covid, Altman Report, published 9 August 2022.

> "There is a strong scientific, ethical and moral case to be made that the current COVID vaccine administration must stop until all raw data has been subjected to fully independent scrutiny…..It will take a lot of time and effort to rebuild trust in these institutions, but the health - of both humanity and the medical profession - depends on it."[38]

The lack of safety and efficacy data available at the time mandates were implemented raises serious health and safety considerations. Accumulated real world national and international data and research needs now to be seriously considered when assessing the continuing risk benefit analysis of these policies for the health, safety and wellbeing of Australian workers. Where there are serious safety and efficacy concerns there can be no exclusions from anti-discrimination laws nor can the control measure be deemed an inherent requirement for health care and care workers or State, Territory and Commonwealth employees.

Adverse Events

There is now a large body of peer-reviewed scientific evidence to support the psychological and physical adverse effects of COVID-19 vaccine mandates. The threat of loss of income, livelihood, career, reputation, social interaction and access to health care, all created through vaccine mandates, imposed a substantial psychological burden upon the population. Discussion surrounding physiological adverse events or vaccine damage is becoming less taboo as time goes on, but only among the general population. The medical system is most reluctant to enter into it. It is, however, now more difficult to dismiss the accumulating evidence of serious adverse events and personal injury accounts.

Several hundred accounts of COVID-related injury have been documented in the recent Commonwealth Government's Long COVID committee of inquiry submissions[39] and through groups such as Coverse[40] and Jab Injuries Australia.[41] Dr Kerryn Phelps in her submission raised the importance of acknowledging and investing in more research into COVID vaccine injuries after both she and her wife suffered profound adverse reactions, cardiac and neurological respectively. Dr Phelps further stated in a recent interview regarding anecdotes she is hearing from colleagues:

> "And they're experiencing a whole range of different types of vaccine events. They're experiencing things like cardiovascular events, with myocarditis and pericarditis. That's not just confined to young males – I've spoken to middle-aged female doctors who have had this effect. People who have neurological side effects, have musculoskeletal and joint pain. We're looking at immune system problems with reactivation of auto-immune disease."[42]

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[38] Malhotra, Curing the pandemic of misinformation on COVID-19 mRNA vaccines through real evidence-based medicine - Part 2,
[39] Submissions to Inquiry into Long Covid and Repeated Covid Infections, Standing Committee on Health, Aged Care, and Sport, Australian Parliament, ongoing and open to the public. <https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/LongandrepeatedCOVID/Submissions>
[40] Converse Website, Converse Ltd, 2022. <https://coverse.org.au/>
[41] Jab Injuries Australia on Instagram, ongoing.
[42] 'Ask AHPRA': Dr Kerryn Phelps doesn't know why regulator silenced doctors on vaccine injuries, Frank Chung, News.com.au, published 21 December 2022.

Physical adverse events reported need to be considered with reference to a number of crucial factors. First, both the initial Pfizer trial data and the expanding body of peer-reviewed evidence indicate a causal link with these provisionally-approved genetic vaccines and the unprecedented injuries being documented.

Unprecedented pharmacovigilance safety signals

The TGA has received more than six times the Adverse Event reports in 2021 through December 2022 for the COVID-19 vaccines than have been seen for all other vaccines combined in the entire preceding 50-year period. This extraordinary fact is verified according to TGA's Database of Adverse Event Notifications.[43]

This unprecedented reporting rate is corroborated by international pharmacovigilance counterparts such as VAERS, Yellow Card, Eurovigi, and Vigiaccess. A comparable increase in Adverse Event reports has been experienced internationally in countries which implemented similar policies as summarised by the World Council for Health.[44] We must also acknowledge that passive adverse event reporting systems such as the TGA DAEN suffer from under-reporting. The magnitude of under-reporting varies in estimation but is widely recognised as a factor from 10:1 to 100:1.[45] This underreporting factor needs to be considered to accurately understand the likely incidence of vaccine damage heavily affecting and sometimes destroying the health and wellbeing of Australian workers.

For a thorough review of data on the COVID-19 vaccines safety and efficacy please see the following two documents. *Time of Covid* is a report which is heavily referenced in discussion of vaccine safety; it can be found via the AMPS website. A second document was prepared as an affidavit for the Doctors Against Mandate group. It is titled, *Report of Expert Witness Dr Andrew Madry prepared for the Supreme Court of Queensland*[46], and service of it preceded revocation of the Public Health Direction affecting standing of the applicants.

Safety signals and mechanisms being published

The need for a comprehensive risk-benefit analysis is becoming increasingly apparent as our understanding of these vaccines' pathophysiological and clinical consequences is increasing. A study published by Seneff et al in June 2022[47] outlines a number of the adverse immune system complications arising from mRNA vaccinations with potential causal links to disease. The paper titled, *Innate immune suppression by SARS-CoV-2 mRNA vaccinations: The role of G-quadruplexes, exosomes, and MicroRNAs* presented evidence that:

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[43] Database of Adverse Event Notifications, Therapeutic Goods Administration, Australian Government, updated weekly.
[44] Covid-19 Vaccine Pharmacovigilance Report, World Council for Health, Updated 20 December 2022.
[45] Google Scholar search terms: "EMA ADR under-reporting".
[46] Report of Expert Witness Dr Andrew Madry prepared for the Supreme Court of Queensland, Applicant Evidence to the Supreme Court of Australia, Doctors Against Mandates.
<https://www.doctorsagainstmandates.com/wp-content/uploads/2022/09/Expert-Witness-Report-Madry-15-Aug-2022-B.pdf>
[47] Seneff et. al., Innate immune suppression by SARS-CoV-2 mRNA vaccinations: The role of G-quadruplexes, exosomes, and MicroRNAs, published June 2022.

> "…. vaccination induces a profound impairment in type I interferon signalling, which has diverse adverse consequences to human health. Immune cells that have taken up the vaccine nanoparticles release into circulation large numbers of exosomes containing spike protein along with critical microRNAs that induce a signalling response in recipient cells at distant sites. We also identify potential profound disturbances in regulatory control of protein synthesis and cancer surveillance. These disturbances potentially have a causal link to neurodegenerative disease, myocarditis, immune thrombocytopenia, Bell's palsy, liver disease, impaired adaptive immunity, impaired DNA damage response and tumorigenesis."

After completing extensive research for his journal publications, following the untimely death of his father, prominent UK cardiologist Dr Aseem Malhotra concluded that "contrary to my own initial dogmatic beliefs, Pfizer's mRNA vaccine is far from being as safe and effective as we first thought." Dr Malhotra's comprehensive two-part review of vaccines safety and efficacy data can be found in the *Journal of Insulin Resistance* published on September 26, 2022, "Curing the pandemic of misinformation on COVID-19 mRNA vaccines through real evidence-based medicine."[48]

These vaccine technologies are novel. The Astrazeneca (AZ) vaccine is documented as a Genetically Modified Organism, as demonstrated through its application to Australia's Gene Technology Regulator for a "Licence for dealings involving an intentional release of a GMO into the environment"[49]. AZ is classified as a genetically-modified COVID-19 vaccine.

Review of risk-benefit of policies

It is unknown if the mRNA vaccines were required to submit such applications, although there is now research demonstrating that the mRNA vaccines may be reverse transcribed (that is, incorporated) into one's DNA around the body, with unknown consequences.[50] A published review from Tunni and Lefringhausen[51] points out that emerging data has demonstrated alterations in gene expression following vaccination and has described how various mechanisms of the mRNA vaccines interfere with DNA repair. They concluded:

> "COVID-19 vaccines cause more side effects than any other vaccine, a fact that is attributed to its interactions with the immune system. Not only does the spike protein produce unwanted side effects, but the mRNA and nanoparticles do as well."

There were obvious safety signals present even in the initial trial data, with regard to both the adverse events of special interest and all-cause mortality. An analysis of the Pfizer mRNA trial data published in the *New England Journal of Medicine* found there were four cardiac arrests in the

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[48] Malhotra, Curing the pandemic of misinformation on COVID-19 mRNA vaccine through real evidence-based medicine - Part 1, *Journal of Insulin Resistance*, published 26 September 2022 <https://doi.org/10.4102/jir.v5i1.71>.

[49] Licence for dealings involving an intentional release of a GMO into the environment, Licence Holder: AstraZeneca Pty Ltd, Office of the Gene Technology Regulator, Australian Government, issued 8 February 2021.

[50] Aldén et. al., Intracellular Reverse Transcription of Pfizer BionNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Sell Line, *Current Issues in Molecular Biology*, published 25 February 2022. <https://doi.org/10.3390/cimb44030073>

[51] Turni & Lefringhausen, COVID-19 vaccines - An Australian Review, published 21 September 2022. ISSN: 2475-6296.

vaccine arm of the study and only one in the placebo group.[52]

In terms of adverse events, reference must be made to the serious adverse events of special interest included in the Pfizer 5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021[53] dated 30 April 2021 (Pfizer's Adverse Events Report) (released in or about November 2021 pursuant to court ordered disclosure expedited under the Freedom of Information Act):[54] It includes 1223 deaths, as seen on page seven. Further, the report outlined nine pages, around 1200+, adverse events of special interest, many of which are identifiable on TGA's Database of Adverse Event Notifications. These adverse events of special interest were discussed in the Journal *Vaccine*, in a paper titled "Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults." This study reviewed the available data from both the Pfizer and Moderna phase-3 randomised trials in adults. The findings stated:[55]

> "In the Moderna trial, the excess risk of serious AESIs (15.1 per 10,000 participants) was higher than the risk reduction for COVID-19 hospitalization relative to the placebo group (6.4 per 10,000 participants). [3] In the Pfizer trial, the excess risk of serious AESIs (10.1 per 10,000) was higher than the risk reduction for COVID-19 hospitalization relative to the placebo group (2.3 per 10,000 participants).
>
> "The excess risk of serious adverse events found in our study points to the need for formal harm-benefit analyses, particularly those that are stratified according to risk of serious COVID-19 outcomes. These analyses will require public release of participant level datasets."

The evidence outlined may provide insight into the unprecedented rates of adverse reactions our country is experiencing. According to a statement[56] of the Australian Bureau of Statistics (ABS) the excess all-cause mortality now exceeds an astonishing 17 per cent, and it comes along with a concerning increase in anxiety and depression.[57]

A preprint review of Australia's all-cause mortality data by Wilson Sy[58], using the Bradford-Hill criteria, demonstrates a causal link with the COVID-19 vaccination roll-out. We appear to be experiencing what he calls an iatrogenic pandemic, as a direct result of what was promoted by Greg Hunt as the world's largest clinical trial: "The youngest 0-44 age group with lowest risks of Covid infection and death has suffered disproportionately the highest multiples of excess mortality

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[52] Polack FP, Thomas SJ, Kitchin N, et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. N Engl J Med. 2020;383(27):2603–2615. https://doi.org/ 10.1056/NEJMoa2034577.

[53] Cumulative Analysis of Post-Authority Adverse Event Reports of PF-07302048 (BNT162b2) received through 28-FEB-2021, Pfizer, Approved on 30 April 2021. <https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf>

[54] FDA released document: Pfizer 5.3.6 Cumulative analysis of post-authorization adverse event reports of pf-07302048 (bnt162b2) received through 28-feb-2021 – page 6.

[55] Fraiman et. al., Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9428332/>

[56] Provisional Mortality Statistics, Australian Bureau of Statistics, released 22 December 2022. <https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/latest-release?fbclid=IwAR3fpywSvxWCXTRUaZx99M6s_w_%20kBRdMa3b_13msQ3bNPRanFjGHi-wWTZQ>

[57] COVID-19 pandemic triggers 25% increase in prevalence of anxiety and depression worldwide, World Health Organisation, published 2 March 2022.

[58] https://www.researchgate.net/publication/368426122_Australian_COVID-19_pandemic_A_Bradford_Hill_analysis_of_iatrogenic_excess_mortality

with the advent of Covid injections…" This should suggest to medical and political authorities that these vaccines pose serious potential risks to working-age Australians and health professionals who are themselves at very low risk from the infection that causes COVID-19.

A fairly recent and peer-reviewed publication in the British Medical Journal found that mandatory COVID-19 vaccination policies have been having dire detrimental effects on the communities and workplaces they impose upon. We offer some excerpts. Full citations are available in the footnotes.

> "The pandemic has created immense strain on health systems, contributing to disruptions in global immunisation programmes and burnout in healthcare and social care workers that risk worsening clinical outcomes for all patients. These trends may be exaggerated by the current policy push towards mandatory COVID-19 vaccination of healthcare/social care workers and firing of unvaccinated staff.
>
> "Current vaccine policies may erode core principles of public health ethics. As some of those supporting mandates recognise, and contrary to the media portrayal that 'the unvaccinated are entirely free to decline', many COVID-19 vaccine policies clearly limit choice and the normal operation of informed consent."[59]

Perhaps termination and coercion of workers, absent indisputable evidence, is a direct factor of health-worker shortages including burn-out, psychological or physical injury, and the trust crisis of the public and a substantial portion of the healthcare workforce.

Psychological harms of the mandate policies can be summed up in a recent judgement and payout handed down in the NSW Personal Injury Commission. The uncertain employment status of a teacher was found to be "at least a substantial contributing factor" to her psychological injury.[60]

The issue of harms from mandates are acute; they are underreported, and in urgent need of attention. Vaccine mandates cause potential harms at an individual employee level, both physically and mentally, and further contribute to serious workforce shortages in hospitals, exacerbating the health crisis. Across the country we are witnessing unprecedented ambulance ramping, staff shortages, excessive waiting times in emergency departments, specialist appointments and elective surgery. Unscientific mandates are discriminating against those who made an informed choice not to receive a provisionally-approved COVID-19 vaccination without a full risk assessment, absent proper consultation and due consideration of available evidence.

No employee should be excluded from anti-discrimination laws; there must always be a mechanism for challenge to anything deemed an inherent requirement of employment.

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[59] Bardosh et. al., The unintended consequences of COVID-19 vaccine policy: why mandates, passports and restrictions may cause more harm than good. *BMJ Global Health*, published 29 July 2022. 7(5), e008684, doi: 10.1136/bmjgh-2022-009759.

[60] Dawking v Secretary (Department of Education) [2002] NSWPIC 611 (3 November 2022), updated 16 November 2022 & Tasmin Rose, 'Psychological injury': NSW teacher wins compensation payout over handling of vaccine mandate, *The Guardian*, published 5 November 2022. https://www.theguardian.com/australia-news/2022/nov/05/psychological-injury-nsw-teacher-wins-compensation-payout-over-handling-of-vaccine-mandate

Recommendation: Drop all mandates and stop all provisionally approved COVID-19 vaccines pending a full independent investigation with access to all raw data. Frontline health or care workers or employees of the Commonwealth, State or Territory governments should not be discriminated against on the basis of their COVID-19 vaccine status. There is no reasonable rational basis for COVID-19 vaccine mandates/directives to be considered an inherent requirement when medical and political authorities acknowledge the vaccines fail to accomplish its stated goal of stopping or measurably reducing the spread of SARS-CoV-2 from person to person.

Conclusion

We provide a brief overview of why a critical review of mandates is strongly advocated and why there should be no exclusions from anti-discrimination law based on occupation or government employment status, and any inherent requirement must undergo thorough risk assessment analysis in open, transparent consultation.

This brief review of the epidemiological, pathophysiological, clinical, and legal consequences of the COVID-19 vaccines illustrates why many are concerned about the apparent serious risks of these investigational products. The vaccines do not and cannot accomplish their stated goal and there is therefore no rationale for mandates. The health, safety and wellbeing issues that have arisen as a direct result of vaccine mandate policies constitute a continuing threat to public health and safety, putting further pressure on a health system already in crisis. An analysis of mandates as a control measure using up-to-date evidence-based research and data on transmission, safety, efficacy and vaccine harms is required for the health and safety of all workers across Australia. There is no suggestion this is being provided by the existing medical system.

To date AMPS is not aware of any risk-benefit assessments having been completed that accurately address the issues raised in this letter, nor of the multifaceted loss being incurred. Without ensuring a comprehensive review of mandate policies and their consequences to Australians' health and safety, the continuance of such a policy seems at best an unreasonable, costly, reckless gamble. The potential benefits of these vaccines are difficult to justify in light of the evidence presented. Any potential efficacy wanes over time, ultimately resulting in a negative effect where later (booster) injections actually increase the patient's susceptibility to infection with COVID-19[61]. Controls implemented under emergency measures were for variants that have become less virulent, and for which the treatment has become outdated; indeed, they may now be fuelling antibody-resistant escape variants and adverse immune modulatory effects.

In fact, a discerning assessment of publicly available data appears to indicate more harm than benefit to Australian workers from these mandated investigational products. Australia is witnessing increasing morbidity and mortality that cannot be explained by COVID deaths alone. And while correlation does not equal causation, the coincidence poses a serious potential and continuing health and safety risk to workers. This risk is worthy of prompting immediate precautions and investigations. Sadly, as outlined in the *Journal of Surgical Neurology International*, there are growing numbers of qualified people with outstanding expertise affirming that these vaccines are deadly.[62]

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[61] https://www.opastpublishers.com/open-access-articles/covid19-vaccinesan-australian-review.pdf

[62] Russell Blaylock, COVID UPDATE: What is the truth?, *Surgical Neurology International*, published 22 April 2022.

The object of mandates was to secure the health and safety of workers and the Australian public. To meet the object of these bills, AMPS posits that recognition of the legitimate concerns raised in this letter are critical to ensuring workers' human rights. The right to bodily autonomy, the right to informed consent and the right to a safe work environment are imperatives that need to be fulfilled. At present, they are being denied. Those who have been genuinely injured because of unscientific, unreasonable and likely unlawful mandates need to begin to be acknowledged and receive the help they so desperately need and deserve.

Sincerely,

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