OPERATION COVID SHIELD

A PUBLIC INTEREST REPORT

Exposing vaccine safety and efficacy concerns, government misinformation, and undisclosed conflicts of interest

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This document may be updated periodically with new information.
Version 1.8 (Additional references added, minor edits and corrections made.)
8 August 2021
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Operation COVID Shield: "personal freedoms" leveraged to incentivise vaccine uptake

Although the Australian government continues to claim that Covid-19 vaccines will be voluntary,[1] the new operations manual for 'Operation COVID Shield', Australia's mass Covid-19 vaccination rollout, openly acknowledges the government will leverage personal freedoms to incentivise mass vaccine uptake.[2]

Although they were never recommended in Australia's pandemic management plans prior to 2020, restrictive societal lockdowns were originally touted as a public health measure to "slow the spread" and "flatten the curve" of Covid-19 infections, buying time to "better prepare our health system and put measures in place to protect Australian lives".[3]

However, the justification for lockdowns has evolved. State and federal governments have had almost a year and a half to respond to Covid-19 by increasing health response capacity and implementing sustainable community management measures. Nevertheless, cases of Covid-19 in the community are still considered sufficient justification for locking down entire cities, despite the fact that the federal government acknowledges Covid-19 presents as a mild illness for most people.[4]

In New South Wales, the justification for societal lockdown has recently evolved further—now the city is locked down because of "low vaccination rates".[5] On the 28 July 2021, NSW Premier Gladys Berejiklian announced that "the only way to guarantee the further easing of restrictions" included higher vaccination rates.

In Operation COVID Shield's manual, which was released 3 August 2021, the evolution of the justification for societal lockdown and restrictions has evolved even further. It openly says that the government will "leverage key incentives" such as "personal freedoms" to "drive vaccine up-take", and intends to coordinate the use of these incentives across the public, private and community sectors. Prime Minister Scott Morrison has flagged that no "special" laws will be implemented at a state or federal level, which would be subject to parliamentary oversight and normal democratic protections. Instead, the states would enact "public health orders" under their emergency powers to allow employees to require vaccination or to prevent unvaccinated people from entering businesses through the newly-announced "vaccine passport" measures.[6]
The lifting of restrictions and lockdowns is to be contingent upon *the achievement of vaccination thresholds.* This is in spite of the fact the TGA's Covid-19 vaccine product information says that

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[1] "Getting vaccinated for COVID-19", Department of Health, (health.gov.au)

[2] "Operation COVID Shield National COVID Vaccine Campaign Plan", Department of Health, (health.gov.au)

[3] Media Statement, Prime Minister's Office, 22 March 2020 (pm.gov.au)

[4] Media Statement, Prime Minister's Office, (pmc.gov.au), 22 March 2020; Coronavirus Disease 2019 (COVID-19), CDNA National Guidelines for Public Health Units, Version 4.7, Department of Health, 24 June 2021 (health.gov.au), page 10; Australian Health Protection Principal Committee (AHPPC) coronavirus (COVID-19) statement on 17 March 2020, Department of Health, (health.gov.au), 17 March 2020

[5] "Certainty for the community as restrictions adjusted and vaccines ramped up", NSW Government, 28 July 2021, (nsw.gov.au)

[6] Media Statement, Prime Minister's Office, 6 August 2021 (pm.gov.au); Media Statement, Prime Minister's Office, 3 August 2021, (pm.gov.au)

vaccination does not mitigate the need to continue other public health measures, until more information about vaccine efficacy is available. (See footnote 99)

This public interest report documents:

- Provably false claims state and federal government officials and public health officials have made about Covid-19 vaccine safety, efficacy, and effects on transmission.
- The federal government's disturbing misinformation about the safety of Covid-19 vaccine in adolescents and pregnant women, two groups prioritised for Operation COVID Shield's vaccine rollout.
- Alarming errors in key modelling which formed the basis of restrictive public health measures such as lockdowns.
- Serious concerns raised about the legal standing of key Covid-19 response decision-makers.
- Undisclosed potential conflicts of interest with pharmaceutical companies which have manufactured the provisionally approved Covid-19 vaccines.
- Silencing of Australian health practitioners, who have been threatened with prosecution and regulatory action if they do not adhere to the government's Covid-19 vaccine messaging.

SAFETY AND EFFICACY CONCERNS

Safety and efficacy of the Pfizer and AstaZeneca Covid-19 vaccines

Operation COVID Shield's aggressive nationwide operation to coerce Australians into receiving a Covid-19 vaccine leveraging "personal freedoms" is bizarre, given the fact that Australia's chief health bureaucrats, Australia's drug regulator, and the vaccine manufacturers themselves admit they do not know if the vaccines are effective or not.

The nation-wide rollout of Operation COVID Shield means that if Australian do not take part in what Health Minister Greg Hunt has admitted is the world's largest clinical trial in history,[7] their "personal freedoms" are forfeit. This violates the government's own immunisation protocols, which say that for consent to be legally valid, "it must be given voluntarily in the absence of undue pressure, coercion or manipulation."[8]

The two Covid-19 vaccines which have been given provisional approval in Australia by the drug regulator, the Therapeutic Goods Administration, are manufactured by Pfizer and AstraZeneca. Both manufacturers admit the efficacy and duration of protection of their vaccines is unknown. Efficacy and safety for older people, adolescents, Aboriginal and Torres Strait Islander peoples, and the immunocompromised is unknown; yet Operation COVID Shield has prioritised these demographics in the vaccine roll out. The effects on people with autoimmune or inflammatory disorders, or people with a history of anaphylaxis is unknown. There is inadequate data about the effects on reproduction, fertility or foetal development. The interaction of the vaccines with other drugs and vaccines is unknown. Long term immunity and vaccine induced autoimmune disease were not studied. Pfizer is not planning Australia-specific post-market studies.[9]

Despite the fact that Pfizer's vaccine uses a novel therapeutic mRNA technology which has not been approved for use in humans before, there were no genotoxicity or carcinogenicity studies performed.

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[7] Health Minister Greg Hunt, interview with David Speers on ABC Insiders on the COVID-19 vaccine rollout, Department of Health, 21 February 2021, (health.gov.au)

[8] Preparing for vaccination, Valid Consent, Department of Health, (immunisationhandbook.health.gov.au)

[9] Australian Product Information - Comirnaty (BNT162b2 [mRNA]) Covid-19 Vaccine, Therapeutic Goods Administration, (tga.gov.au); Australian Product Information, Covid-19 Vaccine AstraZeneca (ChAdOx1-S), Therapeutic Goods Administration, (ebs.tga.gov.au); Australian Public Assessment Report for BNT162b2 (mRNA), Therapeutic Goods Administration, (tga.gov.au); Australian Public Assessment Report for ChAdOx1-S, Therapeutic Goods Administration, (tgs.gov.au)

According to a filing to the US Securities and Exchange Commission by Moderna, a Covid-19 vaccine manufacturer using the same novel mRNA technology as Pfizer, mRNA is considered a “gene therapy” in the United States and Europe.[10]

Importantly, Pfizer admits that there was “no meaningful clinical differences” in overall vaccine efficacy for participants whose comorbidities increased their risk of severe Covid-19. On 28 July 2021, Pfizer published the results from a large six month clinical trial which showed the vaccine made no meaningful difference in overall mortality at all.[11] This clinical trial acknowledged that Pfizer could not collect duration of protection, efficacy or safety data in a blinded, placebo-controlled manner because placebo recipients were also immunised with the vaccine.

In a dubious endorsement of the safety and efficacy of Covid-19 vaccines, the government introduced a “no fault indemnity scheme” for general practitioners who administer Covid-19 vaccines.[12] The Australian government has extended indemnity to vaccine suppliers against liability for side effects.[13] The TGA has made the unprecedented decision to allow any party to offer cash rewards and other prizes to people who have been fully vaccinated under the government’s Covid-19 vaccination program. Ordinarily, health practitioners are not allowed to endorse a medicine, however, the TGA has waived this prohibition for Covid-19 vaccines.[14]

At the time of writing, the United Kingdom’s vaccine reporting system reports 98,432 adverse event reports (275,820 total reactions) and 478 deaths following the Pfizer vaccine; and 225,871 adverse event reports (806,085 total reactions) and 1024 deaths following the AstraZeneca vaccine.[15] In the United States, there have been 203,069 adverse event reports (848,553 total reactions) and 2,012 deaths following the Pfizer vaccine.[16] (There is no specific data for AstraZeneca.) Notably, the reporting systems are voluntary and may not represent the true extent of adverse events.

The TGA acknowledges that there is no established immunological correlate of protection against Covid-19 from the AstraZeneca or Pfizer vaccines.[17] The TGA acknowledges that questions about the vaccines’ efficacy against asymptomatic infection and viral transmission have not been addressed.[18]

Covid-19 vaccine safety and efficacy in pregnant women and breastfeeding women

The Australian government has produced a brochure: ""COVID-19 vaccination decision guide for women who are pregnant, breastfeeding or planning pregnancy”.[19] The Australian government

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[10] Moderna Inc, quarterly report for the period ending June 2020, United States Securities and Exchange Commission, (sec.gov)

[11] Thomas et al, “Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine”, BMJ, 28 July 2021, (medrxiv.org)

[12] Virtual Press Conference Transcript, Prime Minister’s Office, 28 June 2021, (pm.gov.au)

[13] Dana McCauley, “Vaccine suppliers given indemnity for 'inevitable' side effects”, Sydney Morning Herald, (smh.com.au), 8 October 2020

[14] “Communicating about COVID-19 vaccines”, Therapeutic Goods Administration, (tga.gov.au), 30 July 2021

[15] “Coronavirus vaccine - weekly summary of Yellow Card reporting”, UK Government, (gov.uk); “COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print”, (gov.uk), Retrieved 7 August 2021; "COVID-19 AstraZeneca Vaccine Analysis Print”, (gov.uk), Retrieved 7 August 2021

[16] Vaccine Adverse Reporting System (VAERS), US Centers for Disease Control and Prevention, (wonder.cdc.gov), Retrieved 7 August 2021

[17] Australian Public Assessment Report for BNT162b2 (mRNA), Therapeutic Goods Administration, (tga.gov.au), page 35; Australian Public Assessment Report for ChAdOx1-S, Therapeutic Goods Administration, (tgs.gov.au), page 16

[18] Australian Public Assessment Report for BNT162b2 (mRNA), Therapeutic Goods Administration, (tga.gov.au), page 34

[19] “COVID-19 vaccination decision guide for women who are pregnant, breastfeeding or planning pregnancy”, Version 5, Department of Health, (health.gov.au), 30 July 2021

recommends pregnant women, women who are trying to conceive, or who are breastfeeding are vaccinated with the Pfizer vaccine. Pregnant women are a “priority group” for Covid-19 vaccination. The Australian Technical Advisory Group on Immunisation (ATAGI) recommends that pregnant women “be routinely offered the Pfizer vaccine at any stage of pregnancy.”[20]

The Australian government's brochure claims that pregnant women with Covid-19 have an increased risk of needing admission to hospital (5 times higher than non-pregnant women). However, the government’s reference to support this claim is from a pre-print study which has not been peer reviewed, and as such the medical journal warns it “should not be used to guide clinical practise”. The study notes: “Asymptomatic women and women with milder symptoms were not captured and classified as infected in our data. … As pregnant women may be more likely to be admitted to hospitals than non-pregnant women with similar symptoms, restricting studies to women hospitalized with COVID-19 may complicate interpretation of results. We found a higher risk of hospitalization when pregnant, but a similar duration of the hospital stay and slightly lower proportion with co-registrations of lower respiratory illness, compared to non-pregnant women. This may suggest that, in Norway, when hospitalized, there is no substantial difference in severity of disease in pregnant women, although more detailed data is needed to address this. … We found that pregnant women were not at higher risk of SARS-CoV2 infection per se, however, our results support the current evidence that there may be an increased risk of hospitalization when infected during pregnancy.”[21]

The Australian government’s brochure says that pregnant women with Covid-19 had an increased risk of needing admission to an intensive care unit (2-3 times higher than non-pregnant women) and needing invasive ventilation (3 times higher than non-pregnant women). These figures are described in an unnecessarily alarmist manner. This is revealed in the brochure’s reference data. The study the brochure references to support these claims says that yes, likelihood of Covid-19-positive pregnant women being admitted to ICU was 2-3 times higher than non-pregnant women. But this was a total 10.5 pregnant women versus 3.9 non-pregnant women *per 1,000 total cases.* Similarly, the Australian government’s brochure says pregnant women with Covid-19 were at 3 times higher risk for needing invasive ventilation, but the reference data clarifies that this was a total 2.9 pregnant women versus 1.1 non-pregnant women *per 1,000 cases*. The brochure’s reference data comes from the US Centers for Disease Control (CDC), which acknowledges that although pregnant women were at increased risk for severe Covid-19-associated illness compared to non-pregnant women, the “absolute risks for severe outcomes” were low.[22]

The Australian government’s alarmist rhetoric contradicts the advice of the UK Government’s National Health Service (NHS), which says: “If you’re pregnant your chance of getting COVID-19 is not higher than anyone else and it’s very unlikely you’ll get seriously ill with it. Pregnant women are in the moderate risk (clinically vulnerable) group as a precaution. This is because you can sometimes be more at risk from viruses like flu if you're pregnant.”[23]

The Australian government’s brochure says that Covid-19 during pregnancy increases the risk of complications for the newborn, including a risk of premature birth, stillbirth and needing hospital admission. The reference to support these statements is a single study which does not appear to have

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[20] “Who can get vaccinated for COVID-19?”, Department of Health, (health.gov.au)

[21] Magnus et al, “Pregnancy and risk of COVID-19”, medRxiv, (medrxiv.org), 26 March 2021

[22] Zambrano et al, “Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–October 3, 2020”, Centers for Disease Control and Prevention, (cdc.gov), 6 November 2020

[23] “Pregnancy and coronavirus (COVID-19)”, NHS, (nhs.uk)

achieved final peer approval.[24] The study acknowledges limitation in the analysis, including poor reporting which made it difficult to determine the “true impact of the disease”, and acknowledged that societal and economic changes due to pandemic health measures may have influenced results. The study observed an increased number of premature births in women with Covid-19, however acknowledged that these could have been “medically indicated” as the overall rates of premature births were broadly similar to those observed pre-pandemic. The indications for hospital admission for neonates were not reported (meaning it was unknown if Covid-19 had any influence on infant hospitalisation), and the study acknowledged that local policy on observation and quarantine of infants may have influenced the data. Contrary to the Australian government's alarmist rhetoric, the study referenced in the brochure says the “overall rates of stillbirths and neonatal deaths do not seem to be higher than the background rates”.

The Australian government's alarmist brochure contradicts the UK government’s advice, which says: “There's no evidence COVID-19 causes miscarriage or affects how your baby develops in pregnancy. Although it's very rare for pregnant women to become seriously ill if they get COVID-19, it may be more likely later in pregnancy. If this happens, there's a small chance your baby may be born early or you may be advised to give birth earlier than your due date. While the chances of having a stillbirth are low, there is some emerging evidence that the risk may be higher if you have COVID-19 at the time of birth. … There's no evidence COVID-19 causes miscarriage or affects how your baby develops in pregnancy. … It may be possible for you to pass COVID-19 to your baby before they're born. But when this has happened, the babies have got better.”[25]

The Australian government recommends Pfizer’s Covid-19 vaccine at all stages of pregnancy and before conception. The government's Covid-19 pregnancy vaccination brochure claims that “mRNA vaccines have been shown to be safe in pregnant women” based on “‘real-world evidence”, referencing a US study. However, the US study acknowledges that the data is “preliminary” and “from a small sample” of vaccinated pregnant women, which were primarily vaccinated in the third trimester (84.6 per cent). “We were unable to evaluate adverse outcomes that might occur in association with exposures earlier in pregnancy, such as congenital anomalies, because no pregnant persons who were vaccinated early in pregnancy have had live births … follow-up is ongoing.”[26] The study acknowledged limitations of the data, because the “preliminary analysis uses participant-reported data and has limited information on other potential risk factors for adverse pregnancy and neonatal outcomes”. Among pregnancy-specific conditions reported after vaccination, miscarriage was the most common. The study acknowledges that “the proportion of pregnant persons who reported spontaneous abortion may not reflect true postvaccination proportions because participants might have been vaccinated after the period of greatest risk in the first trimester, and very early pregnancy losses might not be recognized. Whereas some pregnancies with vaccination in the first and early second trimester have been completed, the majority are ongoing, and a direct comparison of outcomes on the basis of timing of vaccination is needed to define the proportion of spontaneous abortions in this cohort.”
The study concluded that “[c]ontinued monitoring is needed to further assess maternal, pregnancy, neonatal, and childhood outcomes associated with maternal Covid-19 vaccination, including in earlier stages of pregnancy and during the preconception period.”

The Australian government's Covid-19 vaccine and pregnancy advisory brochure also references a "number of smaller studies” which it claims showed that “receiving an mRNA vaccine during

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[24] Alloty et al, “Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis”, BMJ, (bmj.com), 1 September 2020

[25] “Pregnancy and coronavirus (COVID-19)”, NHS, (nhs.uk)

[26] Shimabukuro et al, “Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons”, The New England Journal of Medicine, (nejm.org), 17 June 2021

pregnancy does not increase the risk of pregnancy complications for women or their babies". These studies only involved 30-105 participants.

Despite the limitations of the supporting data referenced in the government's vaccine brochure, and the Pfizer vaccine's unknown safety profile for pregnant women, the Australian government has determined pregnant women are a "priority" group for its vaccine rollout, and *universally recommended Covid-19 vaccination* for pregnant women at all stages of pregnancy, breastfeeding women, and women who are trying to conceive.

The TGA acknowledges that women who were pregnant or breastfeeding *were not included in Pfizer's clinical trial*.[27] The Australian government's brochure says that a clinical trial of the Pfizer vaccine is underway in the US.[28] However, the brochure does not disclose that this trial is not independent, but is being conducted by the vaccine's manufacturer. It will not be completed until June 2023. The brochure also does not disclose that the initial safety assessment portion of the clinical trial only includes women in the third trimester. Curiously, pregnant participants who received the placebo will also receive the Pfizer vaccine "at defined time points as part of the study".

The TGA's literature says that "data to support safety in pregnancy are inadequate at this stage".[29] The TGA also says that there is "limited experience with use of [Pfizer] COMIRNATY in pregnant women", and that administration of Pfizer's vaccine in pregnancy "should only be considered when the potential benefits outweigh any potential risks for the mother and fetus."[30]

The Australian government recommends Pfizer vaccines at all stages of pregnancy, despite the fact that the Australian government's brochure admits that "[o]verall the data on COVID-19 vaccines in pregnant women are still limited". It also acknowledges "[t]here is limited research on the safety of COVID-19 vaccines in breastfeeding women, however, there are no *theoretical* safety concerns." (Emphasis added) The brochure claims that "[v]accination does not affect fertility", although notably Pfizer has only conducted animal trials on female fertility, embryofetal development and postnatal development. Notably, the AstraZeneca vaccine, which is now being offered to Australians as young as 18, acknowledges "It is unknown whether COVID-19 Vaccine AstraZeneca may impact fertility. No data are available".[31]

The Australian government's brochure, "COVID-19 vaccination decision guide for women who are pregnant, breastfeeding or planning pregnancy", appears to have deliberately manipulated information to frighten pregnant women into receiving a vaccine of unknown safety and side effects. This violates the government's own Immunisation Handbook, which acknowledges that for consent to be legally valid, "It can only be given after the potential risks and benefits of the relevant vaccine, the risks of not having it, and any alternative options have been explained to the person. … It must be given voluntarily in the absence of undue pressure, coercion or manipulation."[32]

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[27] Australian Public Assessment Report for BNT162b2 (mRNA), Therapeutic Goods Administration, (tga.gov.au), page 19

[28] "Study to Evaluate the Safety, Tolerability, and Immunogenicity of SARS CoV-2 RNA Vaccine Candidate (BNT162b2) Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older", Clinical Trials, (clinicaltrials.gov), 15 February 2021

[29] Australian Public Assessment Report for BNT162b2 (mRNA), Therapeutic Goods Administration, (tga.gov.au), page 29;

[30] Australian Product Information - Comirnaty (BNT162b2 [mRNA]) Covid-19 Vaccine, Therapeutic Goods Administration, (tga.gov.au), Page 8

[31] Australian Public Assessment Report for BNT162b2 (mRNA), Therapeutic Goods Administration, (tga.gov.au), Page 15; Australian Product Information, Covid-19 Vaccine AstraZeneca (ChAdOx1-S), Therapeutic Goods Administration, (ebs.tga.gov.au) Page 5

[32] Preparing for vaccination, Valid consent, Australian Immunisation Handbook, Department of Health, (health.gov.au)

Covid-19 vaccine safety and efficacy in adolescent children

On 23 July 2021, the TGA approved Pfizer's vaccine for children over twelve years of age,[33] and the age cohort of 12-15 years is determined a "priority group" in Operation COVID Shield.

The government's Communicable Disease Network Australia (CDNA), a sub-committee of the Australian Health Protections Principal Committee (AHPPC), acknowledges that Covid-19 is generally mild in children, with the risk of severe disease almost 25 times less than in adults.[34]

The TGA has approved administration of Pfizer's vaccine to adolescents, despite acknowledging limitations in the data, and that efficacy against asymptomatic and transmission is unknown.[35] The TGA acknowledged that in Pfizer's clinical trial "vaccine efficacy for adolescents was not a pre-specified endpoint … The efficacy analysis is therefore considered as descriptive, not as hypothesis testing". The TGA noted that "a specific level of neutralising antibodies has not yet been established to correlate with protection, and other aspects of the immune response, such as cellular immunity, were not analysed." Vaccine efficacy against "variants of concern" was not addressed.[36]

The TGA observed that the number of adolescents in the study was not sufficient to detect rare adverse events, and that long term safety and efficacy is unknown (42% of participants had less than two months follow up after their second dose, before the trial's cut off date). One participant had a life threatening adverse reaction, but had since turned 16 and was not included in the data. The TGA acknowledged higher than normal instances of myocarditis and pericarditis (inflammation of the heart muscle) had been observed in adolescents after receiving the Pfizer vaccine. The TGA stated "it may be postulated that myocarditis and pericarditis could be systemic inflammatory reaction due to an immune response to the vaccine", but claimed a "causal association ... with the vaccination is not yet clear".

The TGA acknowledges that Covid-19 is usually mild in adolescents. None of the adolescent participants in the trial (vaccinated or placebo) had any severe Covid-19 symptoms. The TGA has warned that severe disease and death can occur in Covid-19 disease, especially in adolescents with underlying medical conditions. However, adolescents with immunodeficient status or high health risks *were not assessed* in the study of Pfizer's effectiveness in adolescents.

The Therapeutic Goods Administration's safety and efficacy assessment of Covid-19 vaccines

The head of the TGA, John Skerritt, has acknowledged the efficacy of both the Pfizer and AstraZeneca vaccines is unknown,[37] however claimed the "safety evidence is pretty thorough".[38] This is despite the fact that, for example, the TGA has acknowledged that in the AstraZeneca vaccine "there are

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[33] "TGA approves Pfizer COVID-19 vaccine for 12 to 15-year-olds", Department of Health, (health.gov.au)

[34] Coronavirus Disease 2019 (COVID-19), CDNA National Guidelines for Public Health Units, Version 4.7, Department of Health, 24 June 2021 (health.gov.au), page 10

[35] Australian Public Assessment Report for BNT162b2 (mRNA), Extension of Indications, [Adolescents] Therapeutic Goods Administration, (tga.gov.au), page 30

[36] Australian Public Assessment Report for BNT162b2 (mRNA), Extension of Indications, Therapeutic Goods Administration, (tga.gov.au), page 30

[37] Mr Skerritt's answers to Senator Malcolm Roberts, Community Affairs Legislation Committee, Health Portfolio, Hansard, (parlinfo.aph.gov.au) 1 June 2021

[38] "'Safety evidence for the Pfizer vaccine is pretty thorough': TGA head", The Weekend Australian, (theaustralian.com.au), 7 August 2021

significant concerns about the robustness of the data" and that "the study design was not entirely fit for purpose to evaluate efficacy in high risk groups".[39]

The TGA claims "Australians can be confident" its review process of both vaccines was "rigorous and of the highest standard."[40] However, the TGA's 21 May 2021 response to a Freedom of Information request has revealed that the TGA has not seen the raw data from clinical trials,[41] and is essentially 'taking the manufacturers word for it'.

The TGA acknowledges that the decision to approve Covid-19 vaccines was based on information (including safety, efficacy and risk management) which was *submitted by the manufacturers*.[42] There have been no independent studies on safety and efficacy, as all clinical trials of the vaccines have been conducted by the vaccine manufacturers or developers.[43]

Independent clinical trials should have been an essential condition of the TGA's provisional approval of Covid-19 vaccines, particularly as both AstraZeneca and Pfizer have collectively paid billions of dollars in fines for egregious misconduct.[44]

Originally, the therapeutic use of Pfizer's vaccine in Australia was indicated "in an officially declared pandemic", however, *upon the TGA's request* Pfizer removed that specific condition.[45] Now Pfizer's vaccine is broadly indicated for use "in accordance with official recommendations"—no 'official pandemic' is required. This is an essential distinction to allow for regular ongoing "booster shots", even after the Covid-19 pandemic is declared over. Chief health officials and the Operation COVID Shield manual have determined that booster shots will be required or are likely to be required,[46] although it is unclear what information this is based on, as vaccine efficacy is not yet established. Notably, the vaccine rollouts and potentially indefinite booster shots are highly lucrative for pharmaceutical companies including Pfizer, which is projected to rake in tens of billions of dollars in revenue this year.[47]

Should Australians trust the drug regulator?

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[39] Australian Public Assessment Report for ChAdOx1-S, Therapeutic Goods Administration, (tgs.gov.au), page 28

[40] "COVID-19 vaccine: Pfizer Australia - COMIRNATY BNT162b2 (mRNA) - approved for use in individuals 12 years and older", Therapeutic Goods Administration, (tga.gov.au), 23 July 2021; "COVID-19 vaccine: AstraZeneca ChAdOx1-S", Therapeutic Goods Administration, 26 March 2021 (tga.gov.au)

[41] Email response from the Therapeutic Goods Administration sent 21 May 2021, regarding FOI 2289, (accessed via web archive doctor4covidethics.org

[42] "Covid-19 Vaccine AstraZeneca", Therapeutic Goods Administration, (tga.gov.au), 16 February 2021; "Comirnaty" [Pfizer's Covid-19 Vaccine], Therapeutic Goods Administration, (tga.gov.au) 25 January 2021

[43] Australian Public Assessment Report for BNT162b2 (mRNA), Table 3, Therapeutic Goods Administration, (tga.gov.au), page 15; Australian Public Assessment Report for ChAdOx1-S, Therapeutic Goods Administration, (tgs.gov.au), page 15

[44] "Pharmaceutical Giant AstraZeneca to Pay $520 Million for Off-label Drug Marketing", United States Department of Justice, (justice.gov), 27 April 2010; AstraZeneca: US$1.1 billion penalties paid since 2000, via Violation Tracker; "Justice Department Announces Largest Health Care Fraud Settlement in Its History, Pfizer to Pay $2.3 Billion for Fraudulent Marketing", United States Department of Justice, (justice.gov), 2 September 2009; Pfizer: US $4.6 billion penalties paid since 2000, via Violation Tracker

[45] Australian Public Assessment Report for BNT162b2 (mRNA), Therapeutic Goods Administration, (tga.gov.au), page 37

[46] Chief Medical Officer Professor Paul Kelly's answers to Senator Malcolm Roberts, Community Affairs Legislation Committee, Health Portfolio, Hansard, (parlinfo.aph.gov.au) 1 June 2021; "Operation COVID Shield National COVID Vaccine Campaign Plan", Department of Health, (health.gov.au), page 3

[47] Donato Paolo Mancini, Hannah Kuchler, Mehreen Khan, "Pfizer and Moderna raise EU Covid vaccine prices", (ft.com), 1 August 2021

The Therapeutic Goods Administration (TGA) regulates medicines and therapeutic goods in Australia. There have been serious concerns raised over the TGA's "regulatory capture". The agency's funding model requires the TGA to fully fund itself through "fees for service" charged to the companies it regulates.[48] Essentially, this means the pharmaceutical industry pays the TGA to regulate it! This model has led to the TGA being accused of being too cosy with Big Pharma, and its independence questioned.[49]

Just going by recent history, Australians would be unwise to simply trust the assurances of the drug regulator. A recent and horrifying example would be the transvaginal mesh scandal, where thousands of Australian women underwent surgical procedures which implanted defective mesh products to supposedly treat prolapse. A 2018 Senate Inquiry into the matter documented how these women experienced serious complications, incontinence, sexual dysfunction and years of debilitating chronic pain, which was so bad that some women have committed suicide.[50] Up to 18,000 Australian women have suffered complications from the defective transvaginal mesh devices, which the 15 June 2019 Sydney Morning Herald reported "sentenced thousands of women to a life of pain".[51]

The Senate Inquiry into the matter found that TGA did not require independent clinical evidence about most of the mesh products, over one hundred of which it approved for use. During the Senate Inquiry, it was revealed that the majority of the women did not give informed consent to the procedure. Women were not informed that there was little robust data on the safety and efficacy of the product, their doctors did not adequately explain the serious risks involved, and did not inform them that, in a number of cases, the procedure may have not been necessary at all.

During the Senate Inquiry, the TGA was questioned over its action of approving the devices "without a strong evidence base", and without clinical trials. During the inquiry, TGA head John Skerritt shifted the blame on to the US drug regulator, the Food and Drug Administration, for approving the products.

In an April 2019 National Forum on Mesh Injury held by the Health Consumers Council (WA) and WA Pelvic Mesh Support Group, both John Skerritt and Health Minister Greg Hunt were guest speakers. A summary reported was provided to the December 2019 Ministerial Roundtable on Mesh.[52] The report published comments from participants gathered from a post-forum feedback survey. Attendees were highly critical of both Skerritt and Hunt.

Hunt did not attend in person, and attendees found him "condescending". Participants commented: "To not have the opening statements from Hon Greg Hunt and Hon Catherine King was extremely disappointing for everyone. Maybe he was having another photo with the CEO of Johnson & Johnson. He makes an apology to the mesh sufferers around Australia and then is seen in that photo was insulting. We all wanted to ask him so many questions and didn't have the chance."

Several attendees pointed out that Skerritt spent an "inappropriate" amount of time on his phone during the event: "Watching Professor John Skerritt on his phone the majority of the time the presentation was being shown. He showed no interest or compassion throughout this presentation

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[48] About the TGA: Fees and Payments, Therapeutic Goods Administration, (tga.gov.au)

[49] Melissa Davey, "Therapeutic Goods Administration rejects claims it is 'too close' to medical industry", The Guardian, (theguardian.com), 8 November 2017

[50] "Number of women in Australia who have had transvaginal mesh implants and related matters", Senate Community Affairs References Committee, (aph.gov.au), 28 March 2018

[51] Amanda Hooton and Joanne McCarthy, "The 'eight-minute' cure: how transvaginal mesh sentenced thousands of women to a life of pain", Sydney Morning Herald, (smh.com.au), 15 June 2019

[52] Report on National Mesh Injury Forum—5th April 2019, Health Consumers Council (WA) Inc. and WA Pelvic Mesh Support Group, (hconc.org.au)

and he was distracted during the panel discussions as well, talking with Danny while others were talking. The presentations had taken Mesh sufferers so many overwhelming emotions to put together and he couldn't even give them the respect they deserved. He put his head up a couple of times to watch with still no response of emotion. With women crying nearby him. No matter what important message was on his phone it could of waited for that brief time. Disgraceful!!!"

"The testimonials were well presented and heartfelt. Pity John Skerritt didn't take notice or feel they were important to watch."

Mesh sufferers reported a demonstrable lack of interest and compassion for their suffering from TGA head John Skerritt, whose agency approved the products without a strong evidence base or clinical trials. This does not bode well for any Australians who suffer complications or adverse reactions from Covid-19 vaccines. It is notable that under Health Minister Greg Hunt, pharmaceutical companies have enjoyed a meteoric escalation of approvals for the lucrative taxpayer-funded Pharmaceutical Benefits Scheme.[53]

Covid-19 vaccines: other "regulatory capture" concerns

The 22 July 2021 Australian Financial Review reported the recent "shake-up" of the leadership of the government's top immunisation advisory body, the Australian Technical Advisory Group (ATAGI).[54] Prime Minister Scott Morrison denied that the change in leadership was related to the PM's widely-reported push[55] for the ATAGI to change its advice about the appropriateness of administering AstraZeneca to younger people, after deaths and adverse reactions from blood clotting disorders had restricted its use to those over 50.[56]

Several days after the appointment of the ATAGI's new head, Professor Nigel Crawford, ATAGI's advice changed to recommend all Australians over 18 years of age "strongly consider getting vaccinated with any available vaccine" including AstraZeneca.[57]

ATAGI does not disclose[58] that its new head, Professor Nigel Crawford, has served as an advisory board member for Pfizer,[59] and oversees vaccine research trials for the Murdoch Children's Research Institute (MCRI), which itself receives funding from pharmaceutical companies.[60] Crawford's bio on MRCI's website only lists government funding and does not disclose that his MCRI research has received funding from Pfizer.[61] Similarly, other members of the ATAGI do not disclose the full extent of potential conflicts of interest from their connections with, or funding from, pharmaceutical companies and organisations funded by pharmaceutical companies.[62]

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[53] Greg Hunt: 'Speech - Medicines Australia PharmAus 2019'

[54] Tom McIlroy, "ATAGI shake-up not connected to vaccine advice: PM", Australian Financial Review, (afr.com), 22 June 2021

[55] Tom McIlroy and Tom Burton, "'A constant appeal': experts reject PM's vaccine frustration", Australian Financial Review (afr.com), 21 July 2021

[56] "ATAGI statement on revised recommendations on the use of COVID-19 Vaccine AstraZeneca, 17 June 2021", Department of Health, (health.gov.au), 17 June 2021

[57] "ATAGI Statement, Response to NSW COVID-19 outbreak 24th July 2021", Department of Health, (health.gov.au), 24 July 2021

[58] Australian Technical Advisory Group on Immunisation (ATAGI) Declarations of Interest, Department of Health, (health.gov.au)

[59] Crawford et al, "An australian audit of vaccination status in children and adolescents with inflammatory bowel disease", University of Melbourne, (unimelb.edu.au),

[60] New Vaccines: Infection and Immunity, Murdoch Children's Research Institute, (micru.edu.au); Vaccine and Immunisation Research Group (VIRGo), (micro.edu.au),

[61] Professor Nigel Crawford, Murdoch Children's Research Institute, (micru.edu.au)

[62] "Conflicts of Interest in Australian Vaccination Policies: References", Informed Medical Options Party, (imoparty.com)

Australian health practitioners silenced

The Australian public will not be privy to any genuine concerns about the Covid-19 vaccines from health practitioners, including those who may have prescribed and administered the Covid-19 vaccines, or who have treated patients who have experienced adverse effects from the vaccines. Health professionals who may have concerns about the safety or efficacy of the provisionally approved Covid-19 vaccines have been silenced.

The Australian Health Practitioner Regulation Agency (AHPRA) has threatened health practitioners with regulatory action if they contradict the government's public health messaging.[63] AHPRA has reminded practitioners in its Covid-19 vaccine position statement that "it is an offence under the National Law to advertise a regulated health service (including via social media) in a way that is false, misleading or deceptive." AHPRA has determined that "advertising" will also include "false, misleading or deceptive claims about COVID-19", which includes "anti-vaccination material". If health practitioners "advertise" anti-vaccination material on their own social media, this "may result in prosecution by Ahpra".

AHPRA informed health practitioners that "any promotion of anti-vaccination statements" or health advice which "seeks to actively undermine the national immunisation campaign (including via social media) … may be in breach of the codes of conduct and subject to investigation and possible regulatory action". AHPRA has directed that health practitioners must make sure their social media activity "does not contradict or counter public health campaigns or messaging, such as the Australian COVID-19 Vaccination Policy".

The Pharmacy Board Chair, Brett Simmonds, informed health practitioners that "[t]here is no place for anti-vaccination messages in professional health practice, and any promotion of anti-vaccination claims including on social media … may be subject to regulatory action."[64]

The TGA has instructed health practitioners that "Commonwealth messaging about the COVID-19 vaccines is crafted to both *facilitate optimal uptake* and to ensure the public receives accurate information about safety and efficacy. References to the safety and efficacy of COVID-19 vaccines *must be in alignment with Commonwealth health messaging*."[65] (Emphasis added) Notably, as referenced in this report, the TGA's own product information documents contain safety and efficacy information which, if publicised by health practitioners, would likely not 'align with Commonwealth health messaging'.

The government has mandated Covid-19 vaccines for nurses and healthcare workers in aged care settings by mid-September 2021. The Nurses Professional Association of Queensland (NPAQ) has opposed mandatory Covid-19 vaccination, pointing out that "Nurses are tertiary educated medical professionals and should be left to make their own informed decision regarding vaccination".[66] NPAQ states that "Many nurses, particularly those that are older and more experienced, have stated that they would rather leave the profession than be forced to vaccinate." In April 2021, NPAQ President Marg Gilbert stated that nurses already had to take a series of tried and tested vaccines to obtain a job, but

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[63] "Position statement: Registered health practitioners and students and COVID-19 vaccination", Australian Health Practitioner Regulation Agency (AHPRA), (ahpra.gov.au), 9 March 2021

[64] "Registered health practitioners and students: What you need to know about the COVID-19 vaccine rollout", Australian Health Practitioner Regulation Agency (AHPRA), (ahpra.gov.au), 9 March 2021

[65] "Communicating about COVID-19 vaccines", Therapeutic Goods Administration, (tga.gov.au), 30 July 2021

[66] "No mandatory Covid vaccines: Defending your right to choose", Nurses Professional Association of Queensland (NPAQ), (npaq.redunion.com.au)

pointed out the Covid-19 vaccine was “an experimental therapy at this point.”[67] Almost one third of Western Australian nurses working in aged care said they would rather quit their jobs than be forced to have a Covid-19 vaccine.[68]

In January 2021, the Australian Health Protection Principal Committee (AHPPC), the government’s peak public health emergency management body, did not recommend mandating vaccines for residential aged care workers because evidence about efficacy in preventing transmission was not yet available.[69] However, in June the AHPPC reversed its position and recommended mandatory vaccinations for this cohort, despite the fact that vaccine efficacy in preventing transmission is still not established.[70]

Australian media, which has been heavily skewed to promoting the government's ‘official line’ on Covid-19 health measures and vaccinations, frequently uses members of the Australian Medical Association (AMA) as a source to support mandatory vaccination policies and to counter any dissenting voices from the medical profession.

However, these media reports do not disclose that the AMA has significant conflicts of interest in its membership of the vaccine lobby group, the Immunisation Coalition, which is funded by vaccine manufacturers.[71] The AMA has been described by the Grattan Institute’s Stephen Ducket as a "powerful lobbyist” which is “adept at dressing up its concerns in high-sounding rhetoric about the public interest. It is also skillful at concealing its weakness in terms of representing a united medical profession”,[72] as the AMA only represents 30 per cent of Australia’s doctors.[73]

PUBLIC HEALTH SECTOR PANDEMIC RESPONSE

Australian government abandoned its own Emergency Response Plan for Covid-19

In February 2020, at the beginning of the Covid-19 outbreak, the Department of Health published the ‘Australian Health Sector Emergency Response Plan for Novel Coronavirus (COVID-19)’,[74] which was “designed to guide the Australian health sector response”. Notably, the Emergency Response Plan says that in 2008 the Australian Health Protection Principal Committee (AHPPC) agreed on an Ethical framework to guide health sector responses, which does not appear to have been adhered to. The Ethical Framework says the AHPPC’s health sector response should:

- Ensure the rights of the individual are upheld as much as possible
- Ensure that measures taken are proportional to the threat
- Ensure that the protection of the entire population [i.e. not only Covid-19 cases] remains a primary focus

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[67] Robyn Ironside and Nicholas Jensen, “Health staff reject ‘experimental’ Covid-19 jabs”, The Weekend Australian, (theaustralian.com.au), 22 April 2021

[68] Evelyn Manfield, “COVID vaccine backlash among WA aged care nurses as hundreds in survey threaten to quit”, ABC, (abc.net.au), 18 June 2021

[69] “Australian Health Protection Principal Committee (AHPPC) statement on COVID-19 and influenza vaccination requirements for aged care workers”, Department of Health, (health.gov.au), 23 January 2021

[70] “Australian Health Protection Principal Committee (AHPPC) statement on residential aged care worker COVID-19 vaccination”, Department of Health, (health.gov.au), 29 June 2021

[71] Membership, Immunisation Coalition, (immunisationcoalition.org.au); About Us: Funding, Immunisation Coalition, (immunisationcoalition.org.au)

[72] Stephen Ducket, “Patient advocate or doctors’ union? How the AMA flexes its political muscle”, The Grattan Institute, (grattan.edu.au), 9 June 2016

[73] Dr Bill Coote, “How low can the AMA go?”, (medicalrepublic.com.au), 30 April 2018

[74] Australian Health Sector Emergency Response Plan for Novel Coronavirus (Covid-19), Department of Health, (health.gov.au)

- Ensure that when individuals are asked to take measures or perform duties for the benefit of society as a whole, their acts are appropriately recognised and legitimate needs associated with these acts are met where possible

The February 2020 Covid-19 Emergency Response Plan states it is based on the Australian Health Management Plan for Pandemic Influenza (the AHMPPI),[75] as "key committees and expert groups have agreed the approach and activities of the AHMPPI are relevant and broadly applicable to the novel coronavirus outbreak". The AHMPPI was last updated in August 2019, and is "the key nationally agreed document to guide Australia's response". However, the public health measures enacted in response to Covid-19 have **not** followed the AHMPPI's directions, and in many cases, were explicitly contraindicated.

The AHMPPI says that isolation and quarantine of close contacts is to be "voluntary", and that proactive or reactive school closures, (P145-146) workplace closures, (P147) cancellations of mass gatherings (P149) are **not** generally recommended. There are a number of health measures which have been enacted to manage Covid-19 that the pandemic plan explicitly **does not** recommend, because of poor efficacy and costs to the community. These include thermal scanners, (P136) screening of passengers on cruise ships prior to disembarkation, (P138) quarantine of contacts at the border, (P140) exit screening, (P141) or internal travel restrictions across state or territory borders or within the states and territories (P142). Measures must be regularly reviewed so they could be adjusted "to be more appropriate to the level of risk", and tailored to different populations.

The February 2020 Australian Health Sector Emergency Response Plan for Novel Coronavirus (Covid-19) says that "[c]linical severity [of the disease] is likely to be critically important in making an estimate of impact." Determining clinical severity is one of the focuses of the "Initial Action stage". However, information on Covid-19's clinical severity is still not readily available on the Department of Health's website.

Even so, the Communicable Disease Network (CDNA) has acknowledged Covid-19 presents as a mild disease for most people, and severe or fatal outcomes occur more frequently in the elderly and those with comorbidities.[76] The CDNA's description appears to fit the AHMPPI's definition of a pandemic with "low clinical severity". AHMPPI describes 'low clinical severity' as "The majority of cases are likely to experience mild to moderate clinical features. People in at-risk groups may experience more severe illness." (P22)

The Australian Health Sector Emergency Response Plan for Novel Coronavirus (Covid-19) describes 'low clinical severity' as "[t]he majority of cases are likely to experience mild to moderate clinical features. People in at-risk groups and those with comorbidities may experience more severe illness." 'Moderate clinical severity' is described as follows: "People in at-risk groups may experience severe illness. As the number of cases grows the number of people presenting for medical care is likely to be higher than for severe seasonal influenza". (P12)

Notably, in 2019 Australia experienced one of the worst influenza seasons on record. There were 310,011 cases of confirmed influenza. There were 812 influenza-attributed deaths; 3,915 people admitted to hospital, of which 246 (6.3%) were admitted to ICU. The median age of death was 86

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[75] Australian Health Management Plan for Pandemic Influenza (AHMPPI), Department of Health, (health.gov.au), August 2019

[76] Coronavirus Disease 2019 (COVID-19), CDNA National Guidelines for Public Health Units, Version 4.7, Department of Health, 24 June 2021 (health.gov.au), page 10.

years, although there were deaths in the age range of under one years old to 106 years.[77] In Western Australia alone, influenza caused 1389 hospitalisations, and 80 deaths, including five children aged under 10 years old.[78]

The Department of Health's latest figures for Covid-19 state that of the 3,269 cases of Covid-19 reported in Australia from 1 January 2021 to 18 July 2021, the estimated proportion of cases hospitalised was 9.9% (209/2,119) and the proportion of cases admitted to the intensive care unit (ICU) was 2.5% (52/2,119). (I note that hospital data was only available for 2,119 of 3,269 total cases.) The case fatality rate for the year to date is 6 people, or 0.2 per cent.[79]

The AHMPPI states that the trigger for the "Standdown" stage of the public health response should occur when the CDNA advises that "the needs of the situation can be met by seasonal influenza arrangements and monitoring for change is in place". (P114) The AHPPC will then consider moving to "Standdown".

Doherty Institute's modelling errors possibly influenced government's lockdown strategy

The Doherty Institute's modelling and advice has been central to the government's public health response to Covid-19. Early in the Covid-19 outbreak, the Doherty Institute's April 2020 Covid-19 modelling, of which Professor Jodie McVernon was co-author, predicted armageddon-like scenarios of unmanageable pressure on the public health system.

From Professor McVernon's modelling, which was released by the National Cabinet,[80] the Australian government produced a report, 'Impact of Covid-19'.[81] This report documented that "theoretical scenario modelling by the University of Melbourne (Doherty Institute) Pandemic Modelling Team finds an uncontrolled coronavirus pandemic would overwhelm our health system for many weeks. Around 89 per cent of people would catch the virus, with 38 percent requiring some medical care. ICUs would be well beyond capacity for a prolonged period."[82] The Doherty/McVernon modelling suggested that 65.9% of people over 80 years old could be hospitalised (19.4% ICU). Of those aged 70-79, 35.8% could be hospitalised (4.55% require ICU). The modelling suggested that 5.4% of all people in Australia would be hospitalised, and suggested an infection rate of 89.1%.

However, the Doherty Institute's early modelling for the government's Covid-19 response used deeply flawed data from the Imperial College, which predicted catastrophic death tolls from Covid-19. The Imperial College's data has since been exposed as vastly exaggerated and woefully inaccurate.[83]

Troublingly, a major error was also discovered in the Doherty/McVernon modelling and reported in April 2020, but the Institute did not publish a correction or admit the error until September 2020, after it was

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[77] Australian Influenza Surveillance Report, No. 12, 2019, Department of Health, (health.gov.au)

[78] "WA records lowest flu numbers in history", Media statement from Deputy Premier and Minister for Health Roger Cook, (wa.gov.au), 2 May 2020

[79] Communicable Disease Intelligence 2021, Volume 45, Covid-19 Australia: Epidemiology Report 46, Reporting period ending 18 July 2021, Department of Health, (health.gov.au), page 2

[80] Media Statement, Prime Minister, (pmc.gov.au), 7 April 2020

[81] "Impact of Covid-19: Theoretical modelling of how the health system can respond", Australian Government, (pmc.gov.au)

[82] Media Statement, Prime Minister's Office, (pm.gov.au), 7 April 2020

[83] Phillip W Magness, "The Failure of Imperial College Modeling Is Far Worse than We Knew', American Institute for Economic Research, (aier.org), 22 April 2021; Peter St One and Gael Campan, "The Flawed Covid-19 Model That Locked Down Canada", MEI, (idea.org), 5 June 2020

revealed in the media that a critical error in the modelling had dramatically overestimated the impact of Covid-19 on the healthcare system.[84]

After noticing the discrepancy between the modelling and Australia's actual Covid-19 ICU demand, James Cook University Professor of Infectious Diseases Epidemiology and Modelling, Emma McBryde, and her research team, requested that the Doherty Institute share the model's underlying code, however this was refused. However, McBryde's team was able to work out the error without the code, and realised that Doherty/McVernon had mistakenly transposed the number of hospital admissions with ICU admissions. This error reportedly exaggerated the projected demanded on ICU beds *by fourfold*.

McBryde's team say they notified the Doherty Institute of the error in April 2020, but the Institute did not correct or revise their model. The Doherty Institute says they informed the government of the error in June. The Doherty Institute and McVernon did not publicly acknowledge the error until 10 September 2020,[85] after it was exposed by the Daily Telegraph, which reported the "financially crippling lockdown" was based on a "calculation error". According to McBryde,"[l]eaving something inaccurate uncorrected on the public record is pretty close to research misconduct".

Health Minister Greg Hunt was dismissive of the modelling error, claiming that it wouldn't have affected the government's actions at all.[86] McVernon also dismissed the impact of the error, arguing that the model had accurately concluded "response strategies needed to ensure ICU capacity were not exceeded". McVernon said the error in the model did not affect its implications for policy.[87]

However, the model's prediction of ICU demand exceeding at best 5,000 beds a day (while implementing strict quarantine and social distancing measures) and at worst 35,000 beds a day, was widely reported by the media[88] and referenced by Australia's top health officials.

On 7 April 2020, Chief Medical Officer Professor Brendan Murphy presented the Doherty Institute's modelling at a parliamentary press conference, and referenced the modelling's "horrendous" figure of ICU demand exceeding 35,000 beds per day.[89]

Professor Murphy said: "the modellers looked at what would happen in this highly artificial situation if right across Australia we had diffuse seeding of this virus so that nearly 90% of the population, 23 million people, were infected at the same time. That's an incredibly unlikely scenario, that the whole country gets infected at the same time. But that, in microcosm, has been seen in some cities in the world, where we've had these huge outbreaks that have overwhelmed the system. But if that happened in Australia, you would see a very, very big peak. … in this scenario, which is what we call the unmitigated scenario, this is where you just let the virus spread, you do nothing, and treat people as they seek medical attention. And as you can see, and as has been seen in some countries, this is

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[84] Matthew Benns, "Coronavirus Australia: Lockdown based on calculation error", The Daily Telegraph, (dailytelegraph.com.au), 10 September 2020

[85] "Statement regarding Doherty Institute modelling", Doherty Institute, (doherty.edu.au), 10 September 2020

[86] Doorstop interview on 10 September 2020, Health Minister Greg Hunt, Department of Health, (health.gov.au), 10 September 2020

[87] "Statement regarding Doherty Institute modelling", Doherty Institute, (doherty.edu.au), 10 September 2020

[88] Professor Tony Blakely, "Yes, we're flattening the coronavirus curve but modelling needs to inform how we start easing restrictions", The Conversation, (theconversation.com), 8 April 2020

[89] Press Conference, Australian Parliament House, ACT: 7 April 2020: National Cabinet meeting; coronavirus modelling; Easter weekend; commercial tenancies; schools; economic response plan; JobKeeper Payment; and social distancing, (aph.gov.au), 7 April 2020

an horrendous scenario. … you would see an ICU daily demand for new intensive care beds … of 35,000-plus, completely beyond the realm of any country like Australia to create. So, very important message. If you had this highly artificial, very unlikely diffuse outbreak, you couldn't meet demand."

As part of its Covid-19 management response, Australia tripled its ICU capacity to 7,000 beds.[90] The Doherty Institute incorrectly predicted 35,000 ICU daily patients in the "worst case scenario" for unmitigated spread ("let the epidemic rip"), with no public health measures implemented at all, such as isolation of sick people. It should be taken into account that some of the data used to make these assumptions was based on the deeply flawed and inaccurate Imperial College data. There still has not been modelling released using real-world data from Australia, even though the National Cabinet requested this from the Doherty Institute in April 2020.[91] Chief Medical Officer Brendan Murphy reiterated this at the 7 April 2020 press conference, when he was questioned about using real Australian data in the modelling: "We now have data on nearly 6,000 Australians. That data is currently in the hands of our modellers and they are doing just as you say. It's still very early data yet. Once we have something that is scientifically valid and useful, the National Cabinet has asked us to share it with them and they will share it with you."

Concerns raised about Australia's Covid-19 modelling and statistics

Members of the Australian public have raised serious concerns about the modelling and statistics used to inform Australian Covid-19 response. This includes Mr John Clark, formerly of the government's National Measurement Institute (NMI). Mr Clark was appointed to the NMI as a "Legal Metrologist", which means that his measurement reports are considered evidence in a court of law. In a 10 July 2021 open letter to Health Minister Greg Hunt, Mr Clark expressed concern about systemic deficiencies in the government's modelling of Covid-19 disease and risk parameters.[92] Clark described the "abuse of key vaccine safety statistics", which he claims have been manipulated to present a false picture of efficacy to the public.

Clark referred to a question he had personally asked Hunt during a recent online webinar, and expressed his alarm that Hunt's answer showed he evidently did not understand the most basic measurements essential to understanding the severity of Covid-19. Clarke asks Hunt in his letter, "if you don't have an objective, tangible measure of how deadly COVID-19 is, how can you decide what responses are appropriate and proportional to the risk? … It is not as though these measures have not been available. They have been available for at least 12 months."

Clark recommends: "The time may be right to reconsider your position and to advocate in Parliament for a complete root-and-branch reassessment of the COVID-19 risk data and vaccine safety data, "red team" style", which "is the creation of a completely independent team of skilled doctors, scientists and researchers (with a preference to select those who have a demonstrated history of opposition or scepticism to the current consensus) tasked with the root-and-branch review and critical audit and assessment of the analysis and reports of the groups that currently advise you."

VACCINE ROLLOUT

The National Cabinet dictates "Standdown" to be based on vaccine take-up

Many of the public health measures enacted in response to the Covid-19 outbreak have contradicted the 'Australian Health Sector Emergency Response Plan for Novel Coronavirus (COVID-19)'. Although

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[90] "Impact of Covid-19: Theoretical modelling of how the health system can respond", Australian Government, (pmc.gov.au)

[91] Media Statement, Prime Minister, (pmc.gov.au), 7 April 2020

[92] Letter to Health Minister Greg Hunt from Mr John Clark, 10 July 2021

the Plan says it “should be considered a living document that will be periodically updated”, it has not been updated since April 2020.

This may be because of the March 2020 formation of the National Cabinet, which replaced the Council of Australian Governments (COAG). The National Cabinet is an intergovernmental body comprised of the Prime Minister and the State Premiers. Since its formation, the National Cabinet has been used to coordinate the nationwide public health response, and has directed some of the most restrictive and unprecedented health measures. This includes the decision to pursue a 'suppression strategy',[93] to mandate vaccinations for residential aged care workers,[94] restrictions of gatherings and business closures,[95] and to place additional restrictions on Australians trying to enter the country, and prevent Australians citizens from leaving Australia.[96]

Prime Minister Scott Morrison has declared that the newly-formed “National Cabinet” was subject to longstanding Westminster conventions which protected its deliberations from disclosure in Freedom of Information requests. There have been concerns raised by parliamentarians that the government has used the National Cabinet as a vehicle to avoid transparency over its decision making.[97]

Anne Twomey, Professor of Constitutional Law and Director of the Constitutional Reform Unit at Sydney Law School at the University of Sydney, has described the distinction between a federal cabinet body and the National Cabinet: “A critical element of a “cabinet” is that it derives its existence from, and is accountable to, parliament. This is a fundamental aspect of the principle of “responsible government”. Ministers are responsible to parliament for their actions as ministers. The lower house can hold the government to account for cabinet’s decisions by voting no confidence in it, forcing its resignation or an election.”

However, the “National Cabinet” was not subject to normal parliamentary oversight, and made sweeping decisions which impacted Australians in an unprecedented way. Many of the National Cabinet's decisions were contraindicated by the February 2020 ‘Australian Health Sector Emergency Response Plan for Novel Coronavirus (COVID-19)’.

A 5 August 2021 federal court ruling determined that the “National Cabinet” could not be found to be a part of federal cabinet. The judge found, “The mere use of the name “National Cabinet” does not, of itself, have the effect of making a group of persons using the name a “committee of the Cabinet”. Nor does the mere labelling of a committee as a “Cabinet committee” have that effect. … Another point of distinction is that unlike other cabinet committees, the national cabinet is not comprised, at least substantially, of ministers of the federal government.” The National Cabinet “is not even comprised of persons belonging to the same government, let alone the same political party.” The judge observed that members of the so-called “National Cabinet” (such as the state premiers) were not even members of the Australian parliament.[98]

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[93] Coronavirus (Covid-19) in Australia—Pandemic Health Intelligence Plan, Department of Health, (health.gov.au); Media statement, Prime Minister’s Office, (pm.gov.au), 16 April 2020

[94] Media Statement, Prime Minister’s Office, (pmc.gov.au), 28 July 2021

[95] Media Statement, Prime Minister, (pmc.gov.au), 18 March 2020; Media Statement, Prime Minister’s Office, (pmc.gov.au), 22 March 2020

[96] Media Statement, Prime Minister, (pmc.gov.au), 22 April 2021

[97] Chapter 7: National governance, coordination and communication, First Interim Report, Senate Select Committee on Covid-19, (aph.gov.au)

[98] Patrick v Prime Minister, Administrative Appeals Tribunal, Freedom of Information Division, (accessible here) 5 August 2021; Max Maddison, “Judge rejects Scott Morrison’s call on national cabinet privilege”, The Australian, (theaustralian.com.au), 6 August 2021

On 2 July 2021, rather than complying with the “Standdown” procedures outlined in the Australian Health Sector Emergency Response Plan for Novel Coronavirus (COVID-19)’, the National Cabinet announced the formulation of their own "National Plan”, which is the bedrock of Operation COVID Shield. This four-phase "National Plan” dictated that the lifting of restrictions and lockdowns would be contingent upon *the achievement of vaccination thresholds.* This is in spite of the fact the TGA’s Covid-19 vaccine literature says: “At this stage, efficacy in preventing asymptomatic disease and transmission is unknown. … **It is important that the population understand the facts about the efficacy of the vaccine, and limitations of the data, and the need to continue other public health measures** to prevent the spread of disease **until more information about vaccine efficacy is available.**” “Vaccination does not mitigate the need to follow other official recommendations to prevent the spread of COVID-19.” [99]
The National Plan is focused on transitioning Australia from “pre vaccination settings” (focused on continued suppression of community transmission) to “post vaccination settings” (focused on prevention of serious illness, hospitalisation and fatality, and the public health management of other infectious diseases).[100]

Instead of the trigger for “Standdown” depending on advice from the Communicable Disease Network (CDNA) that the pandemic can be managed with seasonal influenza arrangements, the National Cabinet’s plan has relied on modelling and advice from Professor Jodie McVernon of Melbourne’s Doherty Institute to “transition Australia's Covid response”.[101]

Doherty Institute’s modelling the basis for Operation COVID Shield's vaccine rollout

Despite the serious errors made in the Doherty Institute's earlier Covid-19 modelling, and ethical questions over its secrecy and failure to publicly correct vital mistakes which resulted in catastrophic consequences for many Australians, the National Cabinet recently commissioned the Doherty Institute again—to model Australia’s “Standdown” from public health measures.

The Doherty Institute’s modelling is the basis for the National Cabinet’s ‘National Plan’, which is the foundation of the lifting of restrictions and Operation COVID Shield’s vaccine rollout. Professor Jodie McVernon’s modelling predicts that with only 50 per cent vaccine coverage, there would be 10,311 deaths in Australia. The best-case outcome of 80 per cent vaccination coverage is 2,309 deaths. (P17) [Notably, TGA and the vaccine manufacturers acknowledge that the efficacy of both vaccines in preventing transmission in unknown.]

Notably, the Doherty Institute’s modelling appears to significantly differentiate from the real-world Covid-19 experience in Australia. The Australian government's official Covid-19 figures record millions of tests conducted, with a positive result rate of 0.1%.[102] In the Department of Health’s latest figures, there have been 3,269 cases of Covid-19 reported in Australia from 1 January 2021 to 18 July 2021, and of those, the case fatality rate is 6 people, or 0.2%.[103] As described below, the Doherty Institute’s modelling does not use real-world data from Australia.

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[99] Media Statement, Prime Minister, (pmc.gov.au), 2 July 2021; Australian Public Assessment Report for ChAdOx1-S, Therapeutic Goods Administration, (tgs.gov.au, page 37; Australian Product Information, Covid-19 Vaccine AstraZeneca (ChAdOx1-S), Therapeutic Goods Administration, (ebs.tga.gov.au), page 3

[100] “Operation COVID Shield National COVID Vaccine Campaign Plan”, Department of Health, (health.gov.au), page 3

[101] Doherty Institute Modelling Report to advise on the National Plan to transition Australia's National COVID Response, Department of Health, (health.gov.au), 3 August 2021

[102] Coronavirus (COVID-19) case numbers and statistics, Department of Health, (health.gov.au), retrieved 7 August 2021

[103] Communicable Disease Intelligence 2021, Volume 45, Covid-19 Australia: Epidemiology Report 46, Reporting period ending 18 July 2021, Department of Health, (health.gov.au), page 2

The ‘Doherty Institute Modelling Report to advise on the National Plan to transition Australia's National COVID Response’, authored by Professor McVernon, has determined that lifting of restrictions is contingent upon large-scale vaccination. (Even though, as previously stated, the TGA states efficacy of the Covid-19 vaccines and their effect upon transmission, including on “variants of concern" such as the Delta variant, is unknown.[104])

However, there are basic questions about the report that need answering. The Doherty Institute/ McVernon modelling used “assumptions” to make its recommendations.[105] This includes assumptions about age-specific effects on susceptibilities to infection and probability of symptomatic disease which are based on a single paper.[106] This paper is over a year old, does not use epidemiological data from Australia, and “acknowledges limitations to the study”, such as uncertainty due to “information drawn from early stages of the epidemic”. Although the paper says that the researchers were not able to estimate how infectious asymptomatic cases were, Doherty’s modelling references this paper for their assumptions about transmissibility estimates.

The Doherty Institute's modelling makes “assumptions” about the probability of hospital admission, ICU admission and death using a pre-print study which has not been peer reviewed. The publishing journal warns this study “should *not* be used to guide clinical practise” (emphasis in original text).[107]

Doherty/McVernon’s modelling estimates vaccine effectiveness against overall (asymptomatic and symptomatic) infection of the Delta variant, with estimates comparing Pfizer and AstraZeneca effectiveness. (Table S2.1) Doherty’s modelling is based on a study which says it "had insufficient numbers of hospital admissions to compare between vaccines” and “no formal significance test to compare the vaccines was done”, although it observed the AstraZeneca vaccine “appeared” less effective. The study defined a Covid-19 hospital admission as being within 14 days of testing positive, or testing positive within two days of a hospital admission. The study also said that the data suggested that “there was no evidence of a differential vaccine effect on hospital admissions among those first testing positive”. The study warned that “[g]iven the observational nature of these data, estimates of vaccine effectiveness need to be interpreted with caution.”[108]

Doherty/McVernon’s modelling bases “[v]accine effectiveness estimates on transmission to household members in case of breakthrough infections in vaccine recipients for the Delta variant” (Table S2.2) on a study which states that vaccinated people “*might have been* less infectious than those who were unvaccinated … Data are needed to inform the reduction in transmissibility of the virus after the receipt of two vaccine doses.” (Emphasis added)[109]

Doherty/McVernon’s modelling estimates vaccine effectiveness against ICU admission for the Delta variant (87% for Pfizer and 90% for AstraZeneca), but acknowledges, “[f]ew studies report VE [vaccine

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[104] Australian Public Assessment Report for BNT162b2 (mRNA), Extension of Indications, Therapeutic Goods Administration, (tga.gov.au), page 30; Australian Product Information COVID-19 Vaccine AstraZeneca, Therapeutic Goods Administration, (tga.gov.au), page 11

[105] “Doherty Institute Modelling Report for National Cabinet”, Doherty Institute, (doherty.edu.au), 3 August 2021

[106] Davies et al, “Age-dependent effects in the transmission and control of COVID-19 epidemics”, Nature Medicine, (nature.com), 16 June 2020

[107] Knock et al, “The 2020 SARS-CoV-2 epidemic in England: key epidemiological drivers and impact of interventions”, BMJ, (medrxiv.org), 13 January 2021

[108] Sheik et al, “SARS-CoV-2 Delta VOC in Scotland: demographics, risk of hospital admission, and vaccine effectiveness”, The Lancet, (thelancet.com), 14 June 2021

[109] Harris et al, “Effect of Vaccination on Household Transmission of SARS-CoV-2 in England”, The New England Journal of Medicine, (nejm.org), 23 June 2021

effectiveness] against ICU admission. … *we assume* the same reductions in ICU admission given vaccination as for hospitalisation." (Emphasis added)

The author of the Doherty Institute's modelling for the government's four-phase "National Plan" to lift restrictions and lockdowns, Professor Jodie McVernon, claims that young people aged 20 to 39 are the "peak spreaders" of the Delta variant of Covid-19, and should now be reoriented as the focus of the vaccine rollout strategy.[110] (Again, efficacy of the Covid-19 vaccines and their effect upon transmission is unknown. The safety of the vaccines is unknown. Young people are at lower risk for severe Covid-19.[111])

Notably, although it is widely claimed by public health officials that the "Delta" variant is responsible for the current outbreak, it is not clear if this variant can actually be differentiated by current Covid-19 testing. The NSW Government's 'COVID-19 Critical Intelligence Unit' states that PCR "testing and detection" of the Delta variant is "*estimated* to be effective in detecting and quantifying [this] variant", based on two pre-print (non-peer reviewed) papers from Singapore and Israel. The NSW Government cautions that this is "[p]reliminary data, not fully established, in some cases small numbers or short follow up; interpret with caution".[112]

Notably, during official government press conferences, and in highly publicised media articles and interviews with Professor McVernon regarding her modelling for the government, she has not disclosed potential conflicts of interest.

The Doherty Institute has received millions of dollars in funding from the Australian government for Covid-19-related activity.[113] The Doherty Institute also receives funding from, and collaborates with, the Gates Foundation and Gavi (the global Vaccine Alliance, founded by the Bill & Melinda Gates Foundation) on a number of projects.[114] The Gates Foundation is a biotech and pharmaceutical company masquerading as a non-profit organisation, and is in fact one of the world's largest single investors in biotechnology for pharmaceutical products in the world.[115] The Gates Foundation's timely September 2019 investment into BioNTech, the manufacturer of the Pfizer Covid-19 vaccine, has resulted in lucrative profits for the Foundation.[116] The Gates Foundation has extraordinary influence over global public health policy as one of the World Health Organisation's largest donors.[117] This private foundation operates under a banner of philanthropy, but has been implicated in vaccine-related misconduct committed on a vast scale, including illegal medical experimentation on children in developing nations, to the financial benefit of pharmaceutical companies.[118,119,120,]

In March 2020, the Doherty Institute collaborated with Coalition for Epidemic Preparedness Innovation (CEPI), "a global alliance financing and coordinating the development of vaccines against emerging

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[110] Press Conference, Prime Minister's Office, (pmc.gov.au), 3 August 2021

[111] Coronavirus Disease 2019 (COVID-19), CDNA National Guidelines for Public Health Units, Version 4.7, Department of Health, 24 June 2021 (health.gov.au), page 10.

[112] COVID-19 Critical Intelligence Unit, Living Evidence—SARS-CoV-2 variants, (health.nsw.gov.au)

[113] "Australian Government invests in new medicines for COVID-19", Doherty Institute (doherty.edu.au), 2 June 2020

[114] Doherty Institute: 'Where we work'

[115] Annual Survey of International & Comparative Law, Sharmeen Ahmed (2017): 'Accountability of International NGOs: Human Rights Violations in Healthcare Provision in Developing Countries and the Effectiveness of Current Measures'

[116] Bill & Melinda Gates Foundation, Investment, BioNTech

[117] Bulatlat, Romeo F Quijano (2019): 'Vaccination: most deceptive tool of imperialism'

[118] Parliament of India Rajya Sabha (2013): 'Alleged Irregularities in the Conduct of Studies using Human Papilloma Virus (HPV) Vaccine by Path in India (Department of Health Research, Ministry of Health and Family Welfare)'

[119] NEJM, White (2011): 'First Results of Phase 3 Trial of RTS,S/AS01 Malaria Vaccine in African Children'

[120] Oller et al (2017): 'HCG Found in WHO Tetanus Vaccine in Kenya Raises Concern in the Developing World'

infectious diseases",[121] to develop a Covid-10 vaccine.[122] CEPI was founded at the 2017 World Economic Forum in Davos, and received $460 million in startup funding from the Bill and Melinda Gates Foundation, the Wellcome Trust and the governments of Germany, Japan and Norway. CEPI Board Members include representatives from the World Health Organisation, World Bank, and the Bill & Melinda Gates Medical Research Institute and Foundation.[123] Members of its Scientific Advisory Board include pharmaceutical/vaccine companies Sanofi Pasteur, Johnson & Johnson and Pfizer. Notably, in April 2020 Professor Peter Doherty, the Doherty Institute's founder, suggested the concept of 'vaccine passports' which he suggested could "potentially test and give people an immunology certificate or a passport or something that would say, "Yes I've had the infection, I'm not going to infect you", to allow people to "possibly trickle back into the workforce".[124]

Professor McVernon has served on the Australian government's Australian Technical Advisory Group on Immunisation (ATAGI) since 2014.[125] Professor McVernon also serves as Chair of the Scientific Advisory Committee for the National Centre for Immunisation Research and Surveillance.[126] Professor McVernon has "been an investigator on vaccine and epidemiological studies sponsored by a range of vaccine manufacturers"[127], and has received funding from pharmaceutical companies which produce vaccines including Pfizer.[128,129] In January 2017, Professor McVernon was featured on Norman Swan's ABC's Health Report, 'Deadly meningococcal W concerns'[130] discussing a new meningococcal vaccine available in Western Australia, but did not disclose that she or her employer, the Doherty Institute, received funding from pharmaceutical companies and international organisations such as the Gates Foundation, which have commercial relationships with vaccine manufacturers.[131]
From the earliest period of the Covid-19 outbreak, Professor McVernon has appeared committed to vaccines as the primary solution to managing Covid-19.[132]

Doherty Institute Director, Professor Sharon Lewin, has participated in advisory boards for a number of pharmaceutical companies which produce vaccination products. Professor Lewin is also a consultant to companies which produce vaccination products.[133,134]

On 6 August 2021, the Prime Minister announced the National Cabinet had agreed for further work to be done by the Doherty Institute and Professor McVernon to for "further understanding of the calibration of the public health measures and the impact … on the virus". This indicates that the Doherty Institute and Professor McVernon will be responsible for assessing the effectiveness of the public health measures they have recommended, including nationwide vaccination.[135]

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[121] CEPI: 'New vaccines for a safer world'

[122] University of Queensland (2020): '$17m shot in the arm for UQ's Covid-19 vaccine research'

[123] CEPI: Leadership

[124] Twitter, Australian Academy of Sciences, April 9th, 2020'

[125] ATAGI: Meningococcal Working Party

[126] National Centre for Immunisation Research and Surveillance: 'Scientific Advisory Committee'

[127] University of Melbourne, McVernon et al (2015): 'Antibody Persistence in Australian Adolescents Following Meningococcal C Conjugate Vaccination'

[128] American Journal of Epidemiology, McVernon et al (2017): 'Determining the Best Strategies for Maternally Targeted Pertussis Vaccination Using an Individual-Based Model'

[129] ATAGI Conflicts of interest (archived version of site as current link broken)

[130] ABC Health Report (January 2017): 'Deadly meningococcal W concerns'

[131] Doherty Institute, "Where we work"

[132] ABC, Sabra Lane (April 2020): 'We cannot promise lives will not be lost': Modelling expert'

[133] NHMRC: 'Health Translation Advisory Committee'

[134] MedPage Today, Molly Walker (2020): 'After 30 months, 'London Patient' still in HIV remission'

[135] Press Conference, Canberra ACT, Prime Minister, (pmc.gov.au), 6 August 2021

ANTIVIRAL SUPPRESSION

Doherty Institute discounted Covid-19 antiviral treatments

The Doherty Institute swiftly dismissed certain oral anti-viral treatment early in the Covid-19 crisis. The Doherty Institute was awarded a government grant to conduct a clinical trial of antivirals lopinavir/ritonavir and the now notorious hydroxychloroquine and their possible use in treatment of Covid-19. The clinical trial began in April 2020, but the Doherty Institute abandoned it in June 2020, despite the fact that it had so far only enrolled 33/2500 participants.[136]

The Doherty Institute's decision to abandon the trial was based on a "media release" from Oxford University, the developer of the AstraZeneca vaccine, which was conducting a clinical trial of both antivirals for treatment of Covid-19. Oxford's media release announced that there were "no clinical benefits" from the use of lopinavir/ritonavir and hydroxychloroquine in hospitalised Covid-19 patients, but did not include the full results of the clinical trial.[137] The Doherty Institute canceled its government-funded clinical trial of these antivirals in June on the basis of Oxford's media release, although the full results of Oxford's clinical trial were not published until October 2020. Oxford's study has since come under criticism for inappropriate and dangerous dosage levels used in the clinical trial, and significant errors in its analysis.[138]

Although Oxford and the Doherty Institute swiftly dismissed ritonavir, Pfizer itself recently announced it is pursuing oral anti-viral therapeutic treatments in combination with ritonavir to treat Covid-19.[139]

The position of the Doherty Institute, public health officials and the TGA in regards to the efficacy of antivirals, including the antiviral hydroxychloroquine, in Covid-19 treatment protocols is contradicted by health practitioners who are outside of the government.

This includes Robert Clancy, Emeritus Professor Of Pathology at the University of Newcastle Medical School and member of the Australian Academy of Science's COVID-19 Expert Database, who writes: "Poorly constructed studies of the anti-viral HCQ [hydroxychloroquine] on hospitalised COVID-19 patients mistakenly led to the drug being categorised as a "failed" therapy. That misunderstanding continues to dominate many official sites, despite there being at least 27 clinical studies in early disease – 10 of which were randomised clinical trials – showing a composite level of 63 per cent protection against admission to hospital and/or death. Similar data supported use in prevention of infection (as it did for malaria). … The early RCTs [randomised controlled trial] showing no benefit for HCQ, were on hospitalised patients, which was the wrong group to study. Subsequent trials were mainly quality Observational Studies, which sat poorly with purists who neither understood the disease, nor the "real life" circumstances of a pandemic and refused to move on with the data. Denial was reinforced by bureaucrats, media and the Pharma industry (which has no interest in cheap drugs without patents)."[140]

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[136] "AustralaSian COVID-19 Trial (ASCOT) removes hydroxychloroquine and lopinavir/ritonavir arms of the trial", ASCOT, (ascot-trial.edu.au), 30 July 2020; Australian New Zealand Clinical Trials Registry, ACTRN12620000445976, (anzctr.org.au

[137] "No clinical benefit from use of lopinavir-ritonavir in hospitalised COVID-19 patients studied in RECOVERY", RECOVERY, (recoverytrial.net)

[138] Le Collectif Citoyen pour FranceSoir, "Oxford, the authors of the British clinical trial Recovery attempt to hide deaths by overdose", FranceSoir, (francesoir.fr), 18 July 2020; Le Collectif Citoyen pour FranceSoir, "Oxford-Recovery clinical trial and overdose: a hard pill to swallow", FranceSoir, (francesoir.fr), 20 June 2020

[139] "Covid-19 antiviral efforts", Pfizer, (pfizer.com)

[140] Professor Robert Clancy, "COVID-19: A realistic approach to community management", Quadrant, (quadrant.org.au), 17 January 2021

Only a small fraction (<$19 million) of the Australian government's investment into Covid-19 treatments and diagnostics was committed to antiviral research,[141] compared to $350 million for vaccine and other diagnostic research and $5 *billion* in vaccine supply agreements.[142] Numerous antiviral trials in Australia have been rapidly abandoned after international studies reported the drugs were ineffective.[143] One example is the Doherty Institute's swift cancelling of its hydroxychloroquine/ritonavir clinical trial after seeing a media release of preliminary results from Oxford University (the manufacturer of the AstraZeneca vaccine).

Other antiviral trials have moved at a curiously glacial pace, compared to the rapid trial and approval of vaccines. For example, the Walter and Eliza Hall Institute was awarded $3 million in government funding to trial hydroxychloroquine efficacy. The clinical trial began taking enrolments in April 2020,[144] but is not expected to release any results until late 2021—when Operation COVID Shield's nationwide vaccine rollout is estimated to have been largely completed. Importantly, the Walter and Eliza Hall study is not using the antiviral in a combination regimen with other drugs which have been found to be essential for hydroxychloroquine's efficacy in treating Covid-19.[145] This is consistent with an international trend of "poorly constructed" studies examining the antiviral's use in treatment of Covid-19.

Early antiviral treatment key to Covid-19 management

The Australian government's national guidelines for prevention, control and public health management of Covid-19 in residential care facilities, including aged care, recommends vaccination (although vaccine safety and efficacy in people aged over 65 is unknown) *but not antiviral treatment*.[146]

Professor Robert Clancy writes that "[v]accines, however, do have limitations. They need to be paired with effective, safe drug treatment …. two candidates [to treat Covid-19] are safe, cheap, available and effective. They are ivermectin and hydroxychloroquine. Australian health authorities, however, say there is not enough evidence to support their use in the treatment of COVID-19. I disagree with them. … Poorly constructed studies of the anti-viral HCQ on hospitalised COVID-19 patients mistakenly led to the drug being categorised as a "failed" therapy. That misunderstanding continues to dominate…"[147]

Professor Clancy writes the "basic principal in treating viral infections is to treat early. … Although obvious that different phases of the disease require different therapies, confusion over the different causes of each phase has led to an incorrect assessment of drug efficacy early in the course of the pandemic. It also has influenced criticism from many with narrow backgrounds, and little or no clinical experience. Thus several failed Randomised Clinical Trials (RCT) of HCQ in hospital patients have been

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[141] "Life Saving and Job Creating Medical Research – COVID-19 pandemic response", Budget 2020-21, Department of Health, (health.gov.au)

[142] "Australia's vaccine agreements", Department of Health, (health.gov.au)

[143] Liam Mannix, "'We have not delivered': Dozens of Australian COVID trials fail to learn anything new", Sydney Morning Herald, (smh.com.au), 20 November 2020

[144] "COVID-19 prophylaxis with hydroxychloroquine in Front-line Health and Allied-Health Care Workers: The COVID-SHIELD Trial", Australian Clinical Trials, (australianclinicaltrials.gov.au)

[145] "COVID Shield FAQs", WEHI, (wehi.edu.au) ; Dr Donald C. Pompan MD, and Michael M. Jacobs, MD, MPH, "The Assault On Early COVID-19 Treatment: Congressional Hearing Speaks Volumes about Our Failed Pandemic Response", (covidmedicalnetwork.com), 3 December 2020; Professor Robert Clancy, "COVID-19: A realistic approach to community management", Quadrant, (quadrant.org.au), 17 January 2021

[146] CDNA national guidelines for the prevention, control and public health management of COVID-19 outbreaks in residential care facilities in Australia, Department of Health, (health.gov.au)

[147] Professor Robert Clancy, "I'm the virus expert cited by MP Craig Kelly. Vaccines are critical, but he's not all wrong", Sydney Morning Herald, (smh.com.au), 4 February 2021

used to dismiss the value of HCQ in early treatment, without recognising differences between the pathogenesis of the two phases. Every study of early treatment, has shown protection, confirmed in multiple meta analyses. Both drugs have a high level safety record."[148]

Professor Clancy writes that "[t]he data base supporting the value of early treatment of Covid19 disease [with antivirals ivermectin and hydroxychloroquine] is so strong, that it is hard to understand the current philosophy of "wait until you are sick enough, then go to hospital" … Suggested reasons for unscientific denial include: ideological unmovable mind sets; a rapidly evolving pandemic where new data appears on a daily basis making it hard to keep up with the data flow; failure to understand the value of non RCT data sets which from a scientific and ethical viewpoint are appropriate to the circumstances of a pandemic; and *a total focus on an anticipated Covid-free world following the release of vaccines.*" (Emphasis added)

Antiviral treatments were a key component of the AHMPPI and the 'Australian Health Sector Emergency Response Plan for Novel Coronavirus (COVID-19).

Antiviral treatment was key in prior pandemic response plan

The February 2020 'Australian Health Sector Emergency Response Plan for Novel Coronavirus (COVID-19)' noted "[e]arly clinical trials of candidate antiviral drugs in severe cases *will be of great importance*". (Emphasis added)

The Emergency Response Plan for Covid-19 was based on the Australian Health Management Plan for Pandemic Influenza (AHMPPI). AHMPPI included antiviral pharmaceutical measures for disease treatment, and for use in pre-exposure and post-exposure for contacts, at-risk groups and healthcare workers. The use of antivirals could shorten the length of time needed for isolation and quarantine. Antivirals were recommended as part of contact tracing, intending to reduce morbidity and mortality.

The use of antivirals, while frequently referenced in the AHMPPI and the Australian Health Sector Emergency Response Plan for Novel Coronavirus (COVID-19), is not mentioned in the Doherty Institute's modelling for the government's initial Covid-19 response measures, or in the modelling for the nationwide 'opening up', which is instead contingent primarily upon vaccine uptake.

The Doherty Institute and government public health officials continue to dismiss early treatment of Covid-19 with antivirals, despite apparently well-documented efficacy. It is troubling that the government's national guidelines for prevention, control and public health management of Covid-19 in residential aged care facilities (in a cohort of people likely to be at high risk for severe Covid-19), recommends vaccines of unknown safety and efficacy *but not antiviral treatment*.

The implications are extremely troubling, given that it is proposed that early use of antivirals reduces Covid-19 mortality rates. Professor Clancy notes that the use of antiviral ivermectin in treating Covid-19 "was missed by many authorities. More than 30 studies have led to impressive meta-analyses, most recently by Therese Lawrie, an epidemiologist. Data from 17 studies showing a reduction of death by 83 per cent was so dramatic that she concluded it was now unethical to include untreated patients as controls. Both drugs are used extensively in many countries, with dramatic reductions in COVID-19 deaths."[149] Notably, as recently as July 2021 the Doherty Institute has

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[148] Professor Robert Clancy, "COVID-19: A realistic approach to community management", Quadrant, (quadrant.org.au), 17 January 2021

[149] Professor Robert Clancy, "I'm the virus expert cited by MP Craig Kelly. Vaccines are critical, but he's not all wrong", Sydney Morning Herald, (smh.com.au), 4 February 2021

continued to claim there was no apparent benefit to Covid-19 treatment using readily available antivirals.[150]

The absence of reference to antivirals in any of the Doherty Institute's modelling papers is perplexing, given that *Professor McVernon herself* was the co-author of antiviral studies which the AHMPPI's antiviral treatment recommendations were based on.[151]
The government's supplementary report to support the AHMPPI, 'Antivirals Evidence summary', was based on studies co-authored by Professor McVernon. The report, which summarised the evidence presented in McVernon's studies, concluded that the efficacy of antivirus treatment against severe disease "resulted in a a marked reduction in the number of deaths reported ... and could substantially reduce critical care requirement." A reduction in case load could be achieved with community based antiviral delivery strategy, and (Professor McVernon's) modelling showed that "community-based antiviral distribution over and above treatment of the severely ill confer additional benefits to the population". Targeted pre-exposure prophylaxis and community-based prophylaxis were observed for healthcare workers in all scenarios modelled, "resulting in far lower rates of disease than those reported from the general population … Provision of antivirals to contacts would be likely to reduce morbidity and mortality in this group."
This 'Antivirals Evidence summary' for the effectiveness of antiviral measures in a pandemic found: "Antiviral medications can be used for treatment of infected cases, prophylaxis of exposed contacts, and pre-exposure prophylaxis for healthcare workers at high risk of infection. Treatment with antivirals aims to reduce symptoms in individuals and hence lower morbidity and mortality. Prophylactic use of antivirals aims to reduce the risk of infection and illness in contacts, potentially lowering the spread and hence disease attack rate. A reduction in mortality and morbidity, and transmission, will assist in minimising impact on health care services during a pandemic. … As surveillance information becomes available, the antiviral strategy can be modified to more effectively manage the specific pandemic. For example, in a pandemic with high mortality and morbidity, preventing illness in as many individuals as possible is important to minimise mortality and morbidity, reduce transmission to others and maintain the health workforce. When severity is lower, protecting those at risk of severe outcomes becomes the focus. Rapid distribution is key to the effectiveness of antivirals at a population health level."

The February 2020 Australian Health Sector Emergency Response Plan for Novel Coronavirus (Covid-19) noted that experts had agreed that the AHMPPI, which included antiviral measures, was applicable to managing the Covid-19 response.
The 'Australian Health Sector Emergency Response Plan for Novel Coronavirus (COVID-19)' instructed that state governments should "coordinate distribution of antiviral drugs and disseminate protocols on the use of antivirals". The federal and state and territory governments are "jointly responsible" for "antiviral drug utilisation (if shown to be of benefit)".

LEGAL AND HUMAN RIGHTS ISSUES

State and federal governments and health bureaucrats have communicated false information to the Australian public

Disturbingly, Prime Minister Scott Morrison has communicated false information about Covid-19 vaccines to the public, which directly contradicts the information provided by the TGA and the vaccine manufacturers.

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[150] Professor Peter Doherty, "Issue #66: Where are the small molecule drugs to treat COVID-19?", Doherty Institute, (doherty.edu.au), 19 July 2021

[151] Antiviral Evidence Summary, Australian Health Management Plan for Pandemic Influenza (AHMPPI), Department of Health, (health.gov.au)

This includes the Prime Minister's claims that: "There's *no doubt* that as vaccination rates rise, that tempers the ability of the virus to spread."[152] [The TGA acknowledges that questions about the vaccines' efficacy against asymptomatic infection and viral transmission have not been addressed.[153] The Communicable Disease Network (CDNA) states that "It is not yet clear how widespread vaccination will affect the risk of SARS-CoV-2 transmission."[154]]

Morrison has also claimed: "Both vaccines are *proven* to generate robust immune responses in a majority of people…"[155] (Emphasis added) [The TGA acknowledges that there is no established immunological correlate of protection against Covid-19 from the AstraZeneca or Pfizer vaccines.[156]]

Morrison has claimed the Covid-19 vaccines are "safe and effective" and that "both vaccines are … highly effective at preventing severe disease, hospitalisation and death."[157] Health Minister Greg Hunt has also claimed the Covid-19 vaccination is "safe, it's effective, it will help protect you, but it will also help protect your mum and dad, your grandparents, your nonna, all of Australia."[158] [The TGA, public health officials and the vaccine manufacturers all acknowledge that safety and efficacy of both Covid-19 vaccines have not been established.[159]]

Morrison has claimed that "if you're not vaccinated, you present a greater health risk to yourself and to others than people who were vaccinated".[160] [Again, the TGA acknowledges the efficacy of the vaccine in preventing transmission is unknown.] Morrison has announced societal restrictions would be put on people who were not vaccinated because "they're a danger to themselves and others",[161] despite the fact that the Communicable Disease Network (CDNA) has acknowledged Covid-19 presents as a mild disease for most people.[162]
The CDNA's position is supported by the Department of Health's latest figures, which state that of the 3,269 cases of Covid-19 reported in Australia from 1 January 2021 to 18 July 2021, the estimated proportion of cases hospitalised was 9.9% (209/2,119) and the proportion of cases admitted to the intensive care unit (ICU) was 2.5% (52/2,119). (I note that hospital data was only available for 2,119 of 3,269 total cases).

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[152] Press Conference Transcript, Canberra ACT, Prime Minister's Office, (pm.gov.au), 3 August 2021

[153] Australian Public Assessment Report for BNT162b2 (mRNA), Therapeutic Goods Administration, (tga.gov.au), page 34

[154] Coronavirus Disease 2019 (COVID-19), CDNA National Guidelines for Public Health Units, Version 4.7, Department of Health, 24 June 2021 (health.gov.au), page 11

[155] Letter to constituent from Prime Minister Scott Morrison, Reference: MC21-076901, 20 July 2021, published by constituent.

[156] Australian Product Information, Covid-19 Vaccine AstraZeneca (ChAdOx1-S), Therapeutic Goods Administration, (ebs.tga.gov.au), page 11; Australian Public Assessment Report for ChAdOx1-S, Therapeutic Goods Administration, (tgs.gov.au), page 16

[157] Letter to constituent from Prime Minister Scott Morrison, Reference: MC21-076901, 20 July 2021, published by constituent.

[158] Health Minister Greg Hunt, interview with David Speers on ABC Insiders on the COVID-19 vaccine rollout, Department of Health, 21 February 2021, (health.gov.au)

[159] Australian Product Information - Comirnaty (BNT162b2 [mRNA]) Covid-19 Vaccine, Therapeutic Goods Administration, (tga.gov.au); Australian Product Information, Covid-19 Vaccine AstraZeneca (ChAdOx1-S), Therapeutic Goods Administration, (ebs.tga.gov.au); Australian Public Assessment Report for BNT162b2 (mRNA), Therapeutic Goods Administration, (tga.gov.au); Australian Public Assessment Report for ChAdOx1-S, Therapeutic Goods Administration, (tgs.gov.au); Chief Medical Officer Professor Paul Kelly's answers to Senator Malcolm Roberts, Community Affairs Legislation Committee, Health Portfolio, Hansard, (parlinfo.aph.gov.au) 1 June 2021

[160] Prime Minister Scott Morrison, Interview with Neil Mitchell, 3AW, (pm.gov.au), 29 July 2021

[161] Prime Minister Scott Morrison, Interview with Neil Mitchell, 3AW, (pm.gov.au), 29 July 2021

[162] Coronavirus Disease 2019 (COVID-19), CDNA National Guidelines for Public Health Units, Version 4.7, Department of Health, 24 June 2021 (health.gov.au), page 10.

According to the CDNA, the case fatality rate for the year to date is 6 people, or 0.2 per cent.[163] Notably, in Australia in 2017 there were 29,00 hospital admissions with confirmed influenza, of which 8.9% were admitted to ICU. Vaccine effectiveness against hospitalisation was 16%.[164]

State health officials have made similar alarmist and unsubstantiated claims. NSW Health Minister Brad Hazzard has declared Australians who do not wish to get the Covid-19 vaccine are "extremely selfish"[165] and sensationally declared that a person "carrying the virus" would be "effectively carrying a deadly weapon".[166]

On 6 August 2021, Australia's Chief Medical Officer, Professor Paul Kelly, claimed that "*What we do know* is that whilst there is this other wave, [referring to cases of the Delta variant of Covid-19] *vaccine works … we know* that vaccines work to decrease severe illness. It decreases transmission, it decreases death."[167] (Emphasis added) [Vaccine efficacy is unknown. The TGA acknowledges that vaccine efficacy against variants of concern has not been addressed.[168]]
Without evidence, Kelly blamed current Covid-19 cases in Australia on unvaccinated people, even though the vaccine's efficacy on preventing transmission is unknown: "Mostly the outbreaks in other countries, and including here … this is a epidemic or a pandemic of the unvaccinated." Professor Kelly's comments contradict his own parliamentary evidence from several weeks earlier, where he admitted that the vaccine's effect on transmission was unknown. At the same hearing, the head of the TGA confirmed that vaccine effectiveness in preventing transmission was unknown.[169]

Victorian Premier Daniel Andrews has claimed that "every single Victorian" should assume that "if you've got symptoms, you've got COVID, that's what you have to assume".[170] The Australian government's official Covid-19 figures record millions of tests conducted, with a positive result rate between 0.0%-0.2%.[171]

Queensland Chief Health Officer Jeanette Young has claimed that "*We know* that [wearing masks] has protected us … *I am positive* that the reason we've not had community spread recently is because people have been genuinely wearing their masks".[172] (Emphasis added) This contradicts the federal Department of Health's literature which acknowledges there is only "limited, indirect, experimental evidence" that masks can reduce transmission of respiratory droplets, and acknowledged the results

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[163] Communicable Disease Intelligence 2021, Volume 45, Covid-19 Australia: Epidemiology Report 46, Reporting period ending 18 July 2021, Department of Health, (health.gov.au), page 2

[164] 2017 Influenza Season in Australia: A summary from the National Influenza Surveillance Committee, Department of Health, (health.gov.au), 22 November 2017

[165] Crystal Wu, "Health Minister Brad Hazzard hits out at 'selfish' anti-vaxxers as NSW records 239 COVID-19 cases", Sky News Australia, (skynews.com.au), 29 July 2021

[166] Liv Casben, "Up to 1000 police ready to meet protesters", The Canberra Times, (canberratimes.com.au), 30 July 2021

[167] Press Conference, Canberra ACT, Prime Minister's office, (pm.gov.au), 6 August 2021

[168] Australian Public Assessment Report for BNT162b2 (mRNA), Extension of Indications, Therapeutic Goods Administration, (tga.gov.au), page 30; Australian Product Information COVID-19 Vaccine AstraZeneca, Therapeutic Goods Administration, (tga.gov.au), page 11

[169] Chief Medical Officer Professor Paul Kelly's answers to Senator Malcolm Roberts, Community Affairs Legislation Committee, Health Portfolio, Hansard, (parlinfo.aph.gov.au) 1 June 2021

[170] "Victorian Premier: Assume you have COVID if you have symptoms", Sky News Australia, (skynews.com.au), 5 August 2021

[171] Coronavirus (COVID-19) case numbers and statistics, Department of Health, (health.gov.au), retrieved 7 August 2021

[172] Jessica Stewart, "Queensland-NSW border shuts as part of COVID-19 restrictions shake-up. Here are the new rules to live by", ABC News, (abc.net.au), 23 July 2021

of a study which found a significantly *higher* rate of clinical respiratory infections in people who wore cloth masks.[173]

The periodic use of masks in the community has been legally mandated in numerous states, including Queensland, despite any evidence that they have any efficacy in preventing transmission of Covid-19. Queensland's Chief Health Officer Jeanette Young recently claimed masks in the community were "absolutely critical" and instructed that if Queenslanders could not wear a mask (i.e. for medical reasons), they should not even leave their homes.[174] However, the federal Department of Health's literature says, "There is little clinical or epidemiological evidence that airborne transmission of SARS-CoV-2 [Covid-19], at distances greater than 1.5 m occurs frequently in well ventilated settings" (such as outside the home, in the community).

Western Australian Premier Mark McGowan initiated region-wide mask mandates when there were no active cases of Covid-19 in the community,[175] in contradiction to the federal government's literature, which says "In places with little or no community transmission, wearing a mask is not essential and need not be mandated."[176]

State governments have recently been demanding increased testing from wide regions of the population,[177] which is contradicted by the AHPCC, which says that "large-scale, non-targeted, asymptomatic testing in Australia should be strongly discouraged. Non-targeted asymptomatic testing is neither epidemiologically sound nor a cost-effective approach to identify disease transmission."[178] Mass testing also contradicts the national Covid-19 Testing Framework, which states that "Currently, the CDNA, PHLN and the Australian Health Protection Principal Committee (AHPPC) do not support large-scale, non-targeted testing for SARS-CoV-2 in asymptomatic people as part of the public health response. Non-targeted asymptomatic testing is neither epidemiologically sound nor a cost-effective approach to identify disease transmission. Mathematical modelling shows that testing of non-targeted asymptomatic individuals is not an efficient way to detect community transmission."[179]

National Cabinet made key decisions without parliamentary oversight

On the 6 August 2021 Prime Minister Scott Morrison announced that it was "not the intention of the Commonwealth, nor of the states and territories, to create any special laws" where employers may seek to require employees to be vaccinated, or where a business or establishment "may seek to deny access to a premise or a service in relation to people who are vaccinated or are non-vaccinated … ultimately, employers need to consider these matters and make their own decisions".[180]
Any "special laws" enacted would notably come under parliamentary scrutiny and normal democratic oversight, but these have been side-stepped with the formulation of the "National Cabinet", whereby edicts are passed on by State Premiers through public health orders enacted under emergency Covid-19 legislation (and are sometimes just by imposed mere "announcements").

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[173] Question: Are cloth face masks likely to provide protection against COVID-19?, Department of Health, (health.gov.au)

[174] "Masks 'absolutely critical' to protect people", Sky News Australia, (skynews.com.au), 3 August 2021

[175] Rhiannon Shine, "Perth COVID lockdown to end at midnight, WA Premier Mark McGowan announces at press conference", ABC News, (abc.net.au), 2 July 2021

[176] Infection Control Expert Group: The use of face masks and respirators in the context of Covid-19, Department of Health, (health.gov.au), Revised 11 March 2021

[177] Rachel Riga, "Queensland records nine locally acquired COVID-19 cases as Delta cluster centred on Brisbane schools grows", ABC News, (abc.net.au), 1 August 2021

[178] "Australian Health Protection Principal Committee (AHPPC) updated statement on the role of asymptomatic testing", Department of Health, (health.gov.au), 21 August 2020

[179] Coronavirus (COVID-19) – Testing Framework for COVID-19 in Australia, Department of Health, (health.gov.au)

[180] Press Conference, Canberra ACT, Prime Minister, (pmc.gov.au), 6 August 2021

The state and federal government's Covid-19 measures have severely impacted the human rights of Australians. Mandatory vaccination, the leveraging of "personal freedoms" to coerce vaccination, restriction of movement and the right to work, and “vaccine passports” have been demanded of the public without proper parliamentary scrutiny or democratic accountability.

It is the view of the Australian Human Rights Commission, the statutory body which provides human rights scrutiny of federal legislation that “[d]uring the pandemic many decisions have been made at the National Cabinet—not in Parliament—and the responsibility for implementing those decisions has been split between federal, state and territory governments. This complicates the ability to ensure proper human rights scrutiny of the measures. For example, the Australian Human Rights Commission is limited by statute to providing human rights scrutiny of decisions implemented at a federal level – but many of the measures were not implemented at a federal level, even though they relate to federal responsibilities like the border control of Australia. … Some of the decisions were put into legislation, others were introduced in other ways—which means they cannot be easily reviewed, and they don’t automatically require independent human rights scrutiny at the time of the decision. This means any human rights scrutiny happens after the measure is already put in place and affecting people.” The Commission is concerned at the lack of transparency “even for identifying which level of government is responsible for some measures”.[181]

The Commission states: “The checks and balances that ordinarily exist are important to our democracy. Australians have been, and continue to be, exposed to *potentially unnecessary* restrictions of their rights and freedoms because of the lack of transparency and accountability.” (Emphasis added)

The Commission states that Covid-19 emergency measures which put limitations on people's human rights "must be prescribed by law”. This means laws or delegated legislation that are public and made in advance; and must “be clear, specific, targeted and have defined limits”. The Commission says the laws “must not give governments unchecked powers”.
The Commission states that “International human rights law allows governments to restrict many rights and freedoms during a pandemic for the safety of everyone in the community. However, the restrictions that are allowed are very narrow”. The restrictions that are allowed must be "necessary and proportionate to the evaluated risk”; governments must be “transparent about the reasons why they consider restricting human rights is necessary”; “Any limitations on human rights should be the minimum necessary to address the emergency”.
The Commission says that the restrictions must be “consistent with international law” and they “must be prescribed by law" (emphasis in original)

Augusto Zimmermann, Adjunct Professor of Law at the University of Notre Dame (Sydney) and former Law Reform Commissioner with the Law Reform Commission of Western Australia has published an opinion on the constitutional validity of mandatory vaccination: “In other words, no Australian government, either federal or state, or those acting on its behalf, is constitutionally authorised to force any individual to take medicament against his or her own will, or force them or their children to be, among other things, compulsorily vaccinated.”[182]

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[181] “Where is the line on COVID-19 emergency measures?”, COVID19 and Human Rights, Australian Human Rights Commission, (humanrights.gov.au)

[182] Augusto Zimmermann, “Constitutionally Inoculated to Resist Coercion”, Quadrant, (quadrant.org.au), 24 July 2021; Augusto Zimmermann, Connor Court Publishing, (connorcourtpublishing.com.au)

Although he has acknowledged the federal government can't make laws to prohibit entry based on vaccination status, Prime Minister Scott Morrison has said that “these things [mandating vaccines and restricting entry to unvaccinated people] are done through public health orders at a state and territory level … state public health orders” are required “to support those issues legally”.[183] Morrison has announced plans to implement "vaccine passports” which the states would implement through public health orders.[184]

For example, NSW Premier Gladys Berejiklian announced on 5 August 2021 that her government was assessing a ‘no jab, no work' policy, allowing employees under lockdown to return to work if they have been vaccinated.[185] Berejiklian encouraged employers to “put pressure on your staff to get vaccinated”. Berejiklian addressed residents of NSW which were under a strict lockdown: “If people are keen to get back to work, get vaccinated”. Berejiklian has recently announced that construction workers would be allowed back on site to work if they were vaccinated.[186] This appears to violate the government’s Immunisation Handbook, which says for consent to be legally valid, “It must be given voluntarily in the absence of undue pressure, coercion or manipulation.”[187]

Notably, the Australian Human Rights Commission says "the pandemic has demonstrated that the law is very limited in how it protects people’s rights at this time.” The Commission notes that many Covid-19 legislative instruments do not contain the usual democratic protections. “The main legislative instrument under the Biosecurity Act is not disallowable – meaning that it cannot be overturned by Parliament. The main legislative instrument under the Biosecurity Act did not have a statement of compatibility conducted prior to introducing the instrument, meaning there was no standard assessment of human rights impacts and their justification, despite the fact that the instrument did negatively impact on human rights. There was no consultation with human rights experts or the public on the legislative instrument prior to its making.” The Commission observes that “most Australians would be surprised to learn that there are very few legal protections of human rights in Australia. … Australia is one of the only liberal democracies in the world that does not have its own Human Rights Act.”

Although the government continues to claim that Covid-19 vaccines will be voluntary, the new operations manual for ‘Operation COVID Shield’, Australia’s mass Covid-19 vaccination rollout, openly says the government will leverage personal freedoms to incentivise mass vaccine uptake.

This report has documented serious concerns about vaccine safety and efficacy, particularly in pregnant women and adolescents. It has raised serious questions about the government’s Covid-19 pandemic management strategy, including implicating contraindicated and restrictive public health measures which have been catastrophic to many Australians. Troubling questions are raised about the influence of a potentially conflicted organisation, the Doherty Institute, which has given advice central to the government’s pandemic management and vaccine rollout. There are disturbing elements to the government’s framework for prevention and treatment of Covid-19 in elderly people—although they are the most susceptible to severe illness and death, early antiviral treatment and prophylaxis have not been a part of the government’s management framework despite the fact this was recommended in

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[183] Press Conference, Canberra ACT, Prime Minister, (pmc.gov.au), 6 August 2021

[184] Courtney Gould, “George Christensen threatens split with Coalition over vaccine passports”, (news.com.au), 4 August 2021; Press Conference, Canberra ACT, Prime Minister, (pmc.gov.au), 3 August 2021

[185] Alison Xiao, “NSW government to consider 'no jab, no work' policy as incentive to ease COVID-19 lockdown for businesses”, ABC News, (abc.net.au), 5 August 2021

[186] “NSW construction workers allowed back on site amid COVID lockdown if they 'meet vaccination conditions’”, ABC News, (abc.net.au), 8 August 2021

[187] Preparing for vaccination, Valid consent, Australian Immunisation Handbook, Department of Health, (health.gov.au)

the February 2020 Australian Health Sector Emergency Response Plan for Novel Coronavirus (Covid-19). Instead, Operation COVID Shield prioritises this cohort nationwide, despite the fact that the vaccine trials did not include participants who were over 65 years of age, therefore safety and efficacy is unknown. It is in the interest of the Australian public that the state and federal governments, and public health officials are challenged over the information presented here. The coercive nature of Operation COVID Shield, which intends to leverage “personal freedoms” to manipulate the public into nationwide uptake of a vaccine with unproven safety and efficacy, is abhorrent, of dubious legality, and should be challenged.

REFERENCES

1 “Getting vaccinated for COVID-19”, Department of Health, (health.gov.au)
"*COVID-19 vaccines will be voluntary …”*

2 “Operation COVID Shield National COVID Vaccine Campaign Plan”, Department of Health, (health.gov.au)
Page 35 *“The Commonwealth will leverage key incentives to drive vaccine up-take, including … Personal freedoms: providing vaccinated people with greater personal freedoms. … More visible and tangible incentives can be deployed to increase demand, including government and private sector incentives.* (Page 36) *“The use of incentives will need to be coordinated across the public, private and community sectors. This includes … Coordinating the use of incentives between the Commonwealth, States and Territories as part of the ongoing review cycle with jurisdictions. Where possible, incentives will be made consistent across jurisdictions.”* Operation COVID Shield’s *“Motivate workstream” will “coordinate any use of incentives by industry partners. … the Motivate workstream will closely monitor the use of incentives in the private sector.”* (Page 38)

3 Media Statement, Prime Minister’s Office, 22 March 2020 (pm.gov.au)

4 Media Statement, Prime Minister’s Office, (pmc.gov.au), 22 March 2020;
“Parents must be aware that while the majority of adults who contract COVID-19 have mild forms of the virus, the elderly or those with co-morbidities can have more significant symptoms.”
Coronavirus Disease 2019 (COVID-19), CDNA National Guidelines for Public Health Units, Version 4.7, Department of Health, 24 June 2021 (health.gov.au), page 10;
“COVID-19 presents as a mild illness in approximately 80% of cases.”
Australian Health Protection Principal Committee (AHPPC) coronavirus (COVID-19) statement on 17 March 2020, Department of Health, (health.gov.au), 17 March 2020
“COVID-19 is a contagious viral infection that causes mild respiratory illness in most people. Presentation can range from no symptoms to severe illness with potentially life-threatening complications, particularly in people who are vulnerable to infections.”

5 “Certainty for the community as restrictions adjusted and vaccines ramped up”, NSW Government, 28 July 2021, (nsw.gov.au)
“Given low vaccination rates, the current stay at home orders will remain in place for another four weeks … Premier Gladys Berejiklian said higher vaccination rates and following the health orders are the only way to guarantee the further easing of restrictions.”

6 Media Statement, Prime Minister’s Office, 6 August 2021 (pm.gov.au);
Describes issues where "*employers may be seeking to require employees to have vaccines. Similarly, if a business or establishment may seek to deny access to a premise or a service in relation to people who are vaccinated or are non-vaccinated. Now, it is not the intention of the Commonwealth, nor of the states and territories, to create any special laws in these areas. The only area where that has occurred to date has been public health orders around quarantine workers, and also an agreement amongst Premiers and Chief Ministers for those who are moving to put in place those public health orders for aged care workers.”*
Media Statement, Prime Minister’s Office, 3 August 2021, (pm.gov.au)
On vaccine passports: *“we've got to work through them and ensure that the states and territories are supportive of those because they're the ones who have to do it. As a Federal Government, I can't restrict someone going or allow someone going into a sports stadium, or a venue, or even coming into this building. What has to happen is state public health orders to support those issues legally. Similarly, I can't make it the law for someone to require of a customer to declare their vaccination status or to make it compulsory for someone to be vaccinated. These things are done through public health orders at a state and territory level.”*

7 Health Minister Greg Hunt, interview with David Speers on ABC Insiders on the COVID-19 vaccine rollout, Department of Health, 21 February 2021, (health.gov.au)
“The world is engaged in the largest clinical trial, the largest global vaccination trial ever…”

8 Preparing for vaccination, Valid Consent, Department of Health, (immunisationhandbook.health.gov.au)
“Valid consent is the voluntary agreement by an individual to a proposed procedure … For consent to be legally valid, the following elements must be present: … It must be given voluntarily in the absence of undue pressure, coercion or manipulation.”

9 Australian Product Information - Comirnaty (BNT162b2 [mRNA]) Covid-19 Vaccine, Therapeutic Goods Administration, (tga.gov.au)
Page 7 *The duration of protection afforded by COMIRNATY is unknown as it is still being determined by ongoing clinical trials. … As with any vaccine, vaccination with COMIRNATY may not protect all vaccine recipients.*
Page 7 *The data for use in the frail elderly (>85 years) is limited. The potential benefits of vaccination versus the potential risk and clinical impact of even relatively mild systemic adverse events in the frail elderly should be carefully assessed on a case-by-case basis.*
Page 7-8 *Interactions with other medicines and other forms of interactions: No interaction studies have been performed. Concomitant administration of COMIRNATY with other vaccines has not been studied.*
Page 12 *There were no meaningful clinical differences in overall vaccine efficacy in participants who were at risk of severe COVID-19 including those with 1 or more comorbidities that increase the risk of severe COVID-19 (e.g. asthma, body mass index (BMI) ≥ 30 kg/m^2, chronic pulmonary disease, diabetes mellitus, hypertension).*
Page 14 *Neither genotoxicity nor carcinogenicity studies were performed. The components of COMIRNATY (lipids and mRNA) are not expected to have genotoxic potential.*

Australian Product Information, Covid-19 Vaccine AstraZeneca (ChAdOx1-S), Therapeutic Goods Administration, (ebs.tga.gov.au);
Page 1 Approval: *The decision has been made on the basis of short term efficacy and safety data. Continued approval is dependent upon the evidence of longer-term efficacy and safety from ongoing clinical trials and post-market assessment.*
Page 2 *The safety and efficacy of COVID-19 Vaccine AstraZeneca in children and adolescents (aged <18 years old) have not yet been established. No data are available.*
Page 3 *As with any vaccine, vaccination with COVID-19 Vaccine AstraZeneca may not protect all vaccine recipients. Vaccination does not mitigate the need to follow other official recommendations to prevent the spread of COVID-19.*
Page 3 *Hypersensitivity reactions including anaphylaxis and angioedema have occurred following administration of COVID-19 Vaccine AstraZeneca.*
Page 3 *A very rare and serious combination of thrombosis and thrombocytopenia including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed following vaccination with COVID-19 Vaccine AstraZeneca during post-marketing use. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. The majority of the events occurred within the first 21 days following vaccination but have also been reported after this period. Some events had a fatal outcome.*
Whilst specific risk factors for thromboembolism in combination with thrombocytopenia have not been identified, cases have occurred in patients with a previous history of thrombosis, as well as in patients with autoimmune disorders, including immune thrombocytopenia. The benefits and risks of vaccination should be considered in these patients. Cases have also occurred in patients without other risk factors for thrombosis and thrombocytopenia. As a precautionary measure, administration of the COVID-19 Vaccine AstraZeneca in patients with a history of cerebral venous sinus thrombosis with thrombocytopenia or heparin induced thrombocytopenia (HIT) should only be considered when the benefit outweighs any potential risks.
Page 4 *Very rare events of demyelinating disorders have been reported following vaccination with COVID-19 Vaccine AstraZeneca. A causal relationship has not been established. … As with other vaccines, the benefits and potential risks of vaccinating individuals with COVID-19 Vaccine AstraZeneca should be considered.*
Page 5 *The duration of protection has not yet been established. Studies are ongoing.*
Page 5 *There are no safety, immunogenicity or efficacy data to support interchangeability of COVID-19 Vaccine AstraZeneca with other COVID-19 vaccines. … The safety, immunogenicity and efficacy of co-administration of COVID-19 Vaccine AstraZeneca with other vaccines have not been evaluated.*
Page 5 *There are currently limited data available for the efficacy and safety in individuals over 65 years of age. Further information will be collected from ongoing clinical studies and post-market monitoring. The decision to immunise an elderly patient should be decided on a case-by-case basis with consideration of age, co-morbidities, their environment, potential benefits and potential risks.*
Page 5 *There are currently limited data available for the efficacy and safety in individuals with significant co-morbidities. The decision to immunise an individual should be made on the basis of potential benefits over risks to that individual*
Page 5 *It is unknown whether COVID-19 Vaccine AstraZeneca may impact fertility. No data are available.*
Page 5 *There are a limited amount of data from the use of COVID-19 Vaccine AstraZeneca in pregnant women, or women who became pregnant after receiving the vaccine. The data are insufficient to inform on*

vaccine-associated risk. Animal reproductive toxicity studies have not been completed. As a precautionary measure, vaccination with COVID-19 Vaccine AstraZeneca is not recommended during pregnancy. Use of COVID-19 Vaccine AstraZeneca in pregnant women should be based on an assessment of whether the benefits of vaccination outweigh the potential risks.
Page 6 *There are no or limited data from the use of COVID-19 Vaccine AstraZeneca in lactating women. A risk to breastfed newborns/infants cannot be excluded.*
Page 6 *Safety in subgroups including the frail elderly, immunosuppressed, and pregnancy is unknown due to the low number of representative participants from these groups. Further information will become available from ongoing clinical studies and pharmacovigilance programmes.*
Page 11 *The number of COVID-19 cases in the subgroup of participants ≥65 years old were too few to draw conclusions on efficacy. In this sub-population, efficacy has been inferred from immunogenicity data and efficacy demonstrated in the general population.*
Page 11 *Limited data are available on the impact of emerging SARS-CoV-2 variants of concern on vaccine efficacy. Further information will be collected throughout the AZD1222 clinical development program by clinical and surveillance virology monitoring.*
Page 11 *An immunological correlate of protection has not been established; therefore the level of immune response that provides protection against COVID-19 is unknown.*
Page 13 *COVID-19 Vaccine AstraZeneca is a vaccine, as such, genotoxicity (mutagenicity) studies have not been conducted. … COVID-19 Vaccine AstraZeneca is a vaccine, as such, carcinogenicity studies have not been conducted.*
Page 14 *COVID-19 Vaccine AstraZeneca contains genetically modified organisms (GMOs).*

Australian Public Assessment Report for BNT162b2 (mRNA), Therapeutic Goods Administration, (tga.gov.au)
Page 15 *A combined reproductive and developmental study showed no adverse effects on female fertility, embryofetal development and post-natal development (up to weaning) in rats. Pregnancy category B1 is considered acceptable.*
Australian pregnancy category B1: Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals have not shown evidence of an increased occurrence of fetal damage.
Page 19 *It is noted that people with the following conditions were excluded [from Pfizer's clinical trial]:*
- *Other medical or psychiatric conditions, including recent or active suicidal ideation/behaviour or laboratory abnormality that increased the risk of participation or, in the investigator's judgment, made the participant inappropriate for the study.*
- *Immunocompromised individuals and individuals who received treatment with immunosuppressive therapy.*
- *Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate IM injection.*
- *Participants who had previous clinical or microbiological diagnosis of COVID-19 disease.*
- *History of severe adverse reaction associated with a vaccine and/or severe allergic reaction to any component of the study intervention.*
- *Women who are pregnant or breastfeeding.*

Page 34 *The duration of protection is not yet known and is to be assessed in the ongoing trial.*
Page 34 *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.*

Page 34 *Although the vaccine efficacies against certain outcomes have been demonstrated in the pivotal study, the real world vaccine effectiveness when this vaccine is rolled out to a larger and more diverse population is not known. The vaccine efficacy in the Aboriginal and Torres Strait Islander population has not been studied.*
Page 23 "*Although no Australian specific studies have been planned, the data from the studies planned to be conducted overseas are considered applicable to the Australian population.*"

Page 34 *"Pharmacovigilance and risk management plan*
The sponsor has included the following as missing information in the updated EU-RMP (version 1.0):

- *Use in pregnancy and while breast feeding.*
- *Use in immunocompromised patients.*
- *Use in frail patients with co-morbidities (for example, COPD, diabetes, chronic neurological disease, cardiovascular disorders).*
- *Use in patients with autoimmune or inflammatory disorders.*
- *Interaction with other vaccines.*
- *Long term safety data."*

Page 15 *Short term protection studies, lack of pharmacokinetic data for the S antigen-encoding mRNA (BNT162b2 V9), suboptimal dosing interval in the repeat dose study, lack of repeat dose toxicity studies in a second species and genotoxicity studies with the novel excipients, and lack of studies investigating potential for autoimmune diseases were noted. … Long term immunity and vaccine induced autoimmune diseases were not studied in the nonclinical program".*

Australian Public Assessment Report for ChAdOx1-S, Therapeutic Goods Administration, (tgs.gov.au)
Page 14 *No genotoxicity or carcinogenicity studies were performed.*
Page 14 *A mouse study of embryofetal development is ongoing.* Page 15 *Without adequate assessment of effects on embryofetal development, this vaccine is not recommended for use in pregnant women.*
Page 16 *There is no established immunological correlate of protection against SARS-CoV-2.*
Page 19 *These studies were not designed to assess disease transmission.*
Page 27 *Women who were pregnant, lactating, or intended to become pregnant were excluded from the University of Oxford studies, and women of childbearing capacity were required to use continuous birth control.*
Page 28 *Although it is understandable that the clinical development plan needed to evolve in the context of the pandemic and as more knowledge about the vaccine and COVID-19 became available, there are significant concerns about the robustness of the data:*

- *the study design was not entirely fit for purpose to evaluate efficacy in high risk groups;*
- *there is insufficient data about dosing; and*
- *there were a number of patients lost to efficacy analysis.*

Page 28 *The clinical evaluator has the following recommendations to the wording of the indication and PI if the vaccine is to be approved: … The limitations of the data in the elderly, immunosuppressed and pregnant women will be made clear in the precautions sections. It is recommended that these patients speak to their general practitioner or a specialist physician about the risks and benefits of the vaccine for them.*
Page 37 *At this stage, efficacy in preventing asymptomatic disease and transmission is unknown. … It is important that the population understand the facts about the efficacy of the vaccine, and limitations of the data, and the need to continue other public health measures to prevent the spread of disease until more information about vaccine efficacy is available. … One of the major limitations in the study is the short and variable duration of follow up. The duration of follow up, and reasons for missing data in follow up, are important in determining efficacy. … Variable doses and variable dose intervals arose due to procedural issues in the study.*
Page 38 *Another limitation to the clinical development program was that those at high risk of COVID-19, including the elderly and those with significant co-morbidities, were excluded or under-represented. From a regulatory perspective, under the Therapeutic Goods Act, the Delegate must be satisfied that 'quality safety and efficacy have been adequately established for the purpose for which they are to be used'. This is a different assessment to a risk/benefit analysis as the potential risks of vaccination are small, and the potential benefits in this population are large. In the Delegate's opinion, these populations should not be excluded from the indication as it is reasonable to extrapolate efficacy, and the risks of COVID-19 outweigh potential risks of the vaccine. However, there needs to be adequate warning about the limitations of the data in the PI, and a recommendation to prescribers that the potential risks and benefits to an individual be considered prior to proceeding to vaccinate. Similar limitations apply to the data available for use in pregnancy. However, not only was there insufficient patients in the study but also incomplete nonclinical studies.*
Page 38 *The main gap in the proposed ongoing studies is in relation to the optimal dose and dosing interval for vaccine efficacy. The sponsor is requested to provide further information about any proposed future studies.*
Page 41 *It is the sponsor's understanding that confirmatory safety and efficacy data are required to transition to full registration, and that the confirmatory data requirements would be in line with those expected for a standalone new vaccine registration. The studies described in the pharmacovigilance plan are best described as post-authorisation safety studies (Category 3 studies in the RMP), typical for any new product, irrespective of whether approved via full or provisional registration. They are not confirmatory safety and*

efficacy studies and consequently the sponsor considers that these should not form part of the data obligations for conversion to a full registration.
Page 42 *The ACV* [TGA's Advisory Committee] *noted the lack of data on the balance of benefits and potential harms in pregnant women, those with autoimmune/inflammatory diseases, immunocompromised, older people (particularly those with frailty) and those with severe or unstable comorbid medical conditions. There was also insufficient data to assess efficacy in individuals over 55 years of age, noting that the vaccine was immunogenic in this age group"*
Page 42 *The ACV advised that the limitations of the data in older persons should be clearly expressed in the PI. The ACV generally agreed with the proposed wording in the PI, which describes the limitation of data demonstrating efficacy in the population over 55 years of age, and limited data on safety in this age group, particularly in those over 65 years of age.*
Immunogenicity studies demonstrate older participants produce similar or in some cases moderately lower immune responses compared with younger participants. However, there is no immunologic correlate of protection and it is not possible to predict what level of efficacy will be provided for older adults in the absence of further data in this population.
Administration of the vaccine will not negate the need for older people and those around them to follow current precautions and public health guidance to reduce the risk of acquiring COVID-19.
Page 43 *The ACV acknowledged that a longer interval (around 12 weeks) between doses was associated with a trend towards higher levels of antibody post dose 2 and a possible modest increase in efficacy. However, this was based on post hoc secondary subgroup analysis, and confirmatory data may not become available. The ACV also noted that, while again a post-hoc analysis, the short term efficacy following one standard dose (prior to receipt of a second dose) was approximately 60%.*
Page 44 *The ACV advised that the PI section on Use in Pregnancy should also state:*

- *use in pregnancy is not routinely recommended, due to the lack of data and as a precautionary measure*
- *use of the vaccine is not contraindicated*

10 Moderna Inc, quarterly report for the period ending June 2020, United States Securities and Exchange Commission, (sec.gov)
"Currently, mRNA is considered a gene therapy product by the FDA. … . In the European Union, mRNA has been characterized as a Gene Therapy Medicinal Product. In certain countries, mRNA therapies have not yet been classified or any such classification is not known to us, specifically, in Japan, the Pharmaceuticals and Medical Devices Agency has not taken a position on the regulatory classification. Notwithstanding the differences between our mRNA investigational medicines and gene therapies, the classification of some of our mRNA investigational medicines as gene therapies in the United States, the European Union, and potentially other countries could adversely impact our ability to develop our investigational medicines, and could negatively impact our platform and our business. For instance, a clinical hold on gene therapy products across the field due to risks associated with altering cell DNA irreversibly may apply to our mRNA investigational medicines irrespective of the mechanistic differences between gene therapies and mRNA."

11 Thomas et al, "Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine", BMJ, 28 July 2021, (medrxiv.org)
"During the blinded, controlled period, 15 BNT162b2 and 14 placebo recipients died; during the open-label period, 3 BNT162b2 and 2 original placebo recipients who received BNT162b2 after unblinding died. None of these deaths were considered related to BNT162b2 by investigators. Causes of death were balanced between BNT162b2 and placebo groups"

12 Virtual Press Conference Transcript, Prime Minister's Office, 28 June 2021, (pm.gov.au)

13 Dana McCauley, "Vaccine suppliers given indemnity for 'inevitable' side effects", Sydney Morning Herald, (smh.com.au), 8 October 2020

14 "Communicating about COVID-19 vaccines", Therapeutic Goods Administration, (tga.gov.au), 30 July 2021

15 "Coronavirus vaccine - weekly summary of Yellow Card reporting", UK Government, (gov.uk); "COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print", (gov.uk), Retrieved 7 August 2021; "COVID-19 AstraZeneca Vaccine Analysis Print", (gov.uk), Retrieved 7 August 2021

16 Vaccine Adverse Reporting System (VAERS), US Centers for Disease Control and Prevention, (wonder.cdc.gov), Retrieved 7 August 2021

17 Australian Public Assessment Report for BNT162b2 (mRNA), Therapeutic Goods Administration, (tga.gov.au), page 35;
"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."

Australian Public Assessment Report for ChAdOx1-S, Therapeutic Goods Administration, (tgs.gov.au), page 16
"There is no established immunological correlate of protection against SARS-CoV-2."

18 Australian Public Assessment Report for BNT162b2 (mRNA), Therapeutic Goods Administration, (tga.gov.au), page 34
"The following questions have not yet been addressed: … Vaccine efficacy against asymptomatic infection and viral transmission."

19 "COVID-19 vaccination decision guide for women who are pregnant, breastfeeding or planning pregnancy", Version 5, Department of Health, (health.gov.au), 30 July 2021

20 "Who can get vaccinated for COVID-19?", Department of Health, (health.gov.au)

21 Magnus et al, "Pregnancy and risk of COVID-19", medRxiv, (medrxiv.org), 26 March 2021

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27 Australian Public Assessment Report for BNT162b2 (mRNA), Therapeutic Goods Administration, (tga.gov.au), page 19

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30 Australian Product Information - Comirnaty (BNT162b2 [mRNA]) Covid-19 Vaccine, Therapeutic Goods Administration, (tga.gov.au), Page 8

31 Australian Public Assessment Report for BNT162b2 (mRNA), Therapeutic Goods Administration, (tga.gov.au), Page 15; Australian Product Information, Covid-19 Vaccine AstraZeneca (ChAdOx1-S), Therapeutic Goods Administration, (ebs.tga.gov.au) Page 5

32 Preparing for vaccination, Valid consent, Australian Immunisation Handbook, Department of Health, (health.gov.au)

33 "TGA approves Pfizer COVID-19 vaccine for 12 to 15-year-olds", Department of Health, (health.gov.au)

34 Coronavirus Disease 2019 (COVID-19), CDNA National Guidelines for Public Health Units, Version 4.7, Department of Health, 24 June 2021 (health.gov.au), page 10

35 Australian Public Assessment Report for BNT162b2 (mRNA), Extension of Indications, [Adolescents] Therapeutic Goods Administration, (tga.gov.au),
Page 8 *Although the symptomology of COVID-19 in adolescents is usually mild, severe disease and death can occur, especially in adolescents with underlying medical conditions.* Page 30 *The Delegate noted that the submitted data have the following limitations … Adolescents with immunodeficient status/high health risks are not specifically assessed.*
Page 16 *As of 13 March 2021, confirmed COVID-19 cases in the evaluable efficacy population adolescent group without evidence of prior SARS-CoV-2 infection at least seven days after the second dose included 0 cases in the Comirnaty BNT162b2 vaccine group and 16 cases in the placebo group. The observed VE was 100%*
Page 18 *No severe COVID-19 cases (per protocol definition or US Centers for Disease Control and Prevention (CDC) criteria) were reported in adolescents (12 to 15 years of age) as of the data cutoff date (13 March 2021).*
Page 18 *Safety analysis were up to one month post the second dose and for all available data up to 13 March 2021. The median follow up duration for adolescents was > 2 months after the second dose. Almost all (98.3%) of adolescent participants had at least one month of follow up after Dose 2, and 1308 out of 2260 adolescents (57.9%) had at least two months of follow up after Dose 2.*
Page 21 *The overviews of AEs for adolescents and young adults (reactogenicity subset) are reported from the first dose to one month after the second dose, and from the first dose until 13 March 2021.*
Page 24 *Additionally, two adolescents originally randomised to placebo had SAEs that occurred after they turned 16 and were unblinded to receive BNT162b2, therefore the data are not included in the blinded analyses. These events were also considered as life threatening: an anaphylactoid reaction reported in one participant three days after the first dose of Comirnaty BNT162b2 (third dose, first active dose following placebo), considered as related to study intervention and leading to study withdrawal; and depression reported in one participant seven days after the first dose of Comirnaty BNT162b2 (third dose, first active dose following placebo) reported as ongoing/resolving at the time of the data cutoff date, considered as not related to study intervention.*
Page 25 *As of 13 March 2021,* ***no severe COVID-19 cases were reported*** *in adolescents 12 to 15 years of age in Study C4591001*
Page 25 *A review of the sponsor's safety database for spontaneously reported AEs in individuals 12 to 15 years of age received up to 28 February 2021 returned with*
11 cases. The cases were for individuals 15 years of age (four cases), 14 years of age (three cases), 13 years of age (one case), and 12 years of age (three cases). The limited amount of safety information in these reports does not substantially contribute to the base of knowledge of the product safety profile in this age group.
Page 26 *The sponsor's safety surveillance and risk management team conducted a review of spontaneous reports of myocarditis/pericarditis. The details regarding this were provided to the TGA in the April summary monthly safety report. The sponsor's* [Pfizer's] *overall conclusion based on the totality of the available data is that there is not enough evidence to currently support a causal association between the vaccine and myocarditis and pericarditis. However, the sponsor commits to continue surveillance and review of any future data or research. The sponsor also commits to obtain further details on the Israel cases. The TGA's evaluator states that while a plausible mechanism for a causal association of myocarditis and pericarditis with the vaccination is not yet clear, it may be postulated that myocarditis and pericarditis could be a systemic inflammatory reaction due to an immune response to the vaccine. The TGA's post market evaluation team will provide the detailed analysis on this issue to the Advisory Committee on Vaccines (ACV).*
Page 29 *It is acknowledged that neutralising antibody responses were chosen here as an immune biomarker for inferring effectiveness through immunobridging, but a specific level of neutralising antibodies has not yet been established to correlate with protection, and other aspects of the immune response, such as cellular immunity, were not analysed. Although no data were presented on cellular immunity, this is not considered critical in the presence of available descriptive efficacy data.*
Page 29 *It is noted that vaccine efficacy for adolescents was not a pre-specified endpoint and the data cutoff date (13 March 2021) was based on the immunogenicity and safety assessment, not based on the number of COVID-19 cases accrued for the adolescent group. The efficacy analysis is therefore considered as descriptive, not as hypothesis testing.*

Page 29 *There were no cases of COVID-19 among 1,005 vaccine recipients and there were 16 cases of COVID-19 among 978 placebo recipients. The estimate of vaccine efficacy in all participants 12 to 15 years of age (including those with evidence of prior SARS-CoV-2 infection) was also 100% (95% CI: 78.1 to 100.0%). No cases meeting the severe COVID-19 case definition were reported in any participant 12 to 15 years of age as of 13 March 2021.*
Page 29 *In term of safety data, a total of 2260 adolescents (1131 in the vaccine group and 1129 in the placebo group) have been included in the safety population up to the cut-off date. Around 98.3% of these participants had > 1 month of follow up while 57.9% had >2 months of follow up after the Dose 2. Within this follow up period, the vaccine was well tolerated.*
Page 30 *The reactogenicity profile in adolescents in the trial is considered acceptable. The frequency of reported AEs and SAEs in adolescents were low.* ***The sample size is relatively small and is not sufficient for the detection of rare adverse reactions****.*
Page 30 *The Delegate noted that the submitted data have the following limitations:*

- *The long-term efficacy and safety is not known.*
- *The VE against asymptomatic infection and viral transmission is not known.*
- *The number of adolescents in the study not sufficient to detect vary rare adverse events.*
- *No data available on the co-administration with quadrivalent seasonal influenza vaccine.*
- *Adolescents with immunodeficient status/high health risks are not specifically assessed.*
- *The VE against variants of concern has not been assessed.*

Page 30 *The submitted efficacy and safety data is short term at this stage, but the data have fulfilled the requirement as set out in the Access Consortium statement on COVID-19 vaccines evidence. The statement specified the minimum requirement that trial participants must be followed for a median of at least two months after receiving their final vaccine dose. The EMA has stated that conditional marketing authorisation for a COVID-19 vaccine could be based on review of at least six weeks post vaccination safety data.*
Page 30 *The limitations regarding the short term data can be addressed by planned post market studies. The sponsor is requested to specify whether adolescent subjects will be included in some of the post market studies. Provision of six months post the second dose safety data in subjects 12 to 15 years are listed as one of the clinical conditions of the provisional registration.*
Page 30 *The Delegate* [TGA] *has noted the recent international discussions on post market reports of rare cases of myocarditis and pericarditis following vaccination with the sponsor's COVID-19 vaccine in young people. The Vaccines and Related Biological Products Advisory Committee meeting on 10 June 2021 presented the safety data from the Vaccine Adverse Events Reporting System. The preliminary findings suggest there have been a higher than expected number of cases reported, especially after the second dose of mRNA vaccines, in individuals 16 to 24 years of age. The Advisory Committee on Immunisation (US CDC) meeting is scheduled for 18 June with further update on the analysis of myocarditis following mRNA COVID vaccination and benefit-risk assessment. TGA's post market evaluation team has plans to discuss with the ACV the issue of myocarditis and pericarditis reports following vaccination with sponsor's COVID-19 vaccine.*
Page 32 *Even apparently mild episodes of myocarditis may lead to long term sequelae, such as arrhythmias. However, additional data from the USA suggested that the majority of cases of myocarditis and/or pericarditis after mRNA COVID-19 vaccines (both the Pfizer [Comirnaty BNT162b2 (mRNA)] and Moderna [(mRNA) vaccines]) analysed to date occurred in older adolescents and young adults (aged 16 to 30 years), with highest risk in younger males within days after dose 2. Most cases were mild and recovered within days with a median duration of hospitalisation of 1 day. … Thus, myocartitis / pericarditis is a small but significant risk of an important complication in otherwise healthy children*.
Page 32 *[On cases of myocarditis an pericarditis reported following vaccination with Comirnaty in young people] The ACV advised that incidence, severity and outcome data (the true size of the signal) are still emerging. Most cases of myocarditis and pericarditis appeared to be mild and resolve with therapy. Information on longer term outcomes or recurrences is not available.*
Page 33 *The ACV advised that relevant statements should be included in the PI:*

- *Reported events of myocarditis and pericarditis*
- *Risk appears to be greater in adolescents compared to older adults; in males; after the second dose*
- *A high index of suspicion for presentations within a risk time window, within 4 days of either first or second dose, but particularly the second dose; for people presenting with chest pain, dyspnoea, or suggestion of arrhythmia.*

36 Australian Public Assessment Report for BNT162b2 (mRNA), Extension of Indications, Therapeutic Goods Administration, (tga.gov.au), page 30
"*The VE [vaccine efficacy] against variants of concern has not been assessed."*

37 Mr Skerritt's answers to Senator Malcolm Roberts, Community Affairs Legislation Committee, Health Portfolio, Hansard, (parlinfo.aph.gov.au) 1 June 2021

38 "'Safety evidence for the Pfizer vaccine is pretty thorough': TGA head", The Weekend Australian, (theaustralian.com.au), 7 August 2021

39 Australian Public Assessment Report for ChAdOx1-S, Therapeutic Goods Administration, (tgs.gov.au), page 28

40 "COVID-19 vaccine: Pfizer Australia - COMIRNATY BNT162b2 (mRNA) - approved for use in individuals 12 years and older", Therapeutic Goods Administration, (tga.gov.au), 23 July 2021; "COVID-19 vaccine: AstraZeneca ChAdOx1-S", Therapeutic Goods Administration, 26 March 2021 (tga.gov.au)

41 Email response from the Therapeutic Goods Administration sent 21 May 2021, regarding FOI 2289, (accessed via web archive doctor4covidethics.org
The TGA confirmed it "*does not hold any relevant documents relating to*" the applicant's request for raw data ("patient-level anonymised data or equivalent patient-level data") in relation to Pfizer's vaccine trials, or any documents confirming that a process for analysing raw data from Pfizer was undertaken. The TGA stated, "*to be clear, the TGA does not hold Individual Level Patient Data in relation to [Pfizer's] application for provisional registration*" of its vaccine.

42 "Covid-19 Vaccine AstraZeneca", Therapeutic Goods Administration, (tga.gov.au), 16 February 2021; Covid-19 Vaccine Astra Zeneca was approved for therapeutic use. "*The decision was based on quality (chemistry and manufacturing), nonclinical (pharmacology and toxicology), clinical (pharmacology, safety and efficacy) and risk management plan information* ***submitted by the sponsor.*** *The benefit-risk profile of COVID-19 vaccine Astra Zeneca was considered favourable for the therapeutic use approved.*" (Emphasis added)
"Comirnaty" [Pfizer's Covid-19 Vaccine], Therapeutic Goods Administration, (tga.gov.au) 25 January 2021
COMIRNATY (BNT162b2 mRNA), Pfizer's Covid-19 vaccine was provisionally approved for therapeutic use: "The decision was based on quality (chemistry and manufacturing), nonclinical (pharmacology and toxicology), clinical (pharmacology, safety and efficacy) and risk management plan information ***submitted by the sponsor****. The benefit-risk profile of COMIRNATY was considered favourable for the therapeutic use approved."* (Emphasis added)

43 Australian Public Assessment Report for BNT162b2 (mRNA), Table 3, Therapeutic Goods Administration, (tga.gov.au), page 15; Australian Public Assessment Report for ChAdOx1-S, Therapeutic Goods Administration, (tgs.gov.au), page 15

44 "Pharmaceutical Giant AstraZeneca to Pay $520 Million for Off-label Drug Marketing", United States Department of Justice, (justice.gov), 27 April 2010; AstraZeneca: US$1.1 billion penalties paid since 2000, via Violation Tracker; "Justice Department Announces Largest Health Care Fraud Settlement in Its History, Pfizer to Pay $2.3 Billion for Fraudulent Marketing", United States Department of Justice, (justice.gov), 2 September 2009; Pfizer: US $4.6 billion penalties paid since 2000, via Violation Tracker

45 Australian Public Assessment Report for BNT162b2 (mRNA), Therapeutic Goods Administration, (tga.gov.au), page 37

46 Chief Medical Officer Professor Paul Kelly's answers to Senator Malcolm Roberts, Community Affairs Legislation Committee, Health Portfolio, Hansard, (parlinfo.aph.gov.au) 1 June 2021; "Operation COVID Shield National COVID Vaccine Campaign Plan", Department of Health, (health.gov.au), page 3

47 Donato Paolo Mancini, Hannah Kuchler, Mehreen Khan, "Pfizer and Moderna raise EU Covid vaccine prices", (ft.com), 1 August 2021

48 About the TGA: Fees and Payments, Therapeutic Goods Administration, (tga.gov.au)

49 Melissa Davey, "Therapeutic Goods Administration rejects claims it is 'too close' to medical industry", The Guardian, (theguardian.com), 8 November 2017

50 “Number of women in Australia who have had transvaginal mesh implants and related matters”, Senate Community Affairs References Committee, (aph.gov.au), 28 March 2018

51 Amanda Hooton and Joanne McCarthy, “The 'eight-minute' cure: how transvaginal mesh sentenced thousands of women to a life of pain”, Sydney Morning Herald, (smh.com.au), 15 June 2019

52 Report on National Mesh Injury Forum—5th April 2019, Health Consumers Council (WA) Inc. and WA Pelvic Mesh Support Group, (hconc.org.au)

53 Greg Hunt: ‘Speech - Medicines Australia PharmAus 2019'

54 Tom McIlroy, “ATAGI shake-up not connected to vaccine advice: PM”, Australian Financial Review, (afr.com), 22 June 2021

55 Tom McIlroy and Tom Burton, “‘A constant appeal’: experts reject PM’s vaccine frustration”, Australian Financial Review (afr.com), 21 July 2021

56 “ATAGI statement on revised recommendations on the use of COVID-19 Vaccine AstraZeneca, 17 June 2021”, Department of Health, (health.gov.au), 17 June 2021

57 “ATAGI Statement, Response to NSW COVID-19 outbreak 24th July 2021”, Department of Health, (health.gov.au), 24 July 2021

58 Australian Technical Advisory Group on Immunisation (ATAGI) Declarations of Interest, Department of Health, (health.gov.au)

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“Dr Nigel Crawford acknowledges support from a National Health and Medical Research Council (NHMRC) of Australia PhD Postgraduate Public Health Scholarship (437031)NWC has investigator-led study support for a study of Guillain-Barre Syndrome Surveillance post H1N1 influenza vaccination [CSL] and been on a Pfizer [Wyeth] advisory board for pneumococcal vaccines and presented at conferences, for which his MCRI [Murdoch Children’s Research Institute] research fund has received honoraria

60 New Vaccines: Infection and Immunity, Murdoch Children's Research Institute, (micru.edu.au); Vaccine and Immunisation Research Group (VIRGo), (micro.edu.au),

61 Professor Nigel Crawford, Murdoch Children’s Research Institute, (micru.edu.au)

62 “Conflicts of Interest in Australian Vaccination Policies: References”, Informed Medical Options Party, (imoparty.com)

63 “Position statement: Registered health practitioners and students and COVID-19 vaccination”, Australian Health Practitioner Regulation Agency (AHPRA), (ahpra.gov.au), 9 March 2021

64 “Registered health practitioners and students: What you need to know about the COVID-19 vaccine rollout”, Australian Health Practitioner Regulation Agency (AHPRA), (ahpra.gov.au), 9 March 2021

65 “Communicating about COVID-19 vaccines”, Therapeutic Goods Administration, (tga.gov.au), 30 July 2021

66 “No mandatory Covid vaccines: Defending your right to choose”, Nurses Professional Association of Queensland (NPAQ), (npaq.redunion.com.au)

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68 Evelyn Manfield, “COVID vaccine backlash among WA aged care nurses as hundreds in survey threaten to quit”, ABC, (abc.net.au), 18 June 2021

69 “Australian Health Protection Principal Committee (AHPPC) statement on COVID-19 and influenza vaccination requirements for aged care workers”, Department of Health, (health.gov.au), 23 January 2021

70 “Australian Health Protection Principal Committee (AHPPC) statement on residential aged care worker COVID-19 vaccination”, Department of Health, (health.gov.au), 29 June 2021

71 Membership, Immunisation Coalition, (immunisationcoalition.org.au); About Us: Funding, Immunisation Coalition, (immunisationcoalition.org.au)

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73 Dr Bill Coote, “How low can the AMA go?”, (medicalrepublic.com.au), 30 April 2018

74 Australian Health Sector Emergency Response Plan for Novel Coronavirus (Covid-19), Department of Health, (health.gov.au)

75 Australian Health Management Plan for Pandemic Influenza (AHMPPI), Department of Health, (health.gov.au), August 2019

76 Coronavirus Disease 2019 (COVID-19), CDNA National Guidelines for Public Health Units, Version 4.7, Department of Health, 24 June 2021 (health.gov.au), page 10.
“*COVID-19 presents as a mild illness in approximately 80% of cases. … Severe or fatal outcomes occur more frequently in the elderly and those with comorbid conditions. Older adults are at increased risk of severe disease compared with younger individuals due to age-related vulnerabilities. While those with comorbid conditions have a higher incidence of severe or fatal outcomes, there are few studies investigating the relationship between severity and mortality of COVID-19 in the context of comorbidities. …COVID-19 is generally a mild disease in children, with the risk of severe disease being almost 25 times greater in adults. … The majority of cases recover from infection without clinical intervention, however, approximately 20% of identified cases globally to date have resulted in moderate to severe disease requiring hospitalisation. Some individuals remain asymptomatic throughout infection. Estimates of the proportion of cases which remain asymptomatic throughout their infection range from 15 to 48%.*”

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78 “WA records lowest flu numbers in history”, Media statement from Deputy Premier and Minister for Health Roger Cook, (wa.gov.au), 2 May 2020

79 Communicable Disease Intelligence 2021, Volume 45, Covid-19 Australia: Epidemiology Report 46, Reporting period ending 18 July 2021, Department of Health, (health.gov.au), page 2

80 Media Statement, Prime Minister, (pmc.gov.au), 7 April 2020

81 “Impact of Covid-19: Theoretical modelling of how the health system can respond”, Australian Government, (pmc.gov.au)

82 Media Statement, Prime Minister’s Office, (pm.gov.au), 7 April 2020

83 Phillip W Magness, “The Failure of Imperial College Modeling Is Far Worse than We Knew’, American Institute for Economic Research, (aier.org), 22 April 2021; Peter St One and Gael Campan, “The Flawed Covid-19 Model That Locked Down Canada”, MEI, (idea.org), 5 June 2020

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86 Doorstop interview on 10 September 2020, Health Minister Greg Hunt, Department of Health, (health.gov.au), 10 September 2020

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91 Media Statement, Prime Minister, (pmc.gov.au), 7 April 2020

92 Letter to Health Minister Greg Hunt from Mr John Clark, 10 July 2021

93 Coronavirus (Covid-19) in Australia—Pandemic Health Intelligence Plan, Department of Health, (health.gov.au); Media statement, Prime Minister’s Office, (pm.gov.au), 16 April 2020

94 Media Statement, Prime Minister’s Office, (pmc.gov.au), 28 July 2021

95 Media Statement, Prime Minister, (pmc.gov.au), 18 March 2020; Media Statement, Prime Minister’s Office, (pmc.gov.au), 22 March 2020

96 Media Statement, Prime Minister, (pmc.gov.au), 22 April 2021

97 Chapter 7: National governance, coordination and communication, First Interim Report, Senate Select Committee on Covid-19, (aph.gov.au)

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99 Media Statement, Prime Minister, (pmc.gov.au), 2 July 2021
Australian Public Assessment Report for ChAdOx1-S, Therapeutic Goods Administration, (tgs.gov.au)
Page 37 *At this stage, efficacy in preventing asymptomatic disease and transmission is unknown. … It is important that the population understand the facts about the efficacy of the vaccine, and limitations of the data, and the need to continue other public health measures to prevent the spread of disease until more information about vaccine efficacy is available.*
Page 42 *Administration of the vaccine will not negate the need for older people and those around them to follow current precautions and public health guidance to reduce the risk of acquiring COVID-19.*
Australian Product Information, Covid-19 Vaccine AstraZeneca (ChAdOx1-S), Therapeutic Goods Administration, (ebs.tga.gov.au)
Page 3 *As with any vaccine, vaccination with COVID-19 Vaccine AstraZeneca may not protect all vaccine recipients. Vaccination does not mitigate the need to follow other official recommendations to prevent the spread of COVID-19.*

100 “Operation COVID Shield National COVID Vaccine Campaign Plan”, Department of Health, (health.gov.au), page 3

101 Doherty Institute Modelling Report to advise on the National Plan to transition Australia's National COVID Response, Department of Health, (health.gov.au), 3 August 2021

102 Coronavirus (COVID-19) case numbers and statistics, Department of Health, (health.gov.au), retrieved 7 August 2021

103 Communicable Disease Intelligence 2021, Volume 45, Covid-19 Australia: Epidemiology Report 46, Reporting period ending 18 July 2021, Department of Health, (health.gov.au), page 2

104 Australian Public Assessment Report for BNT162b2 (mRNA), Extension of Indications, Therapeutic Goods Administration, (tga.gov.au), page 30;
"The Delegate noted that the submitted data have the following limitations: … The VE [vaccine efficacy] against asymptomatic infection and viral transmission is not known. … The VE against variants of concern has not been assessed."
Australian Product Information COVID-19 Vaccine AstraZeneca, Therapeutic Goods Administration, (tga.gov.au), page 11
"*Limited data are available on the impact of emerging SARS-CoV-2 variants of concern on vaccine efficacy."*

105 "Doherty Institute Modelling Report for National Cabinet", Doherty Institute, (doherty.edu.au), 3 August 2021

106 Davies et al, "Age-dependent effects in the transmission and control of COVID-19 epidemics", Nature Medicine, (nature.com), 16 June 2020
"There are some limitations to the study. Information drawn from the early stages of the epidemic is subject to uncertainty; however, age-specific information in our study is drawn from several regions and countries, and clinical studies support the hypothesis presented here. We assumed that clinical cases are reported at a fixed fraction throughout the time period, although there may have been changes in reporting and testing practices that affected case ascertainment by age. We assumed that subclinical infections are less infectious than clinically apparent infections. We tested the effects of differences in infectivity on our findings … but were not able to estimate how infectious subclinical cases were."
The Doherty Institute's modelling uses data from Davies 2020 to estimate: "Probability of symptomatic disease" Davies 2020 p22; "Age-specific susceptibility and transmissibility estimates from Davies et al. (Nature Medicine 2020)" p30; "age-specific susceptibilities to infection and probabilities of developing symptoms given infection (according to Davies et al Nature Medicine 2020)" p40

107 Knock et al, "The 2020 SARS-CoV-2 epidemic in England: key epidemiological drivers and impact of interventions", BMJ, (medrxiv.org), 13 January 2021

108 Sheik et al, "SARS-CoV-2 Delta VOC in Scotland: demographics, risk of hospital admission, and vaccine effectiveness", The Lancet, (thelancet.com), 14 June 2021
"*In summary, we show that the Delta VOC in Scotland was found mainly in younger, more affluent groups. Risk of COVID-19 hospital admission was approximately doubled in those with the Delta VOC when compared to the Alpha VOC, with* ***risk of admission particularly increased in those with five or more relevant comorbidities****. Both the Oxford–AstraZeneca and Pfizer–BioNTech COVID-19 vaccines were effective in reducing the risk of SARS-CoV-2 infection and COVID-19 hospitalisation in people with the Delta VOC, but these effects on infection appeared to be diminished when compared to those with the Alpha VOC.* ***We had insufficient numbers of hospital admissions to compare between vaccines in this respect.*** *The Oxford–AstraZeneca vaccine appeared less effective than the Pfizer–BioNTech vaccine in preventing SARS-CoV-2 infection in those with the Delta VOC.* ***Given the observational nature of these data, estimates of vaccine effectiveness need to be interpreted with caution."***
"There were 19543 confirmed SARS-CoV-2 infections over the period of interest, of whom 377 [1.92%] were admitted to hospital for COVID-19 … ***A greater number of COVID-19 relevant comorbidities increased the risk of COVID-19 hospital admission*** *… The corresponding hazard ratio for risk of hospital admission for S gene-positive cases was 0·38 (95% CI 0·24–0·58), with an interaction test p value of 0·19,* ***suggesting that there was no evidence of a differential vaccine effect on hospital admissions among those first testing positive*****"**

109 Harris et al, "Effect of Vaccination on Household Transmission of SARS-CoV-2 in England", The New England Journal of Medicine, (nejm.org), 23 June 2021
"HOSTED does not include data on symptoms or cycle-threshold values and has information only on diagnosed cases. Among index patients, those who had been vaccinated were likely to be less severely symptomatic and might have been less infectious than those who were unvaccinated. Studies that involved active follow-up of contacts and that used serologic testing have shown higher rates of household

transmission than were observed in our study; bias could occur if case ascertainment differed between household contacts of vaccinated persons and those of unvaccinated persons. Our findings with respect to the timing of vaccination of index patients are consistent with previous data regarding the timing of individual protection after vaccination and thus support the overall findings. There may have been misclassification of index and secondary cases, which are determined on the basis of testing dates; however, such misclassification would tend to attenuate the estimated protective effect of vaccination. Data are needed to inform the reduction in transmissibility of the virus after the receipt of two vaccine doses. It will be important to consider these findings alongside other emerging evidence to inform the benefits of vaccination."

110 Press Conference, Prime Minister's Office, (pmc.gov.au), 3 August 2021

111 Coronavirus Disease 2019 (COVID-19), CDNA National Guidelines for Public Health Units, Version 4.7, Department of Health, 24 June 2021 (health.gov.au), page 10.
"COVID-19 presents as a mild illness in approximately 80% of cases. … Severe or fatal outcomes occur more frequently in the elderly and those with comorbid conditions. Older adults are at increased risk of severe disease compared with younger individuals due to age-related vulnerabilities."

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On vaccine passports being implemented by state governments: *"but we've got to work through them and ensure that the states and territories are supportive of those because they're the ones who have to do it. As*

a Federal Government, I can't restrict someone going or allow someone going into a sports stadium, or a venue, or even coming into this building. What has to happen is state public health orders to support those issues legally. Similarly, I can't make it the law for someone to require of a customer to declare their vaccination status or to make it compulsory for someone to be vaccinated. These things are done through public health orders at a state and territory level. So working together to define what they are is incredibly important. John Howard made a very good point on the weekend. The states don't have any more powers than they've ever had. They've just never been enlivened in the way that they have through this crisis. They've always had absolute control over public health in this country. But this once-in-100-year pandemic, I think, has shone a spotlight on that and those powers are enlivened through that process, not through any other process."

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