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3 January 2023

Dr Brendan Murphy, Secretary of the Department of Health
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Department of Health and Aged Care
GPO Box 9848
Canberra ACT 2601
Australia
Cc: Prof John Skerritt, Deputy Secretary of the Department of Health
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Re: Evidence for reasons to discontinue COVID-19 vaccines for Infants through 4 years; need for action by the Department of Health

Dear Professor Murphy

We write on behalf of the Australian Medical Professionals' Society (AMPS), regarding the threat to the health and safety of Australia's youngest citizens from the extension of Provisional Approval of the gene-based COVID-19 pharmaceuticals Spikevax and Comirnaty to the 6-month-to-4-year age group.

As you are aware, legislatively speaking, these Provisionally Approved agents have been made exempt from certain safety and efficacy requirements because they are classified as a treatment for the disease known as coronavirus[1], through regulatory amendments made in July 2021. Hence, in the context of profoundly reduced standards placed upon the Sponsor for the demonstration of safety and efficacy, it is misleading, medically negligent, and possibly deceptive to inform parents and guardians these vaccines have been proved safe and effective in young children. Again, although seldom emphasised to the Australian People, the *Provisional Approval Pathway* is by definition an expedited pathway which is open only in special circumstances and is based on preliminary data; the normative standards for safety and efficacy analysis are not required nor supplied in the same way as they are when a pharmaceutical agent is being considered for Full Regulatory Approval under the TGA.

The available and *Provisionally Approved* gene-based COVID-19 pharmaceuticals Spikevax and Comirnaty are clearly subject to ongoing research. However, based on published research, we

[1] https://www.legislation.gov.au/Details/F2021L01032

wish to make it clear to the Department of Health that these agents are now demonstrated to pose more risk than benefit for the youngest cohort of Australians and are therefore unjustified. Scientific evidence clearly demonstrates that these products have little, no, or even negative efficacy; they pose evident short- and medium-term health risks and unknown long-term hazards. As health professionals, we have a duty of care to exercise our freedom of political communication to advocate the best interests of our patients, using good clinical practice and ethical conduct, which demand that we speak up when recommendations deviate from long established standards of risk-benefit analysis and threaten the lives, wellbeing and best interests of Australian children[2][3][4].

It is critical to the health of our Nation that we continue to stand by our Codes of Conduct, predicated as they are on The Hippocratic Oath, the Declaration of Geneva, and the International Code of Ethics. It is essential that we serve the interests of our patients first at all times, above the purported interests of the state, refusing direct or indirect attempts to silence critical appraisal of policy, by AHPRA and National Boards[5]. It is our assessment that publicly fighting these inappropriate approvals is vital to protect our members from being directed to breach their duty of care, under any form of threat from public entities and officials such as Chief Health Officers, Health Ministers, and Hospital administrators, who themselves appear to have liability protection from directing and inciting professional misconduct under the *Health Practitioner Regulation National Law* (Section 136)[6].

The following statements from the Good Medical Practice Code of Conduct [7] are provided for further discussion:

> **2.1 Professional values and qualities of doctors**
> Doctors have a duty to make the care of patients their first concern and to practise medicine safely and effectively. They must be honest, ethical and trustworthy.
>
> **2.2 Public comment and trust in the profession**
> The community trusts the medical profession. Every doctor has a responsibility to behave ethically to justify this trust.
>
> **3.2 Good patient care**
> 3.2.4 Considering the balance of benefit and harm in all clinical-management decisions. 3.2.5 Communicating effectively with patients (see section 4.3).
> 3.2.6 Providing treatment options based on the best available information.
> 3.2.7 Only recommending treatments when there is an identified therapeutic need and/or a clinically recognised treatment, and a reasonable expectation of clinical efficacy and benefit for the patient.

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[2] https://www.legislation.gov.au/Details/C2021C00376
[3] https://humanrights.gov.au/our-work/rights-and-freedoms/freedom-information-opinion-and-expression#:~:text=The%20Australian%20Constitution%20does%20not,government%20created%20by%20the%20Constitution.
[4] https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf
[5] Medical-Board---Code---Good-medical-practice-a-code-of-conduct-for-doctors-in-Australia---1-October-2020%20(7).PDF
[6] http://classic.austlii.edu.au/au/legis/qld/consol_act/hprnl509/s136.html
[7] https://www.ahpra.gov.au/documents/default.aspx?record=WD20%2F30051&dbid=AP&chksum=9BSTs75R4%2FcPJY7vrmzHPg%3D%3D

4.5 Informed consent

Informed consent is a person's voluntary decision about medical care that is made with knowledge and understanding of the benefits and risks involved.

4.6 Children and young people

Caring for children and young people brings additional responsibilities and challenges for doctors. Good medical practice involves:

4.6.1 Placing the interests and wellbeing of the child or young person first.

With reference to the Moderna and Pfizer COVID-19 vaccine products, both are RNA-based gene therapy vaccines, and are by definition "experimental."[789] The unarguable novelty of synthetic mRNA therapeutic platforms is grounds enough for this assessment, and it is equally evident in the fact that Provisional Approval of these agents is based on "preliminary data", knowledge of these products being incomplete. Although this nuance of the vaccine rollout has not been made as clear to the Australian People as it might have been, it is correct that the former Health Minister Greg Hunt referred to the program as "the largest clinical trial, the largest global vaccination trial ever"[8]. These considerations do not apply to children alone. It is important when prescribing and administering these products that practitioners understand they are doing so within the context and framework of continuing research and surveillance of an investigational product. We believe that to be consistent, the use of these experimental products must be considered with reference to the *National Statement on Ethical Conduct in Human Research*[9] which states:

Respect for human beings involves giving due scope to people's capacity to make their own decisions. In the research context, this normally requires that participation be the result of a choice made by participants – commonly known as 'the requirement for consent'. This requirement has the following conditions: consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.

We must also consider a second document. With respect to *The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use*, we draw your attention to the following selected points:

2. THE PRINCIPLES OF ICH GCP [10]

2.1 Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).

2.2 Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.

2.3 The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.

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[8] https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/interview-with-david-speers-on-abc-insiders-on-the-covid-19-vaccine-rollout

[9] https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

[10] https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

2.4 The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.

With a good medical-practice and ethical clinical-trial perspective at the fore, there are some facts, objective data, pharmacovigilance requirements and scientific research evidence that must be highlighted. These must be seriously considered by the TGA in accordance with its legislated regulatory duties, not to mention moral and ethical responsibilities.

Amendments were made to the Therapeutic Goods Regulation Act on 23 July 2021 that reduce the safety and efficacy requirements for any therapeutic that is being assessed for "the treatment or prevention of the disease known as coronavirus disease (COVID-19)." For any therapeutic that meets this indication the following requirements no longer apply.

> (b) either:
>
> (i) no therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods); or
>
> (ii) if one or more therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods) – there is preliminary clinical data demonstrating that the medicine is likely to provide a significant improvement in the efficacy or safety of the treatment, prevention or diagnosis of the condition compared to those goods;
>
> (c) there is preliminary clinical data demonstrating that the medicine is likely to provide a major therapeutic advance;

The TGA is now only legislatively required to classify the disease known as coronavirus disease (COVID-19) as, "of a life-threatening or seriously debilitating condition" to grant provisional approval for its use with Australian babies and preschoolers[11].

Despite considerable research, AMPS finds no evidence to support SARS-CoV-2 as being life threatening to, or producing seriously debilitating outcomes in, Australian babies and preschoolers, particularly in the era of the Omicron variant, and more particularly where most Australian babies and children have acquired natural immunity towards SARS-CoV-2.

As outlined by ATAGI, most children with SARS-CoV-2 infection are asymptomatic or experience a mild illness. Those who are symptomatic typically have a short illness with a median duration of 5 days[12][13]. Research findings demonstrate that children clear the virus more easily than adults and generate a robust, cross-reactive and sustained immune response to SARS-CoV-2.[14][15]This is especially true since the arrival of the Omicron variant, where clinical evidence suggests infections

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[11] https://www.legislation.gov.au/Details/F2022C01026

[12] ATAGI recommendations on the use of the paediatric Pfizer COVID-19 vaccine in children aged 5 to 11 years in Australia

[13]https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.14.2001248#abstract_content

[14] https://www.nature.com/articles/s41467-021-22236-7

[15] https://www.nature.com/articles/s41590-021-01089-8

and their associated symptoms have been generally milder with data showing minimal risk posed to children, including those under 5[1617]. Additionally, the most recent Paediatric SARS-CoV-2 Serosurvey 2022 Australia Summary Report clearly evidences most children and adolescents in Australia have been infected with the SARS-CoV-2, with low rates of hospitalisations[18].

Data from the Australian government department of Health Website: Coronavirus (COVID-19) case numbers and statistics updated in May 2022 demonstrate a Case Fatality Rate (CFR) of 0.0428% for all age groups, with a recent study outlining Children 0-19 years experience an Infection Fatality Rate (IFR) of 0.0003%[19]. Confirming this peer-reviewed literature is the complete absence of any Australian data able to demonstrate any healthy child has died as a direct result of Covid[20].

In the US, data from the CDC calculated a death rate of 0.00049%, while UK ONS data from the whole of 2020 and 2021 clearly show that not a single child aged 1-9 had died with COVID as the sole diagnosis on the death certificate[21].

A Johns Hopkins study published in July 2021 monitored 48,000 children diagnosed with COVID-19 and found a mortality rate of zero among children without a pre-existing medical condition[22]. Additionally, a study in *Nature* demonstrated that children under 18 with no comorbidities have virtually no risk of death[23] from SARS-CoV-2. Furthermore, a recent nationwide Icelandic study[24] of Covid-19 infections in children showed after three waves of infection, including the more severe Delta variant, no Icelandic child required hospitalisation, proving again Covid-19 is not life-threatening to children, nor does it cause serious debilitating outcomes in those children infected. Overall statistics show that the risk of death or serious debilitating conditions, especially in healthy children, is essentially statistically nil[25].

As of June 2022 it is estimated that 89% of 1-4-year-olds had already had SARS-CoV-2 infection[26], with the most recent Paediatric SARS-CoV-2 Serosurvey 2022, Australia Summary report

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[16] https://www.medrxiv.org/content/10.1101/2022.01.12.22269179v1.full.pdf

[17] Ward *et al*: Risk of covid-19 related deaths for SARS-CoV-2 omicron (B.1.1.529) compared with delta (B.1.617.2): retrospective cohort study

[18]https://www.ncirs.org.au/sites/default/files/2022-11/PAEDS%20NCIRS_COVID-19%20Paediatric%20Serosurvey%202022%20Report_3-11-2022_Final.pdf

[19]https://www.medrxiv.org/content/10.1101/2022.10.11.22280963v1

[20] Australian Bureau of Statistics - Causes of Death, Australia: Doctor Certified Deaths, Summary Tables. Reference Period 2019. https://www.abs.gov.au/statistics/health/causes-death/causes{eath-australia/latestrelease

[21] COVID-19 Deaths and Autopsies Feb 2020 to Dec 2021, Table 1: Number of Deaths Where COVID-19 Was the Only Cause Mentioned on the Death Certificate, 1 February 2020 to 31 December 2021, by Sex and Age Group, England and Wales, Jan. 17, 2022, *Office for National Statistics*. https://www.ons.gov.uk/aboutus/transparencyandgovernance/freedomofinformationfoi/covid19deathsandautopsiesfeb2020todec2021

[22] Marty Makari, (19107121) The Flimsy Evidence Behind the CDC's Push to Vaccinate Children, http://www.wsj.com/articles/cdc-covid-19-coronavirus-vaccine-side-effects-hospitalizations-kids-1 1626706868

[23] Clare Smith, David Odd, Rachel Harwood, et al., "Deaths in Children and Young People in England after SARS-CoV-2 Infection during the First Pandemic Year," Nat Med 28 (2022): 185–192, https://doi.org/10.1038/s41591-021-01578-1.

[24]https://journals.lww.com/pidj/pages/articleviewer.aspx?year=9900&issue=00000&article=00124&type=Fulltext

25https://www.cebm.net/covid-19/global-covid-19-case-fatality-rates/

[26] https://www.mrc-bsu.cam.ac.uk/now-casting/nowcasting-and-forecasting-23rd-June-2022/

estimating 82% of children aged 0–19 years who were unvaccinated had been infected[27]. This is a substantial consideration in the paediatric Covid vaccination roll-out as evidence demonstrates that naturally acquired immunity is as good as or more robust than any demonstrable vaccine-induced immunity[28].

Indeed, it has been found that post infection children develop excellent long-lasting immunity which provides very strong protection against severe disease, with no evidence of waning immunity even 14 months after primary infection.[29][30]

It is now clear in adults that any efficacy against severe infection produced by these MRNA vaccines wanes rapidly; this has resulted in a shift in the public health narrative which now has people allegedly needing to receive regular and repeated booster doses.

A large and recent UK study of vaccinated elderly showed yet again the Covid-19 vaccines provide no enduring effective protection, and instead now have increased deaths and hospitalisations within their vaccinated elderly population[31].

The AusPAR for Spikevax (Elasomeran)[32] showed the granting of provisional approval, as outlined on page 8, for the approved therapeutic use: "Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in individuals 6 months of age and older."

The report concluded overall the vaccine demonstrated a low level of protective efficacy against infection. The clinical evaluator noted that the US Food and Drug Administration (FDA) guidelines state that vaccine efficacy should be at least 50%, with a confidence interval that has a lower bound > 30%. However, Spikevax did not demonstrate this level of efficacy in all analyses. The report noted the low protective efficacy, but then went no further than to suggest that the main use of Spikevax in our population of babies 6 months through 5 years of age is "likely" to be to prevent severe disease, rather than infection per se, but there were no clinical data on severe disease endpoints in this age group.

The AusPAR for Comirnaty Covid-19 vaccine was also, as outlined on page 7, provisionally registered for the indication of active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in people 6 months of age and older. However, as the report detailed, the duration of immune resistance is not known, because of the short follow-up period, where the interpretation of vaccine efficacy in Study C4591007 should be approached with caution on account of the low number of COVID-19 cases recorded. Protection against asymptomatic infection, or effect on viral transmission offered by the vaccine in children, was stated to be unknown.

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[27] https://www.ncirs.org.au/sites/default/files/2022-11/PAEDS%20NCIRS_COVID-19%20Paediatric%20Serosurvey%202022%20Report_3-11-2022_Final.pdf

[28] https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/

[29] https://www.medrxiv.org/content/10.1101/2022.07.06.22277306v1

[30] https://www.medrxiv.org/content/10.1101/2022.06.20.22276650v1

[31] https://www.medrxiv.org/content/10.1101/2022.06.28.22276926v1

[32] https://www.tga.gov.au/sites/default/files/2022-08/auspar-elasomeran-220727.pdf

The clinical data used to support both AusPAR outcome recommendations are lacking or missing. The reports clearly demonstrate the vaccines do not prevent coronavirus and therefore do not meet the indication for which they have been approved[33].

In children another study from New York demonstrated the rapidly waning efficacy against the omicron variant, falling to 12% by 4-5 weeks and to negative values by 5-6 weeks post the second dose.[34] Similar findings to the New York study were noted in the Pfizer 0-4s trial with the efficacy after the first 2 doses falling to negative values, necessitating a change to the trial protocol. After the addition of a third dose for young children there were evidence to suggest efficacy from 7-30 days, but there was no data beyond 30 days to demonstrate any ongoing efficacy, waning timeframes or whether negative efficacy developed.[35]Such flawed findings cannot compete with natural immunity against Covid-19 re-infection, as recent studies[36] have clearly proved.

The TGA is in error when approving the application to extend these experimental drugs to infants and children aged 6 months up to 4 years. Approval relied upon data of questionable integrity, being dependent upon surrogate analysis of immunological markers to establish clinical efficacy, supplied by Moderna and Pfizer to the FDA. The TGA again has failed to require safety and efficacy data for carcinogenicity or genotoxicity.

For example, there was only a single clinical trial submitted to the TGA for the Pfizer COMIRNATY paediatric Covid-19 vaccine [37] application for provisional approval. The study seeking to show this vaccine reduced Covid-19 symptoms comprised only 29 children (16 in the treatment arm and 3 in the placebo arm of the trial). These clinical data did not demonstrate in any child that the vaccine prevented any serious clinical symptoms of Covid-19. The only data presented were laboratory measurements of an antibody immune response which was simply assumed to translate into a substantial beneficial clinical effect, an outcome which has never been proved in controlled randomised trials[38]. In fact, the FDA states on its website:

Results from currently authorised SARS-CoV-2 antibody tests should not be used to evaluate a person's level of immunity or protection from COVID-19 at any time, and especially after the person received a COVID-19 vaccination.[39]

Furthermore, the clinical data submitted to the FDA and TGA in support of the safety and efficacy for provisional approval for 5-11-year-olds are very limited and grossly underpowered. The Pfizer clinical trial documentation otherwise has serious deficits and many unanswered questions that should have rung alarm bells for our TGA, when considering provisional approval for any Australians, let alone our youngest.

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[33] https://www.tga.gov.au/sites/default/files/2022-10/auspar-tozinameran-221012.pdf
[34] https://www.medrxiv.org/content/10.1101/2022.02.25.22271454v1.full
[35] https://www.fda.gov/media/159195/download
[36] https://www.medrxiv.org/content/10.1101/2022.07.06.22277306v1
[37] AusPAR report-http://www.tga.gov.au/sites/default/files/auspar-tozinameran-mrna-covid-19-vaccine-211207.pdf
[38] AusPAR report-http://www.tga.gov.au/sites/default/files/auspar-tozinameran-mrna-covid-19-vaccine-211207.pdf
[39]https://www.fda.gov/medical-devices/safety-communications/antibody-testing-not-currently-recommended-assess-immunity-after-covid-19-vaccination-fda-safety

A recent letter from doctors to the UK Health Authorities, regarding approval of Pfizer's vaccine for babies of 6 months through children of 4 years, detailed serious data flaws in the Pfizer documentation presented to the FDA[40]. The letter states:

- *The protocol was changed mid-trial. The original two-dose schedule exhibited poor immunogenicity with efficacy far below the required standard. A third dose was added by which time many of the original placebo recipients had been vaccinated.*
- *There was no statistically significant difference between the placebo and vaccinated groups in either the 6–23-month age group or the 2-4-year-olds, even after the third dose. Astonishingly, the results were based on just three participants in the younger age group (one vaccinated and two placebo) and just seven participants in the older 2–4-year-olds (two vaccinated and five placebo). Indeed, for the younger age group the confidence intervals ranged from minus-367% to plus-99%. The manufacturer stated that the numbers were too low to draw any confident conclusions. Moreover, these limited numbers come only from children infected more than seven days after the third dose.*
- *Over the whole time period from the first dose onwards (see page 39 Tables 19 and 20), there were a total of 225 infected children in the vaccinated arm and 150 in the placebo arm, giving a calculated vaccine efficacy of only 25% (14% for the 6-23 months, and 33% for 2-4s).*
- *The additional immunogenicity studies against Omicron, requested by the FDA, only involved a total of 66 children tested one month after the third dose (see page 35).*

In light of the foregoing, AMPS points out that the clinical data presented by each of Pfizer and Moderna exhibit vaccines with very poor safety and efficacy profiles. No evidence substantiates the assumption these vaccines prevent life-threatening or seriously debilitating outcomes. This would be necessary to meet the legislative threshold required for provisional approval. Instead AMPS impresses upon the Secretary of Health the obvious need to responsibly take into account the vast and unprecedented body of scientific research amassed over the last 18 months evidencing many adverse and crippling outcomes from these vaccines.[41]

Globally there is great concern about myocarditis[4243] associated with these injections in young people, which is sadly but one of the many life-limiting adverse reactions found to be associated with these vaccines[444546].

Within the age group <1-11 years old the following are some of the adverse reactions reported; death, chest pain, cardiac arrest, myocarditis, pericarditis, stroke, vaginal haemorrhage, Kawasaki disease, Bell's palsy, tinnitus, Ginnotti-Crosti syndrome, thrombocytopenia, seizure, and transverse myelitis.

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[40] EUA amendment request for Pfizer-BioNTech COVID-19 Vaccine for use in children 6 months through 4 years of age. *Submitted to the FDA* 15/06/2022. https://www.fda.gov/media/159195/download

[41] https://8630368.fs1.hubspotusercontent-na1.net/hubfs/8630368/AMPS/Altman%20Report%20Final%20Version%2011-8-22%20(1).pdf?utm_source=hs_email&utm_medium=email&_hsenc=p2ANqtz-8HS0cEyUJuQHjoxCYMYvaYAqn1CWxMNk_F4VyGSiymi6QxgE6AEh9SJNXh6yR0hIVEAxxC

[42] https://www.medrxiv.org/content/10.1101/2022.10.13.22281036v1.full

[43] https://www.preprints.org/manuscript/202208.0151/v1?utm_source=substack&utm_medium=email

[44] https://www.mdpi.com/2077-0383/11/8/2219

[45] https://pubmed.ncbi.nlm.nih.gov/35660931/

[46] The Time of Covid

There are now more than a thousand peer-reviewed studies evidencing adverse effects post COVID vaccination[47]. Severe reactions, many involving lifelong harms, are still yet to be properly quantified by public health officials; this brings about an extraordinary state of affairs that calls for the strictest application of the Precautionary Principle in respect of our youngest and most vulnerable children[48]. Extreme caution is required now that it is known there is minimal risk posed to children from SARS-CoV-2.

Prior claims Covid-19 infection leads to increased myocarditis and pericarditis have been found untrue.[49] In fact, it has been shown that Covid-19 vaccination is causing substantial rates of myocarditis and pericarditis[50].

Animal biodistribution studies showed the lipid nanoparticles concentrate in ovaries and testes,[51] with added concern now data are demonstrating that mRNA from Covid-19 vaccines can be reverse-transcribed[52].

It is also critically important to be aware of the as-yet unknown effects on young children's developing immune systems from these novel gene-based drugs. The tiny number of participants in the trial makes it impossible to rule out potential adverse outcomes such as antibody-dependent enhancement, the unanswered question of original antigenic sin, and the possibility of developing impaired immune function[535455].

Additionally, AMPS notes that in all countries that have extensively deployed Covid-19 vaccines astonishing rates of Excess Mortality[56] are now evident.

The AusPAR for Spikevax report detailed how the Advisory Committee on Vaccines (ACV) was of the view that the benefit-risk balance is positive, with the greatest benefit expected to be in children who are at high risk of developing severe disease (that is, children severely immunocompromised or having substantial respiratory/cardiac disease). However, in noting this the ACV highlighted that children at higher risk (that is, with immunosuppression) were excluded from the study[57]. As a result the ACV had no data whatsoever to reach this conclusion.

These concerning data limitations were also identified in the AusPAR for Comirnaty. Where the ACV was of the view that the greatest benefit is expected to be found in infants and children who are at high risk of developing severe disease (that is, children with severe immunocompromise or

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[47] https://react19.org/1250-covid-vaccine-reports/
[48] The Time of Covid
[49] https://www.mdpi.com/2077-0383/11/8/2219
[50] https://www.nature.com/articles/s41467-022-31401-5 ; https://pubmed.ncbi.nlm.nih.gov/35660931/
[51] https://www.naturalnews.com/files/Pfizer-bio-distribution-confidential-document-translated-to-english.pdf
[52] https://www.mdpi.com/1467-3045/44/3/73/htm
[53] Yahi N, Chahinian H, Fantini J. Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination?. *J Infect*. 2021;83(5):607-635. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8351274/
[54] Brown EL, Essigmann HT. Original Antigenic Sin: the Downside of Immunological Memory and Implications for COVID-19. *mSphere* 2021; 6(2): e00056-21. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8546681/
[55] Goldberg Y, Mandel M, Bar-On YM et al. Protection and waning of natural and hybrid COVID-19 immunity. *N Engl J Med* 2022; 386: 2201-12. https://www.nejm.org/doi/pdf/10.1056/NEJMoa2118946?articleTools=true
[56] https://econpapers.repec.org/paper/waieconwp/22_2f11.htm
[57] https://www.tga.gov.au/sites/default/files/2022-08/auspar-elasomeran-220727.pdf

severe respiratory/cardiac disease), the report noted there is a lack of immunogenicity and safety data in immunocompromised patients or children with background autoimmune disease. This expected benefit of the ACV is not based on any objective data[58].

There are consequently no reliable risk-benefit analyses that exist to support vaccination in this age and no evidence to suggest Covid poses "a life-threatening or seriously debilitating condition" to babies and young children.

Australia is recommending vaccinating our youngest, most vulnerable cohort of children in an initiative for which there appear no actual supporting data. At the same time, several nations including Denmark[59], Sweden[60] and Norway[61] are not recommending the vaccines even for 5-11-year-olds, and Holland is not recommending them for children who have acquired natural immunity[62]. The director of the Danish Health and Medicines authority recently stated that with what is now known, the decision to vaccinate children was a mistake[63].

Medical professionals have a duty to ensure the care of the patient is their first concern with treatment decisions to be based on the best available evidence, with the balance of benefit and harm duly considered. In light of the evidence presented it is unethical and contrary to Code of Conduct requirements for health professionals to prescribe or administer these provisional drugs to children 6 months old up to 4 years, because recommending these therapeutics does not meet reasonable clinical efficacy and benefit requirements for babies and preschoolers. Parents and Guardians must be fully informed of this evidence to fulfil informed consent obligations[64].

The combined AMPS clinical medical expertise finds these injections are all risk and no benefit for the treatment of the disease known as coronavirus. The evidence presented demonstrates coronavirus poses a statistically nil risk to healthy children, most of whom likely have durable natural immunity. With minimal if any active pharmacovigilance as is required by the TGA for phase 3 clinical trials, the potential real risk of severe adverse reactions poses an evident threat to the health and safety of children in the short, mid and long term.

It is therefore our responsibility to inform parents of the safety and efficacy of these experimental gene-based pharmaceuticals, the benefits (statistically meaningless) and risks involved (extremely high, based upon unprecedented adverse-event reports of deaths and injury from these provisionally-approved drugs, both here and across the world).

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[58] https://www.tga.gov.au/sites/default/files/2022-10/auspar-tozinameran-221012.pdf
[59] https://www.sst.dk/en/english/corona-eng/vaccination-against-covid-19
[60]https://www.krisinformation.se/en/hazards-and-risks/disasters-and-incidents/2020/official-information-on-the-new-coronavirus/vaccination-against-covid-19/when-is-it-my-turn
[61]https://www.fhi.no/en/id/vaccines/coronavirus-immunisation-programme/coronavirus-vaccine/#vaccination-of-children-and-adolescents
[62]https://www.washingtonpost.com/world/uruguay-suspends-covid-vaccination-for-children-under-13/2022/07/07/5fb0b818-fe41-11ec-b39d-71309168014b_story.html
[63] Denmark admits – in retrospect we didn't get much out of vaccinating the children. *Report from a press conference* 27-06-2022.
https://europe-cities.com/2022/06/27/denmark-admits-in-retrospect-we-did-not-get-much-out-of-vaccinating-the-children/
[64]file:///C:/Users/danan/Downloads/Medical-Board---Code---Good-medical-practice-a-code-of-conduct-for-doctors-in-Australia---1-October-2020%20(7).PDF

The Australian Medical Professionals' Society has now provided you with substantial scientific evidence demonstrating unacceptable error in policy. Legislative thresholds for provisional approvals are not being met. We ask three things:

1: a meeting with you at the earliest convenient time;

2: recognition from you that our interest lies wholly in safeguarding the lives of Australian people in accordance with widely accepted codes of conduct and ethical medical principles;

3: a proposal from you within fourteen days regarding your preferences as to how we should disseminate to the Australian medical community the scientific evidence and emerging data about the failure of the investigational products.

Sincerely,

The Australian Medical Professionals' Society
Dr Christopher Neil MBBS FRACP PhD, President