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28 January 2022

Dr Brendan Murphy
Secretary
Department of Health, Canberra

By email: brendan.murphy@health.gov.au
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Dear Secretary,

Covid-19 vaccines for children **Request to cancel provisional registrations** **Request to recall goods**

1. We are a not-for-profit committed to promoting vaccine safety and efficacy, with a membership of over 3,000 concerned Australians, including parents of children at risk of injury and injured by certain provisionally registered goods indicated for prevention of Covid-19 on the Australian Register of Therapeutic Goods, namely:¹
 - (a) Pfizer Australia Pty Ltd – Comirnaty for individuals aged 12 years and over – 22 July 2021;
 - (b) Pfizer Australia Pty Ltd – Comirnaty for individuals aged 5 years and over – 3 December 2021; and
 - (c) Moderna Australia Pty Ltd – Spikevax for individuals aged 12 years and over – 3 September 2021.
2. On behalf of our affected members, we wish to remind you of your ongoing duty to take appropriate action in respect of on-market therapeutic goods, and hereby request that you exercise your discretion under s.30(1)(a) and s.30(2)(a) of the *Therapeutic Goods Act 1989* (**the Act**) to cancel the above registrations on the grounds that:
 - failure to cancel the registration or listing would create an imminent risk of death, serious illness or serious injury; and/ or
 - the quality, safety or efficacy of the goods is unacceptable.

¹ <https://www.tga.gov.au/covid-19-vaccine-provisional-registrations>

3. Further or alternatively, we request that you impose requirements on the sponsors to immediately recall the goods and publish notices in relation to the recall of the goods on the grounds that the safety or efficacy of the goods is unacceptable for paediatric use, pursuant to item 5A(a) of s.30EA(1) and s.30EA(2) of the Act.
4. Numerous deaths, serious illnesses and injuries have and continue to be caused by the goods in Australia and overseas.
 - (a) The clinical trials had adverse safety outcomes. In the context of a highly truncated development process, Pfizer's randomised clinical trial (RCT) six-month follow-up study² reveals increased deaths and illnesses in the treatment group, including 300% more related adverse events (AEs), 75% more severe AEs and 10% more serious AEs than the placebo group. There were 20 deaths in the treatment group compared to 14 in the placebo group, a staggering 43% increase, with an increased risk of at least 30% for cardiovascular deaths in the treatment group. Further follow up was abandoned due to unblinding.³
 - (b) These goods are clearly causing harm. Pfizer's own post-market safety monitoring report⁴ between 1 December 2020 and 28 February 2021 cites 42,086 confirmed reports of 158,893 events, including 1,223 deaths, 11,361 not recovered at time of report, 520 recovered with sequelae and 9,400 unknowns. In 46 cases the reported age was below 16-years-old and in 34 cases below 12-years-old. Amongst the litany of AEs confirmed in all areas of human biology were 1,403 cardiovascular cases with 136 deaths from 946 serious cases. The long-term damage is unknown.^{5,6}
 - (c) The harm is serious in nature. The Australian government acknowledges these goods cause anaphylaxis, myocarditis and pericarditis,⁷ potentially fatal conditions to which younger age groups are particularly susceptible, and so are not recommended for those below the age of 12.⁸ Overall longer term mortality rates for viral myocarditis are over 20%.⁹ There are now over 1,000 peer-reviewed medical papers submitted to various medical journals evidencing a multitude of adverse events in Covid-19 vaccine

² Thomas et al, *Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months*, 4/11/21, *N Engl J Med* 2021; 385:1761-1773

³ Canadian Covid Care Alliance, *The Pfizer Inoculations for Covid-19 – More harm than good*, Jan 21 <https://www.canadiancovidcarealliance.org/media-resources/the-pfizer-inoculations-for-covid-19-more-harm-than-good/>

⁴ Pfizer, *5.3.6 cumulative analysis of post-authorization adverse event reports of pf-07302048 (bnt162b2) received through 28-feb-2021* <https://phmppt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf>

⁵ Høeg, Krug, Stevenson and Mandrola, *SARS-CoV-2 mRNA Vaccination-Associated Myocarditis in Children Ages 12-17: A Stratified National Database Analysis 8 Sep 2021* <https://www.medrxiv.org/content/10.1101/2021.08.30.21262866v1>

⁶ Dionne et al, *Association of Myocarditis With BNT162b2 Messenger RNA COVID-19 Vaccine in a Case Series of Children 10-Aug-2021* <https://jamanetwork.com/journals/jamacardiology/fullarticle/2783052>

⁷ Australian Product Information, Comirnaty (tozinameran) Covid-19 vaccine; [Australian Government, Pfizer Covid-19 vaccine for children aged 5 to 11: information for parents and guardians, version 1, 20/12/21.](#)

⁸ https://www.health.gov.au/sites/default/files/documents/2021/12/covid-19-vaccination-guidance-on-myocarditis-and-pericarditis-after-mrna-covid-19-vaccines_0.pdf

⁹ Grün, S., Schäufele, T., Derin, T. et al. *Long-term follow-up after viral myocarditis established by endomyocardial biopsy: Predictors of mortality.* *J Cardiovasc Magn Reson* 13, M7 (2011). <https://doi.org/10.1186/1532-429X-13-S1-M7>

recipients, including more than 225 on myocarditis alone.¹⁰ Post-mortem histopathological analyses of cardiovascular deaths shows clear evidence of vaccine-induced autoimmune-like pathology in multiple organs.¹¹ The injected gene forces a child's body to make toxic spike proteins, which often cause permanent damage in children's critical organs, their brain and nervous system, heart and blood vessels, including blood clots, reproductive system, and trigger fundamental changes to their immune system.¹²

- (d) The safety signals are loud and clear. Monitoring systems here and overseas consistently reveal more AE reports in one year for Covid vaccines than for all other vaccines on record. The TGA's database shows over 11 times as many death reports in just 8 months than for 76 other vaccines combined over a period of nearly 51 years.¹³ The U.K. data shows increased death rates concomitant with vaccination rates and a rate of myocarditis of 30 per 100,000 doses.¹⁴ The safety signals cannot be dismissed considering that, for instance, some 40% of reported deaths to the U.S. VAERS occur within 9 days of inoculation. Biases in reporting include an underreporting factor of up to 50, bringing the estimate for Covid-19 inoculation-induced deaths for persons over 12 years to more than 425,000 in the U.S. alone. Further, the TGA documentation fails to examine risks associated with the formulation of the Pfizer children's vaccine containing a tromethamine buffer.¹⁵
- (e) The injury reports are amply supported by anecdotal evidence. Numerous testimonies from medical staff and injured individuals confirm and extend the monitoring signals. A recent pro-vaccination social media post by the World Health Organisation reportedly received over 100,000 testimonies to severe AEs.¹⁶ Suspicious incidents such as spikes in sudden death coronaries in professional athletes, temporary school closures and worker absenteeism following inoculations are further signals to be considered.

5. The listed goods are ineffective, particularly for children.

- (a) The mortality risk for children posed by Covid-19 is negligible. In 2020 Covid was only the 38th leading cause of death in Australia.¹⁷ For those under 20 years of age, the

¹⁰ Various, Peer Reviewed Medical Papers Submitted To Various Medical Journals, Evidencing A Multitude Of Adverse Events In Covid-19 Vaccine Recipients, Jan 22, compiled by S Kirsch and J Gillespie <https://www.peopleforsafevaccines.org/resources>

¹¹ Bhakdi and Burkhardt, *On COVID vaccines: why they cannot work, and irrefutable evidence of their causative role in deaths after vaccination*, 15/12/21, <https://doctors4covidethics.org/wp-content/uploads/2021/12/end-covax.pdf>

¹² Dr. Robert Malone, *Statement on child COVID vaccinations*, 15 Dec 21 <https://globalcovids Summit.org/news/live-stream-event-physicians-alerting-parents>

¹³ The Expose, *Australia has recorded 11 times more Deaths in 8 months following Covid-19 Vaccination than it has Deaths following every other Vaccine combined in over 50 years*, 25 Nov 21 https://dailyexpose.uk/2021/11/25/11-times-more-deaths-due-to-covid-vaccine-than-all-other-vaccines-australia/?utm_source=wnd&utm_medium=wnd&utm_campaign=syndicated

¹⁴ UK Health Security Agency, *COVID-19 vaccine surveillance report, Weeks 47 and 50*

<https://www.gov.uk/government/publications/covid-19-vaccine-weekly-surveillance-reports>

¹⁵ US FDA, *Comirnaty and Pfizer-BioNTech COVID-19 Vaccine*, <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine#additional>

¹⁶ <https://www.lifesitenews.com/news/facebook-users-share-vaccine-injury-stories-after-who-tries-to-downplay-jab-dangers-on-social-media2/>

¹⁷ Australian Bureau of Statistics, <https://www.abs.gov.au/statistics/health/causes-death/causes-death-australia/latest-release>

infection survival rate is above 99.99% or 1 in 76,000,¹⁸ nine times lower than annual road deaths. Moreover, Covid-19 mortality overwhelmingly affects only the very old and ill. In Australia, only around 11% of deaths had no associated conditions, the median age being 86.9 years with over a third suffering from existing chronic cardiac conditions.¹⁹ Further, children have strong innate immunity against Covid-19, which presents as a mild illness with non-specific transient symptoms commonly experienced during childhood such as fever, cough, shortness of breath, loss of taste or smell, sore throat, vomiting and/or diarrhoea.

- (b) These goods do not prevent infection, serious illness or death. In adult RCT populations, the efficacy against the alpha variant, in absolute terms, was only 0.88% for Pfizer and 1.25% for Moderna.²⁰ In the Pfizer 5-11 year old study, in an evaluable population of only 2,268, absolute efficacy was less than 2%.²¹ Moreover, a strong correlation exists between increasing cases and rising vaccination levels worldwide, with case numbers in 98 countries tracking from 84 million in 2020 to around 248 million by 1 November 2021.²² Australia's overall Covid-19 death rate has increased from 32.25 pre-vaccine rollout to currently 122.07 deaths per million persons.²³
- (c) Effectiveness diminishes against new variants. UK authorities report a relative reduction in efficacy for Omicron to around 70% following a Pfizer booster.²⁴ Pfizer Chairman Bourla recently conceded two doses provide "limited protection, if any" against Omicron.²⁵ In NSW, 80% of Omicron and 48% of Delta infections occurred in the fully vaccinated with only 2% and 17% respectively in the unvaccinated.²⁶ The lack of durability is underscored by the plan to administer booster shots every 4 months,²⁷ an approach considered unsustainable by the European Medicines Agency chief,²⁸ especially as new variants are proving more infectious and less virulent.
- (d) Reported diagnostic data is of poor quality. PCR technology may detect and amplify a molecule but is incapable of determining infection status; interpretation of results is

¹⁸ Axfors and Ioannidis, *Infection fatality rate of COVID-19 in community-dwelling populations with emphasis on the elderly: An overview*, 23 Dec 21, preprint <https://doi.org/10.1101/2021.07.08.21260210>

¹⁹ Australian Bureau of Statistics, *COVID-19 Mortality*, 28 Oct 21, <https://www.abs.gov.au/articles/covid-19-mortality-1#covid-19-deaths-by-state-of-registration>

²⁰ Fleming, <https://www.flemingmethod.com/vaccine-chasing>

²¹ Walter et al, *Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age*, 6 Jan 22, *N Engl J Med* 2022; 386:35-46

²² Sy W, *Epidemiological impact of Covid-19 fully vaccinated population*, 27/1/22, Principia Scientific International <https://principia-scientific.com/epidemiological-impact-of-covid-19-fully-vaccinated-population/>

²³ <https://ourworldindata.org/covid-deaths>

²⁴ UK Health Security Agency, *SARS-CoV-2 variants of concern and variants under investigation in England, Technical Briefing 33*, 23 December 2021 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1043807/technical-briefing-33.pdf

²⁵ <https://www.news.com.au/technology/science/human-body/pfizer-boss-says-two-doses-provides-limited-protection-if-any-against-omicron/news-story/9d76126d080e2010f05eb0b4ae5e0c45>

²⁶ NSW Health, *Covid-19 weekly surveillance in NSW, epidemiological week 52 ending 1 January 2022*, 13 January 2022 <https://www.health.nsw.gov.au/Infectious/covid-19/Documents/covid-19-surveillance-report-20220113.pdf>

²⁷ <https://www.who.int/news/item/11-01-2022-interim-statement-on-covid-19-vaccines-in-the-context-of-the-circulation-of-the-omicron-sars-cov-2-variant-from-the-who-technical-advisory-group-on-covid-19-vaccine-composition>

²⁸ Statement of Marco Cavaleri, January 2022, <https://www.redvoicemedia.com/2022/01/europes-fda-makes-stunning-admission-on-jab-booster-narrative-big-tech-censors-it-for-big-pharma-videos/>

subjective and depends on a range of variables.²⁹ A lack of standardisation across PCR platforms results in wide variability of key parameters, such as cycle threshold (Ct). For example, the CDC recommends of 28 Ct for the vaccinated³⁰ whereas 35 to 45 Ct may be used for the unvaccinated in Australia,³¹ while Dr Fauci asserts that Ct above 35 is unreliable.³² PCR is highly susceptible to contamination error, but samples are not routinely re-tested. Even assuming an unlikely real-world PCR mean specificity at or below 99.5%,³³ all PCR-positive results in Australia to date are presumptively false.³⁴ Rapid antigen tests are even less reliable.

- (e) Effective alternative treatments are available. Over 1,300 studies show positive clinical outcomes of treatments such as hydroxychloroquine and ivermectin,³⁵ borne out by testimonies of reputable physicians successfully treating thousands of patients. Intervention is rarely necessary for children due to the benign nature of the illness, conferring a far more robust and durable natural immunity than any notional protection derived from these goods.
6. The data plainly show that these goods have not only failed in the prevention of Covid-19 as per their registered indication and their description as ‘vaccines,’ but have no therapeutic benefit in alleviating illness and death and are causing serious side effects. As healthy children never die from Covid-19, these goods cannot save lives but instead only cause great harm.
7. Many eminent scientists and physicians around the world are calling for a stop to mass vaccination on medical and public health grounds. Over 60,000 scientists and medical practitioners have now signed the Great Barrington Declaration in favour of natural herd immunity,³⁶ and more than 10,000 physicians have endorsed the Rome Declaration resolving against mandatory childhood vaccination, citing numerous studies to show negligible clinical risks from infection, indeterminate long term vaccine safety risks, risks of severe adverse events, and the critical need to for healthy children to reach herd immunity.³⁷
8. The foregoing merely touches on the vast and growing body of evidence which compels the cancellation or recall of the goods for paediatric use. Australians rely on the TGA to keep

²⁹ See eg, Bustin et al, *RT-qPCR Diagnostics: The “Drosten” SARS-CoV-2 Assay Paradigm*, Int J Mol Sci 2021 Aug 13;22(16):8702. doi: 10.3390/ijms22168702. <https://pubmed.ncbi.nlm.nih.gov/34445406/>

³⁰ Centers for Disease Control and Prevention, *COVID-19 breakthrough case investigation: information for public health, clinical and reference laboratories*, April 2021 <https://stacks.cdc.gov/view/cdc/105215>

³¹ Public Health Laboratory Network, *Public health laboratory network guidance on nucleic acid test result interpretation for SARS-CoV-2*, version 1.2, 13 July 2020

<https://www.health.gov.au/sites/default/files/documents/2020/07/phln-guidance-on-nucleic-acid-test-result-interpretation-for-sars-cov-2.pdf>

³² <https://www.youtube.com/watch?v=UhmVLUtds3I>

³³ qPCR performs at mean specificities consistently below 99%, see Au and Cheung, *Diagnostic performances of common nucleic acid tests for SARS-CoV-2 in hospitals and clinics: a systematic review and meta-analysis*, Vol 2, Issue 12, E704-E714, 1 Dec 2021 [https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247\(21\)00214-7/fulltext](https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(21)00214-7/fulltext)

³⁴ On a prevalence of 0.4%.

³⁵ See collection of studies at <https://c19early.com/>

³⁶ <https://gbdeclaration.org/>

³⁷ International Alliance of Physicians and Medical Scientists, *Physicians Declaration – Updated, Global Covid Summit*, 29 October 2021 <https://doctorsandscientistsdeclaration.org/>

them safe from, among other things, the predatory practices of greedy and unscrupulous criminal cartels.³⁸ There is simply no need to endanger our children with nostrums.

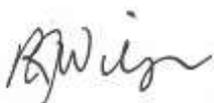
9. Lastly, we draw your attention to recent entries in the TGA's database of cancellations of registered medicines, which include such listings as various over-the-counter skin creams associated with risk of serious skin reactions.³⁹ The TGA's recalls system lists numerous medicinal recalls issued during 2021, including for sunscreen where benzene was detected in 4 batches.⁴⁰ It's plainly obvious that the risks from these cancelled and recalled goods pale into insignificance compared to the widespread harm to children against the absence of benefit conferred by the Pfizer and Moderna goods.

We look forward to your decision at your earliest opportunity, considering the critical importance of this issue to the lives and health of our members and their families.

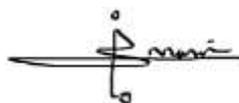
Yours sincerely,
People for Safe Vaccines



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³⁸ Evans, *Tough on Crime? Pfizer and the CIHR*, Health Policy. 2010 May; 5(4): 16–25

<https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC2875889/>

³⁹ <https://www.tga.gov.au/registered-medicines-cancellations-artg>

⁴⁰ <https://apps.tga.gov.au/PROD/SARA/arn-report.aspx>