Australia's erosion of informed consent and the avoidable death of children

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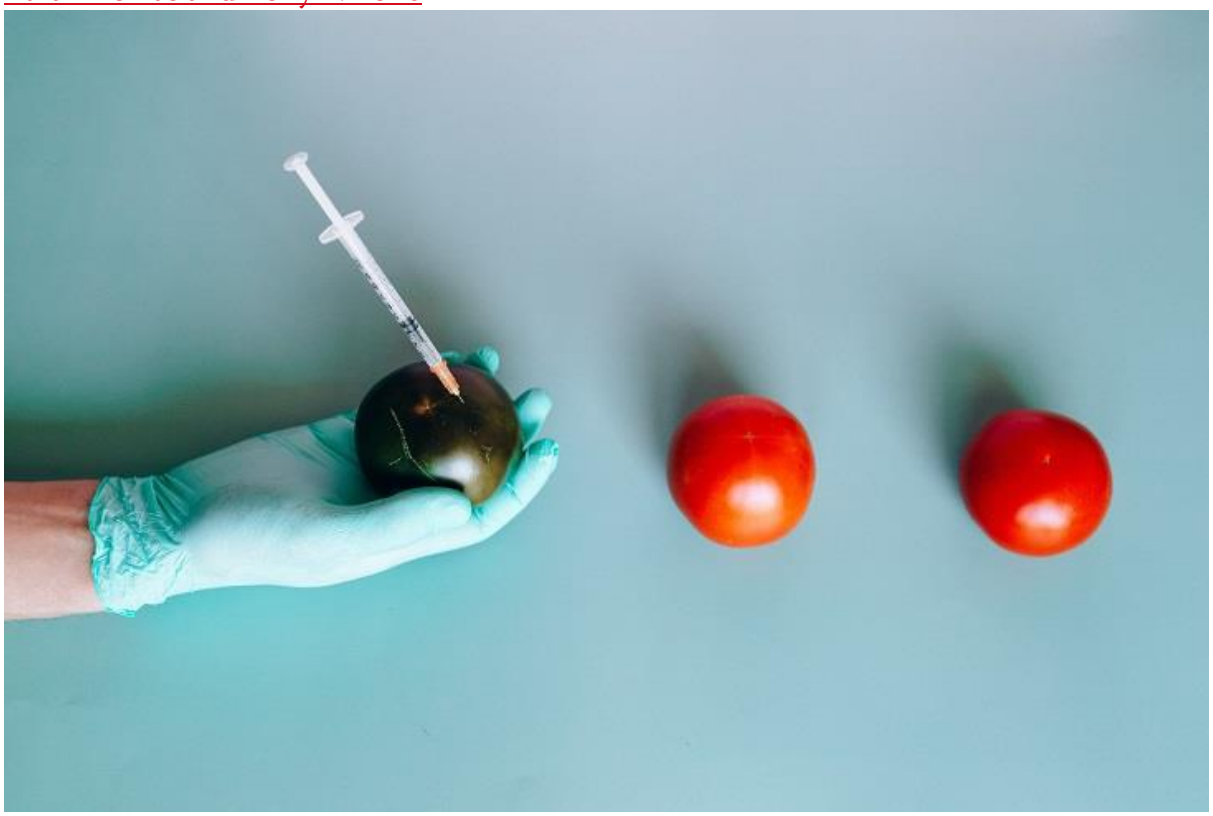

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20 March 2023

Deception can be lethal. The last three years of Covid have taught us that.

Adding to the pile of disconcerting information are revelations from recent Senate Estimate hearings regarding the Therapeutic Goods Administration's (TGA) handling of the deaths of two young children who suffered heart attacks. These sad events have been potentially causally linked to Covid vaccinations.

Which begs the question, have Australian parents, through Department of Health vaccination consent forms, been misinformed into believing these vaccinations are safe and effective and provide more benefit than risk? If so, and the side effects – particularly for young children – outweigh the benefit, could the 'safe and effective' line be perceived as disingenuous?

Such a conclusion would be a revelation so profound that trust in government regulators may be beyond redemption. Can informed consent really be considered valid if regulators do not thoroughly divulge risk?

According to the Australian Government Department of Health immunisation handbook: valid consent is the voluntary agreement by a person to a proposed procedure, which is given after sufficient, appropriate, and reliable information about the procedure, including the potential risks and benefits, has been conveyed.

In this article we argue that Australian parents have potentially been manipulated with unreliable misinformation into consenting to a procedure that the evidence suggests is all risk and no benefit to healthy children.

Authorities deferred to secret health advice to justify mandating these injections to Australia's most vulnerable children, those in care of the state. Yes, they are so confident with their advice that the public is not allowed to see 'the science' behind it.

Those involved supported excluding children from activities to coerce participation using an 'all stick and no carrot' approach, and encouraged parents to inject their children following potentially misleading safety and efficacy claims. Such an approach could be seen as a failure of due diligence.

Vaccine consent forms state, '*for a vaccine to be approved, the TGA must assess that the vaccine is safe, effective and manufactured to a very high quality standard*' however, the government's own reports show there is little-to-no conclusive data to support such claims. It can be argued these experimental gene therapy synthetic lipid nanoparticle messenger RNA vaccines are only provisionally approved, are unnecessary for healthy children, not effective, have questionable mRNA manufacturing integrity, and have not been proved safe.

In our humble opinion, these approvals are a threat to public health and safety and those responsible have demonstrated a wilful and reckless disregard for the wellbeing of our youngest and most vulnerable Australians.

There are no words to describe the pain of losing a child. It hurts to breathe and more importantly, it upsets the natural order where parents are now burying their children. We cannot understand how these injections were approved for healthy children.

It is our opinion that the TGA appears to have failed to evaluate and assess these therapeutics with the health and safety of our children as the priority. What has been revealed through the reported delay of information for these heart-wrenching deaths of precious children and the reported adverse events is an apparent catastrophic failure regarding duty of care. There are questions as to whether the TGA potentially delayed and/or obfuscated information related to showing that adverse events were causally linked to Covid vaccines that resulted in the death of children. Australian parents would likely have been more hesitant had they been fully informed of potential fatal risks.

It seems as though the TGA and Food and Drug Administration (FDA) were in lockstep support of the Dr Eric Rubin 'we're never gonna learn about how safe the vaccine is until we start giving it' model of safety.

In that case, a voting member of the FDA advisory committee replied to the question, 'Based on the totality of scientific evidence available, do the benefits of the Pfizer-BioNTech COVID-10 Vaccine when administered as a 2-dose series outweigh its risks for use in children 5-11years of age?' by stating:

'We're never going to learn about how safe the vaccine is until we start giving it. That's just the way it goes.'

It is unlikely that Australian parents feel the same way about their children 'testing' the safety of mRNA vaccines.

The TGA and the Advisory Committee on Vaccines (ACV) knew, or ought to have known from their own reports, that these provisional injections were all risk and no benefit to healthy children. The information provided to parents on these consent forms is not exactly reliable or truthful.

To understand the sheer magnitude of what could be argued is such a profound level of reckless indifference to human life and criminal negligence leading to death, one only needs to review the TGA's Australian Public Assessment reports (AusPAR) for the provisional approval of Pfizer for the 5-11 roll-out and the Moderna 6 months and up. After this brief comparison of the information found on the AusPAR's with the information provided to parents on the consent forms the public can decide for themselves if the information is accurate for informed consent or misleading deception.
These vaccines are not approved as stated on the consent forms; they are *provisionally approved*. Provisional, by definition, means

experimental because they lack sufficient safety data. The Provisional Approval Pathway is an expedited pathway based on preliminary data with manufacturers provided six years to supply the government with safety and efficacy data. Claiming they are approved is not truthful, reliable information as is required for informed consent.

Parents may also be interested to note in July 2021 the Therapeutic Goods Regulation Act was amended to reduce the safety and efficacy requirements for any medicine that is for the treatment or prevention of Covid. Not only do manufacturers have six years to provide the government with safety and efficacy data on these provisionally approved injections, but they also no longer have to demonstrate they could provide a greater benefit than other available medicines or that the medicine is likely to provide a major therapeutic advance. The only requirement is to claim Covid is a life-threatening or seriously debilitating condition. It is shown below that for most children Covid is neither life-threatening nor does it result in a seriously debilitating condition.

Nowhere on the Pfizer consent form for age 5-11, or the Moderna 6 months to 5 years, is it stated these gene therapy vaccines are experimental lipid nanoparticle synthetic messenger RNA technology never before used for vaccines. Nowhere does it say this technology turns a child's body into a spike protein manufacturing plant.

Nowhere does it say that the TGA is unaware of some of the contents of these injections because they remain commercial in confidence.

Nowhere on these forms does it state these vaccines are part of the black triangle scheme which is supposed to be a reminder to people to report any adverse events related to these new medicines.

If parents knew this, would they give consent?

Before even considering the safety and efficacy of these provisionally-approved vaccines it must be understood that healthy children have a statistically nil infection fatality risk from Covid. The TGA AusPAR report from December 2021 and the Australian Technical Advisory Group on Immunisation (ATAGI) in February 2022 advised that, '…most children who get COVID-19 have mild symptoms or no symptoms at all. Children with some underlying medical conditions might be at higher risk of severe illness, but very few with COVID-19 get sick enough to need hospitalisation. Fatal outcomes in children are very rare.'

This conclusion is supported by the Paediatric SARS-CoV-2 serosurvey 2022, Australia Summary report from November 2022 that found, 'most children and adolescents in Australia have been infected with the virus that causes COVID-19', noting that high rates of infection in unvaccinated preschool aged children has not been accompanied by a high rate of hospitalisation.

A letter recently published by the Australian Medical Professionals Society (AMPS) sent to the Department of Health in response to the extension of provisional approvals of these injections to 6-month-old babies and pre-schoolers outlined substantial evidence showing Covid poses a statistically zero infection fatality risk.

A statistically zero infection fatality risk for healthy babies and children means that it could be argued that these Covid vaccinations do not appear to meet the legislative threshold for extension of provisional approval. To grant approval to make an experimental therapeutic available under the new 2018 provisional approval pathway there must be evidence the condition is serious and life-threatening. The government's reports and the AMPS heavily-referenced letter show Covid is not serious or life-threatening to healthy children.

Claims made on the consent forms that the vaccines reduce transmission to older family members who are at higher risk from Covid are baseless. The AusPAR confirms that protection against asymptomatic infection and the effect on viral transmission offered by the vaccine in children is not known.

In fact, according to an FDA news release from December 2020, 'At this time, data are not available to make a determination about how long the vaccine will provide protection, nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 from person to person.'

There is no evidence to support the claim made to parents that vaccination reduces or slows the spread. Even if there were evidence they reduced transmission, any society that advocates experimental therapeutics in children who don't need them as shields to potentially protect adults is counter-intuitive having regard to the evidence that there has never been any evidence that the injections stop transmission, hospitalisations, or deaths.

If Australian parents had been provided with reliable information about the lack of evidence these injections reduced transmission would they have consented? Indeed, the suppression of information, denigration, and censorship by key Australian institutions potentially acting as 'gatekeepers' of misinformation has compounded access to reliable objective scientific data. For the avoidance of doubt, we use the term 'objective scientific' data purposefully.

The consent form for Pfizer claims the vaccine is effective in preventing Covid. The Moderna consent form claims the vaccine provided some protection against infection with the Omicron variant. The roll-out for the 5-11-year-olds began on January 10. On January 11 it was reported the CEO of Pfizer said, 'The first two doses provide

limited if any protection against omicron.' Omicron was the circulating variant at the time. Further, unlike the consent form claims, both TGA and AusPAR reports state there are no data provided by the sponsor regarding vaccine efficacy against new variants such as Omicron. The reports also state the duration of immune persistence is not known, because of the short follow-up period. The Moderna AusPAR suggests that while it is 'likely' to prevent severe disease there are no clinical data on severe disease endpoints.
It is also worth noting that the Moderna vaccine efficacy was less than 50 per cent and this does not meet the FDA guidelines. Interestingly, both AusPARs use immunogenicity as the primary endpoint for assessing efficacy even though the US FDA states, '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.'

Nowhere on the consent forms does it say these experimental injections are assessed using inappropriate primary endpoints. Nowhere does it say they were not tested for transmission and have poor efficacy of unknown duration against a variant the CEO says they provide limited, if any protection against. Efficacy claims made to parents on the consent forms appear unscientific, being unreliable and inconsistent with valid consent requirements. Would parents be rightly hesitant had they been provided with appropriate AusPAR information on the consent forms?

Obviously, the vaccines are not particularly effective, but are they safe?

Safety is imperative in determining the risks versus benefits required for valid informed consent. The Department of Health consent forms claim the vaccine is safe and most side effects are mild with no specific

safety concerns identified. Both consent forms claim it is safe in children who are immunocompromised. Does the evidence in the AusPARs support these claims?

The AusPAR stated that there were no genotoxicity studies, the safety sample was small, there was missing information on longer-term safety including adverse events of special interest, and there was a lack of safety data for immunocompromised children. The Moderna AusPAR, while recommending the vaccines to high-risk immunocompromised children, indicates that high-risk and immunocompromised children were excluded from the study. The lack of safety data was also outlined in the Feb 2021 European Medicine Agency Assessment Report that showed there were no toxicology data on genotoxicity and carcinogenicity, and also no human reproductive testing. The TGA should also have been aware of the Pfizer 5.3.6 cumulative analysis of post-authorisation adverse event reports that the FDA wanted hidden for 75 years. The report showed within the first 90 days of administration there were 1,223 reported deaths and nine pages of around 1,200-odd adverse events of special interest.

The claim made on the consent form of 'no specific safety concerns' must have been based on the fact that there are in effect no short-term data and a complete absence of any mid or long-term data because the safety follow-up lasted a median of 2.4 months. Australian parents might be angered by being denied the basic level of objective scientific information. The government's reports, if anyone bothered to read them, demonstrate they knew or ought to have known using due skill, care, and diligence these injections have not been proved safe or effective for babies and children.

A preprint review of Australia's all-cause mortality data by Wilson Sy, using the Bradford-Hill criteria, demonstrates a causal link with the Covid vaccination roll-out. We appear to be experiencing what he calls an iatrogenic pandemic, promoted by Greg Hunt as the world's largest clinical trial. 'The fact that the youngest 0-44 age group with lowest risks of Covid infection and death has suffered disproportionately the highest multiples of excess mortality with the advent of Covid injections…' This should suggest to medical and political authorities that these vaccines are all risk and no benefit to healthy children.

Australian parents have a right under valid informed-consent provisions to be told that according to government reports Covid injections appear all risk and next-to-no benefit. These experimental therapeutics don't work as represented by key medical figures, universities, political figures, health ministers, and bureaucrats, and have serious known and unknown safety issues, including death, for a disease healthy children are statistically at no risk from.

Instead of telling the whole truth it looks like our government regulators and politicians told parents these injections were safe and effective and have withheld serious adverse events leading to death so parents didn't lose confidence in the government and become vaccine-hesitant. They appear to have engaged in a strategic campaign of militarised misinformation by using half-truths, omissions, and suppression of information.

Could this be described as a deception of monstrous proportions demonstrating what can only be described as a wilful disregard for the welfare of Australian babies and children? Surely such a campaign cannot exist in a vacuum? If it were to exist, it must be supported by the vassals of government and its key institutions supporting the government policy to have the desired effect.

If these findings are accurate then there must be accountability and justice for this deceit that has gone beyond incompetence into the realm of malfeasance. Bureaucrats, politicians, directors of departments who oversaw the mandating of the largest vaccination trial ever, undermining human rights and the constitution, should have made sure they read their own government reports. Offers to allow independent medical and scientific professionals have been denied at every step of the process. Once a normal part of the participatory democratic model of governance, objectivity and transparency was squashed using censorship, fear and enforcement techniques of the scientific community by intelligence and policing agencies resembling that of paramilitary junta's.

Governments look like they have prioritised creating public confidence in the messaging inspired by big pharma and designed to reduce vaccine hesitancy regardless of the human cost.

Australian parents were told these vaccines were approved, safe, and effective by the Department of Health Covid-19 vaccination consent forms in apparent contradiction to their own TGA reports. They were told there have been no deaths in children when withheld FOI documents show there have been. It is obvious from the TGA AusPAR information outlined above, claims made on consent forms are at best misleading and possibly could be construed as deceptive. Children died following the approval of experimental vaccines they didn't need, that are neither safe nor effective in a risk stratified age group with almost zero chance of serious disease or death. Authorities knew or ought to have known using due, skill, and diligence from their own reports that these injections were and remain more risk no benefit in healthy children. Parents had a right to know.

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