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Public Governance, Performance and Accountability Amendment (Vaccine Indemnity) Bill 2023

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Introduction

Reasons and evidence showing the reasons to support the Public Governance, Performance and Accountability Amendment (Vaccine Indemnity) Bill 2023

The Australian Medical Professionals' Society (AMPS) comprises a collective of medical and allied health experts united by a core mission: safeguarding and advancing the interests of our members and their patients, while advocating optimal health outcomes across Australia. We deeply cherish the tenets of medical ethics, prioritising patient well-being and community welfare. As staunch proponents of these values, AMPS enthusiastically embraces the chance to offer input to the Senate select committee on the Public Governance, Performance and Accountability Amendment (Vaccine Indemnity) Bill 2023. We believe that the issues raised in this bill are vital to the welfare and safety of the Australian public, and they warrant careful consideration by our legislative bodies.

In a world reshaped by the COVID-19 pandemic, the values of trust, transparency and accountability have emerged as pillars upon which public health and safety must stand.

This submission delves into a multifaceted examination of vital themes encompassing the intricate landscape of public health, pharmaceuticals and regulatory frameworks when governments consider providing blanket liability contracts to pharmaceutical companies engaged to produce prophylactic COVID-19 vaccines.

First, we explore the intricate web of incentives that bind pharmaceutical companies to governmental bodies through indemnification agreements, and the ethical concerns that arise when profit motives intersect with public health priorities. We will also delve into the role of regulatory oversight in ensuring that the safety and efficacy of provisionally approved therapeutics meet the highest standards.

Additionally, this submission will shed light on the crucial realm of pharmacovigilance, emphasising the importance of identifying safety signals and the potential consequences of underreporting adverse events. Furthermore, we will scrutinise the development of COVID-19 vaccines, dissecting the scientific and regulatory complexities intertwined with these groundbreaking technologies.

Lastly, we will turn our attention to the shadows cast by unquantifiable contingent liabilities and the fiscal implications they bear. As these liabilities loom large, they raise questions about the legitimacy of contracts and broader ramifications for public health, financial accountability, and the future of regulatory frameworks.

Throughout this submission, we discuss the complex issues that must be considered when governments contemplate indemnifying companies from adverse outcomes from the products they manufacture to ensure a safer, healthier, and more transparent public health system.

Trust, Transparency and Accountability

When governments contemplate indemnifying large multinational corporations against any liability stemming from compulsory administration of provisionally-approved therapeutic vaccines, they must exercise the utmost caution. The preservation of trust in government. medicine and public health hinges on transparency and accountability.

To safeguard against irreparable damage to public trust it is imperative that governments facilitate open discussions and actively engage with the public when considering the imposition of vaccine mandates. Transparency and inclusivity in decision-making processes are essential for maintaining trust. Governments should also steadfastly uphold stringent regulatory standards,

encompassing rigorous manufacturing practices that guarantee the quality and safety of vaccines. This unwavering commitment ensures that public health remains the paramount concern. Furthermore, a proactive pharmacovigilance system must be implemented to swiftly detect and address safety signals. Early identification of adverse events is pivotal for safeguarding the health and safety of the Australian populace.

Trust cannot be maintained in an atmosphere of secrecy. The secrecy surrounding contracts, health advice, vaccine contents 'commercial in confidence', and clinical trial analyses has fomented suspicion. Governments must dispel this mistrust by embracing transparency and openness in their actions and decisions. Our government should critically evaluate demands for indemnification from vested interests. The paramount concern should always be the welfare of the people, rather than acquiescing to these demands. Unfortunately, there was no conclusive evidence that these experimental products were 'safe and effective' and 'prevented transmission and serious illness'. All data surrounding the manufacturing, safety and efficacy of these products were cloaked in secrecy, lacking even minimal transparency until June 2022[1].

Serious concerns have been raised about the safety and efficacy of the warp speed nature of the COVID-19 vaccines by health professionals globally. A non-profit alliance of over 80 public health officers and medical researchers called the Public Health and Medical Professionals for Transparency (PHMPT) filed a FOIA lawsuit in the US District Court, Fort Worth, Texas in September 2021 to obtain and disseminate the original clinical trial data upon which the FDA relied when it licensed Pfizer's (Comirnaty) COVID-19 mRNA vaccine. To quote Dr Aaron Kheriaty, one of the US physicians leading this court filing, "A group of us were concerned about the trial design, the shortened duration of the clinical trial, and the patchwork system that was in place for the post-marketing surveillance of adverse events."[2]

Rebuilding trust in public health necessitates a bedrock of truth and transparency. Australians must have unwavering confidence in the safety and efficacy of government-recommended products. Furthermore, citizens should trust that if they experience adverse events, they will receive prompt and equitable care and compensation. Indemnifying companies for all accountability undermines trust.

Recommendation: AMPS supports this bill as it addresses fundamental issues of transparency and accountability in government contracts, particularly those related to vaccine indemnification. Transparent government actions are crucial in maintaining public trust, especially when public health is at stake.

Incentives for Safety and Ethical Concerns resulting from Indemnification

The bill highlights the issue of indemnification creating an incentive for risk-taking in the pharmaceutical industry, which may not be aligned with the fundamental principles of ethical evidence-based medicine. It raises concerns about the balance between profit motives and public health objectives. People's health and safety should always take precedence over profits.

The rapid development of COVID-19 vaccines was a response to a perceived pressing public health crisis, resulting in their administration to billions of people across the globe. Moreover, these vaccines have yielded extraordinary profits, with pharmaceutical companies, notably Pfizer, reaping at least $100 billion. Has this financial success catalysed a transformation in the standards of scientific and corporate transparency and accountability?

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[1] https://www.preprints.org/manuscript/202309.0131/v1
[2] https://www.preprints.org/manuscript/202309.0131/v1

It is imperative that during public health crises such as pandemics, there is a need to strike a balance between the urgent development and distribution of vaccines and other therapeutics and the ethical considerations surrounding safety and efficacy. This balance requires careful negotiation in contractual arrangements.

Governments have allocated billions of taxpayer dollars to procure an abundance of COVID-19 vaccine doses, providing each Australian with multiple shots of what now appears to be one of the least effective treatments we have ever encountered in our professional experience. Regrettably, they have chosen not to divulge the specifics of their contracts with vaccine manufacturers.

The public is well-informed about the history of corporate pharmaceutical wrongdoing, which has resulted in substantial criminal and civil settlements, including cases involving Pfizer. This often stemmed from questionable marketing practices and the misrepresentation of medication safety and efficacy. Pfizer and the FDA actually asked the government to provide them with a buffer of 75 years before fully disclosing internal documents and communications related to the regulatory process. This complete absence of transparency undermines public trust and reduces the capacity of scientific review to protect the public from potentially undisclosed or missed safety and efficacy issues.

In September 2021, an FDA advisory committee voted 16–2 against boosting healthy young adults in the USA. However, this decision was overridden by the White House and CDC, leading to the resignation of two senior FDA vaccine experts. These actions have heightened concerns that regulatory agencies may be unduly influenced by the industry and may overlook higher-than-usual adverse effect ratios in an effort to manage the pandemic[3].

Medical and political authorities must recognize that within the realm of 'The Science' we may be witnessing a battle between the pursuit of truth and financial interests. Dr Maria Angell, long-time editor-in-chief of the *NEJM* resigned more than 20 years ago after 20 years as editor because of what she described as the rising influence of the pharmaceutical industry. She said in her book, *The Truth about Drug Companies: How they deceive us and what to do about it*, 'Now primarily a marketing machine to sell drugs of dubious benefit, big pharma uses its wealth and power to co-opt every institution that might stand in its way, including the US congress, the FDA, academic medical centres and the medical profession itself.[4]' Health crises and blanket liability are quite the business model for big pharma.

Furthermore, there are apprehensions about the lack of due process in compensation claims for vaccine injuries resulting from COVID-19 vaccines. It is noteworthy that these claims are to be borne by governments rather than pharmaceutical companies.

Recommendation: AMPS endorses this bill because of its aim to restrict financial indemnities that the Commonwealth offers in connection with vaccine use. This approach is in the Australian public's best interest since it guarantees that pharmaceutical companies, which profit from vaccine sales, bear the financial responsibility of any adverse outcomes.

Role of Regulatory Oversight for Provisional Therapeutics: Pharmacovigilance and safety signals

No provisional therapeutic agent, such as drugs, can be deemed "safe," particularly in the absence of conclusive evidence and without providing open access to patient-level data for independent scrutiny. This is very important as numerous clinical trials encounter failures through

[3] https://gh.bmj.com/content/7/5/e008684
[4] https://www.spectator.com.au/2023/08/when-science-becomes-a-threat-to-population-health/

issues related to efficacy, safety concerns, or a combination of both. In some cases, phase 3 trials may achieve the primary endpoint but subsequently discover worsened mortality rates, as exemplified by evolocumab and fibrates[5]. A review of the Pfizer's pivotal mRNA trial in adults did not show any statistically significant reduction in all-cause mortality, and in absolute terms there were actually slightly more deaths in the treatment arm versus in the placebo.[6] Consequently, enhanced pharmacovigilance will be imperative for monitoring these new drugs.[7]

Robust regulatory oversight is indispensable to ensure that vaccines adhere to stringent safety and efficacy standards, especially when governments mandate COVID-19 vaccination as a prerequisite for employment and full participation in society. It is noteworthy that these vaccines lacked any evidence to substantiate their ability to prevent infection or transmission of the virus. Furthermore, they have been associated with the highest incidence of severe adverse events and fatalities, as reported in multiple vaccine passive adverse-event monitoring systems, including the Database of Adverse Event Notification (DAEN), the UK yellow card system, and the Vaccine Adverse Event Reporting System (VAERS) of the US Centers for Disease Control (CDC)[8].

Substantial public apprehensions regarding safety signals and pharmacovigilance have been amplified by the limited transparency surrounding COVID-19 clinical trial data. Additionally, the evolving information on adverse effects, including incidents of blood clotting,[9] myocarditis,[10] and altered menstrual cycles,[11] has contributed to these concerns. These alterations have been linked to changes in vaccination recommendations concerning eligibility for specific vaccines in some nations.

The potential for cognitive dissonance may have been exacerbated by shifting justifications provided for vaccine mandate policies. Initially, these policies centred on achieving herd immunity to halt viral transmission and conveyed the message that vaccinated people could not contract or transmit COVID-19. However, these policies often lacked clear communication, substantiation and transparency. Consequently, this has fuelled continuing uncertainties and public doubts about the reasoning and proportionality behind such mandates.[12]

Safety concerns and potential safety indicators should take precedence when circumventing the conventional premarket approval process and transitioning the drug development experimentation phase into real-world settings. During provisional approval, COVID-19 vaccines were employed in clinical practice before their relative safety and effectiveness were fully understood, lacking the rigorous monitoring and safeguards inherent in clinical trials.[13] This underscores the importance of implementing well-managed active safety systems, as advised by the government Stokes report.[14]

While sponsors are legally obligated to report all adverse outcomes they become aware of, there is no requirement for them to actively seek out adverse events. Given that reporting by clinicians will continue to be voluntary, it is probable that there will be substantial underreporting of adverse reactions to provisionally approved drugs. Ensuring patient protection is paramount, particularly when drugs are being utilised in an experimental capacity, as has been evident in the rollout of the COVID-19 vaccine.

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5 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5895470/

6 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9557944/

7 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5895470/

8 Openvaers.com (last visited 28 June 2023)

9 *Nature* 2021;592:495–6.doi:10.1038/d41586-021-00998-wpmid:http://www.ncbi.nlm.nih.gov/pubmed/33864049

10 *BMJ* 2021;374:n2251.doi:10.1136/bmj.n2251pmid:http://www.ncbi.nlm.nih.gov/pubmed/34521646

11 *BMJ* 2021;374:n2211.doi:10.1136/bmj.n2211pmid:http://www.ncbi.nlm.nih.gov/pubmed/34526310

12 European Journal of Risk Regulation 2021;12:308–20.doi:10.1017/err.2021.36

13 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5895470/

14 https://www.health.wa.gov.au/~/media/Files/Corporate/Reports-and-publications/PDF/Stokes_Report.pdf

Any indemnified provisional vaccine should be part of the Black Triangle scheme. The scheme is designed to improve the rate of reporting by reminding health professionals and consumers to report suspected adverse events related to new medicines, or those being used in new ways. Products included in the scheme feature the black triangle symbol and accompanying text on[15]:

- Product Information (PI) documents
- Consumer Medicines Information (CMI) documents
- other TGA material and literature such as Australian Public Assessment Reports for prescription medicines (AusPARs).

Interestingly, nowhere on the COVID-19 vaccines consent forms we reviewed 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.[16]

The importance of reporting adverse events and vigilant safety monitoring becomes even more pronounced when legislative amendments to the Therapeutic Goods Regulation Act relax safety and efficacy requirements for any medicine intended for the treatment or prevention of COVID. As of July 2021, not only do manufacturers have a six-year window to provide the government with safety and efficacy data for these provisionally-approved treatments, but they are also no longer obliged to demonstrate that their medicine offers a greater benefit than other available treatments, or represents a significant therapeutic advancement.[17] It is worth noting that these changes were implemented shortly before the introduction of mandates.

Pharmacovigilance encompasses the scientific and operational aspects involved in identifying, evaluating, comprehending, and mitigating adverse effects and any other issues associated with pharmaceutical products. Post-marketing pharmacovigilance is indispensable because adverse events frequently emerge only after a drug is in clinical use. Pre-market clinical trials are constrained by their brief duration and relatively small sample sizes.[18]

The WHO says: a safety signal refers to information on a new or known side effect that may be caused by a medicine and is typically generated from more than a single report of a suspected side effect.[19]

Closely scrutinised safety reporting systems are of critical importance to ensure the benefits of any therapeutic outweigh the risks and any safety signals are identified quickly to protect the public. As it is now understood: ‘Adverse drug reactions (ADRs) are estimated to be between the fourth and sixth most common cause of death worldwide, taking their place among other prevalent causes of mortality such as heart disease, cancer, and stroke’.[20] The consequences of thalidomide and Vioxx are two well-known examples of regulatory failure and pharma coverup that cost lives.

Any indemnification must come with the recognition that adverse events signalling potential safety issues are frequently grossly underreported through passive voluntary reporting systems. The limitations of Australian adverse event reporting are noteworthy. In the United Kingdom, it is believed that reported cases likely represent less than 10% of the true number of events. In fact, a

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[15] https://www.tga.gov.au/how-we-regulate/monitoring-safety-and-shortages/report-adverse-event-or-incident/report-adverse-events-medicines-and-biologicals/black-triangle-scheme#:~:text=The%20black%20triangle%20reminds%20health,Product%20Information%20(PI)%20documents

[16] https://www.spectator.com.au/2023/03/australias-erosion-of-informed-consent-and-the-avoidable-death-of-children/

[17] http://classic.austlii.edu.au/au/legis/cth/consol_reg/tgr1990300/s10l.html

[18] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5895470/

[19] https://who-umc.org/signal-work/what-is-a-signal/

[20] https://pubmed.ncbi.nlm.nih.gov/35951160/#:~:text=Adverse%20drug%20reactions%20(ADRs)%20are,disease%2C%20cancer%2C%20and%20stroke.

comprehensive review of 37 studies conducted across 12 countries indicated a median underreporting rate of 94%.[21]

Upon reevaluating the risk of severe adverse drug events observed in the Pfizer and Moderna clinical trials for their COVID vaccines, it became apparent that approximately 1 in 800 people faced the possibility of encountering a serious adverse event.[22] This signifies a 16% higher risk of serious adverse events compared to those who received a placebo, which far exceeds the usual incidence of 1-2 serious adverse events per million reported for vaccines in general.[23]

There are additional indicators suggesting that our systems for reporting adverse drug events may be substantially underreporting the actual occurrence of adverse reactions, disabilities and fatalities linked to COVID vaccines. Life insurance companies globally have been documenting an unprecedented surge in unexpected deaths, indicating that these are not merely statistical anomalies. For instance, Lincoln National, one of the largest insurance companies in the United States, has recorded a staggering 153% rise in life insurance claims in 2021.[24]

It is becoming increasingly evident that we cannot solely depend on the diverse adverse drug-reaction reporting systems to provide a complete and accurate assessment of the safety of COVID vaccines. There may also be concerns related to a potential conflict of interest between the TGA's role in drug regulatory approval and its role in assessing adverse drug reactions linked to these approved drugs. Notably, the TGA derives 96% of its funding from the pharmaceutical companies it is required to oversee.[25]

Recommendation: AMPS believe the passage of this bill could greatly improve public protection against potential unscrupulous marketing tactics from sponsors and poor pharmacovigilance systems. Additionally, to ensure effective regulatory oversight, regulatory agencies should be sufficiently funded, maintain independence, and possess the authority to conduct comprehensive assessments and investigations. Safety signals must be immediately investigated and therapeutics suspended pending a full investigation with access to individual-level patient data from clinical trials.

Vaccines: Development of mRNA Vaccines: Scientific and regulatory issues

In accordance with the principles of public health ethics, the concept of proportionality dictates that any public health intervention should anticipate benefits that outweigh the constraints on individual liberties and the associated burdens.[26] It would be inconsistent with this principle to impose substantial restrictions on personal freedoms (and or inflict harm) in exchange for negligible public health advantages, especially when alternative measures are accessible. The available evidence indicates that the effectiveness of current COVID-19 vaccines in curbing transmission is restricted and temporary.[27] Indemnifying manufacturers against false claims about safety and efficacy does not build public trust in government public health policies.

Our comprehension of the available COVID-19 vaccine mechanisms of action and their long-term performance, particularly in terms of safety and efficacy, still contains gaps. Yet the government indemnified huge multinational pharmaceutical corporations for all liability from novel therapeutics with minimal short-term data and zero long-term data. These novel platforms do require

[21] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5895470/
[22] https://doi.org/10.1016/j.vaccine.2022.08.036
[23] www.hhs.gov/immunization/basics/safety/side-effects/index.html
[24] https://crossroadsreport.substack.com/p/breaking-fifth-largest-life-insurance?utm_source=substack&utm_medium=email
[25] https://www.bmj.com/content/377/bmj.o1538
[26] *Public Health Ethics* 2021;383:phab028.doi:10.1093/phe/phab028
[27] https://gh.bmj.com/content/7/5/e008684#ref-32

additional regulatory considerations as well as many aspects that mirror those applicable to conventional vaccines, including the quality of initial materials, manufacturing consistency, and the need for comprehensive evidence of safety and efficacy obtained from pre-clinical studies, clinical trials, and post-marketing surveillance. Recent reviews have covered regulatory aspects concerning manufacturing, quality control and safety in the context of mRNA vaccines.[28]

One notable concern pertains to the potential risk of RNA and DNA integration into human DNA. Recent findings by Kevin McKernan showing Pfizer batch contamination by DNA plasmids are alarming. McKernan's findings[29] were replicated by Professor Phillip Buckhaults, Professor of Cancer Molecular Genetics, who presented evidence of the contamination to a recent South Carolina Senate hearing.[30] Professor Buckhaults says this synthetic DNA can and likely will integrate into the genomes of transfected cells. Buckhaults, who has a PhD in biochemistry and molecular biology, said 'there is a very real hazard' that these fragments of foreign DNA can insert themselves into a person's own genome and become a 'permanent fixture of the cell.' He said it is a plausible mechanism for what might be 'causing some of the rare but serious side effects like death from cardiac arrest' in people following mRNA vaccination.

Given our Department of Health emphatically state 'No, COVID-19 vaccines do not alter your DNA',[31] AMPS would be interested to know exactly what testing has shown conclusively the absence of this potential risk. Have any vaccinated people been tested for genomic integration?

TGA testing for the presence of DNA plasmids and endotoxins is critical with the knowledge that the manufacturing 'process 1' used during the Pfizer clinical trials 'clinical batches' was different to the manufacturing 'process 2' used for the large-scale production of these provisionally-approved, emergency-use authorisation vaccines. In fact, evidence shows there were no clinical trial data available on the process 2 manufactured vaccines given to the global population. Such a lack of testing of the e coli derived RNA-transcribed synthetic mRNA lipid nanoparticle batches that contain chopped up DNA plasmids could pose a serious threat to population health.[32] A letter to the editor published in the *BMJ* by Professor Guetzkow stated:

> Calls for more transparency in COVID-19 vaccine trials are particularly relevant for data on the manufacturing process….Evidence from existing research and trial documents highlights the importance of publicly disclosing the analysis comparing reactogenicity and safety process 1 and 2 batches as specified in the trial protocol, and more generally patient-level batch and lot data from the trial.

According to Professor Buckhaults, chopping the DNA into tiny pieces indicates awareness of their presence and a failure of purification, yet the manufacturers are indemnified against any adverse outcomes such a failure may pose to Australian lives and future generations.

Furthermore, as we have raised in a previous submission, The Emergency Use Authorisation (EUA) of the Pfizer-BioNTech Covid-19 Vaccine/BNT 162b2 was granted on the efficacy data of 170 patients.[33] The TGA should have been concerned that major disqualifying protocol deviations were identified in the 170 patients upon which the EUA was granted. These protocol deviations raise serious concerns about the legitimacy of the clinical trial and the scientific norms and ethical principles upon which good medical practice is founded. Pfizer gained provisional approval for their

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[28] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7910833/
[29] https://osf.io/b9t7m/
[30] https://www.youtube.com/watch?v=IEWHhrHiiTY
[31] https://www.health.gov.au/our-work/covid-19-vaccines/is-it-true/is-it-true-can-covid-19-vaccines-alter-my-dna
[32] https://www.bmj.com/content/378/bmj.o1731
[33] https://dailyclout.io/report-41-the-170-clinical-trial-participants-who-changed-the-world-pfizer-ignored-protocol-deviations-to-obtain-emergency-use-authorization-for-its-covid-19-mrna-vaccine/

COVID-19 injection following a mere two-month trial, claiming 95% efficacy for the prevention of coronavirus disease.[34, 35]

Transparent evidence-based communication of risk and benefit, the absence of individual patient-level data especially in relation to process two manufactured mRNA vaccines, and the total lack of long-term data of these therapeutics combine to make a critical ethical imperative for valid informed consent.

Recommendation: The poor manufacturing practice and lack of clinical data on process two batches raise serious concerns about the safety of these products. Indemnification reduces the incentive to ensure products are safe. AMPS supports this bill as it puts liability and accountability for the safety of manufactured therapeutic products where it should be on the producer and not the patient.

Unquantifiable Contingent Liabilities

The federal budget papers for 2023-24 have raised concerns about unquantifiable contingent liabilities related to vaccine indemnity. The potential liabilities stemming from indemnification agreements for COVID-19 vaccines, smallpox and monkeypox vaccines, and influenza vaccines pose financial risks that must be addressed. How much risk must the Australian people carry both personally and economically so hugely profitable pharmaceutical giants can relinquish all responsibility for safety and keep all the profit?

Not only do we have concerns about how liability transfer to the taxpayer will affect the safety and efficacy of products but we also have questions about the legitimacy of the contracts, given recent statements by the Hon Senator Katy Gallagher, Minister for Finance, in relation to the signing of the COVID-19 vaccine contracts. Senator Gallagher stated that the signing of Covid-19 vaccine contracts with generous indemnity clauses "…would have occurred at the Public Service level".[36]

Occurring "at the public service level" does raise questions worthy of investigation as the process for granting indemnities to pharmaceutical companies under Sections 60 and 110 of the *PGPA Act* enables the Finance Minister, or their delegate, to grant indemnities on behalf of the Commonwealth. However, when granting indemnification, as stated by the Department of Finance, the written delegation from the Finance Minister requires that an official who is delegated the power to enter indemnities must consider two overarching principles[37]:

- that risks should be borne by the party best placed to manage them and
- benefits to the Commonwealth should outweigh the risks involved.[38]

Considering our brief overview of some of the safety, efficacy and manufacturing practice concerns above it is highly debatable whether the benefits outweigh the risks to the Commonwealth. A 1 in 800 serious side-effect risk is likely to pose extensive financial burdens through the no-fault COVID-19 indemnity scheme.

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

[35] Deplanque & Launay, Efficacy of COVID-19 vaccines: From clinical trials to real life, Therapies, published July-August 2021.

[36] Hansard - Senate 12/09/2023 Parliament of Australia (aph.gov.au)

[37] https://www.finance.gov.au/sites/default/files/2022-07/Attachment%20B%20-%20PGPA%20%28FM%20to%20AA%20of%20NCEs%29%20Delegation%202022%20%28date%20signed%29.pdf

[38] Public Governance, Performance and Accountability (Finance Minister to Accountable Authorities of Non-Corporate Commonwealth Entities) Delegation 2022,

It should also be noted that an official can only grant an indemnity, guarantee or warranty involving a contingent liability in relation to an event on behalf of the Commonwealth if the delegate is satisfied that:

- the likelihood of the event occurring is remote (it has a less than 5% chance of occurring) and
- The most probable expenditure if the event occurred is not significant (it would be less than $30 million).[39]

If an indemnity is beyond these thresholds, a delegate can grant an indemnity on behalf of the Commonwealth if it has been explicitly agreed in a decision of:

- Cabinet
- the National Security Committee of Cabinet (NSC) or its successor or
- the Prime Minister
- or by a written determination by the Finance Minister.[40]

If the existing unquantifiable contingent liability exceeds $30 million, which appears highly probable when considering the adverse events reported, factoring in underreporting, and the evolving understanding of harm mechanisms, then the approval of contracts by public servants may be in excess of their authority.

Recommendation: AMPS believes the passage of this bill ensures the public protection from unquantifiable risks associated with poor governance and financial risk oversight.

Conclusion

In conclusion, the themes of trust, transparency, and accountability echo loudly through the intricate tapestry of our discussions on indemnification, safety, and regulatory oversight. In this era where public health is paramount, these principles should serve as guiding lights, ensuring that the path forward is both ethically sound and truly for the greater good.

Governments must be aware that current vaccine policies have the potential to undermine fundamental tenets of public health ethics. Contrary to the depiction in the media that 'the unvaccinated are entirely free to decline,' it is evident that numerous COVID-19 vaccine policies restrict choices and impede the customary exercise of valid informed consent. This complex situation has placed healthcare professionals in an uncomfortable position, blurring the distinction between voluntary and involuntary vaccination. It is evident that many people chose to be vaccinated because of the substantial repercussions associated with refusal, including the risk of losing employment, livelihood, or access to social activities and travel.[41]

It is imperative that we take a moment to reflect on the extent to which current policies, along with their implementation in clinical settings, establish a precedent that could erode the concept of valid informed consent now and in the future, including the effects of indemnification.

The incentives created by indemnification agreements must be scrutinised with a critical eye. The intersection of profit motives and public health necessitates stringent checks and balances to

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[39] Public Governance, Performance and Accountability (Finance Minister to Accountable Authorities of Non-Corporate Commonwealth Entities) Delegation 2022,
[40] Public Governance, Performance and Accountability (Finance Minister to Accountable Authorities of Non-Corporate Commonwealth Entities) Delegation 2022
[41] https://gh.bmj.com/content/7/5/e008684#ref-113

safeguard the interests of people, communities, and nations. We must ensure from this time on that corporations are actually held to account for the safety and efficacy of their products, and that public health is never again compromised for financial gain.

The role of regulatory oversight is pivotal. Robust systems of scrutiny, pharmacovigilance and proactive identification of safety signals are essential for building and maintaining public trust. These systems serve as early warning systems, helping us protect the health and well-being of the populations we as ethical medical practitioners serve.

As we delve into the development of COVID-19 vaccines and the scientific and regulatory complexities they entail, it becomes clear that transparency in research, clinical trials, and data sharing is foundational to public trust. In this evolving field, accountability is paramount, and regulatory agencies must maintain their independence and diligence.

Lastly, the spectre of unquantifiable contingent liabilities underscores the need for vigilance in financial and public health matters. We must ensure that the delicate balance between advancing public health and protecting fiscal interests is maintained.

By upholding trust, embracing transparency, and demanding accountability, we can ensure indemnity contracts never come at the expense of the safety, health, and well-being of all.