Submission to the Government of Australia's Covid Enquiry December 2023

The issues relating to various Government response to the Covid19 pandemic requires a full inquiry with much broader terms of reference. I believe anything less than a Royal Commission would fall short of what is required.

Preamble

Any inquiry into the Australian government's response to the Covid-19 pandemic must centre around the institutions charged with managing medical services and regulation in Australia including those managed by the various state governments.

The Therapeutic Goods Administration (TGA) is the main body which set the tone for all other authorities in Australia, and therefore, the role it played must be central to any scrutiny by this inquiry. This was the institution at the heart of the Covid19 response and all other agencies followed its lead. It is most appropriate, vital, therefore, to scrutinise the behaviour/actions of the TGA during the Covid-19 pandemic.

TGA boasts on its web site that it is "largely self-funded". (a government entity which makes nothing, sells nothing yet it is largely self-funded?) The main income for the Therapeutic Goods Administration comes through services it offers to its clients, the companies, the industry it is charged with regulating. (just let that sink in for a moment.....) The entity charged with regulating (and therefore approving new drugs/products) is "largely" funded by the manufacturers/suppliers of those products. What could possibly go wrong?

The TGA licences drugs and medical instruments, and in the event of adverse events following vaccination (AEFI), or reactions to drugs or devices, it alone is the arbiter of possible causation.

The TGA as the approving authority is <u>not</u> the appropriate body to investigate possible AEFI's.

As the TGA approves vaccine/drug/medical devices which can be used in Australia, its objectivity could be bought into question in the event of abnormal levels of AEFIs . At best, the TGA management's ability to separate its regulatory and funds procurement functions, could be compromised. It should at least be examined and scrutinised.

If leading bookmakers began funding the regulators (the Race Stewards) of the racing industry or the casinos were paying regulators for services rendered, people would reasonably question the wisdom of that, yet that is what we have in the TGA in Australia.

Regulators must not only **be** independent of the industry they are regulating, but it must be **seen** to be independent. This is not the case here and this inquiry should provide the scrutiny and examination of the TGA and its processes in order to regain the trust of the Australian people in the institutions on which they rely.

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Time lines:

Jan 2021
The Therapeutic Goods Administration released a report entitled **Nonclinical Evaluation Report BNT162b2 [mRNA] COVID-19 (COMIRNATY)**

25th January 2021
The Therapeutic Goods Administration approves (provisionally, subject to ongoing trials) COVID-19 vaccine, COMIRNATY

February 2021
Comirnaty (Pfizer) completes its large scale trial of the Covid-19 vaccine. (Released following FOI demands of US Courts)

TGA in its non-clinical evaluation report stated: point 5 of its Summary;
"Almost similar microscopic lung inflammation was observed in both challenged control and immunised animals after peak of infection (7 days) Rhesus macaques do not show clinical signs and generally develop only mild lung pathology from SARS-Cov-2 infection. There were no studies on protection of older animals from SARS-CoV-2 infection or duration of protection after immunisation.' (1.)

"Almost similar microscopic lung inflammation was observed in both challenged control and immunised animals after peak of infection (7 days)", and yet days later Pfizer's vaccine was approved....

"Almost similar". Is that saying almost no difference between vaccinated and non vaccinated? If this report is true what was the basis for approval?

Following the approval of Pfizer's vaccine the TGA committed to close monitoring the vaccine for safety and efficacy.

"The TGA will continue to actively monitor the safety of the Pfizer vaccine both in Australia and overseas and will not hesitate to take action if safety concerns are identified." TGA website 25th January 2021 (copy supplied below Appendix 1)

Had the TGA waited for the completion of Pfizer's trial (completed in Feb. 2021) it would have found 43,000 adverse events following Immunisation, including 1223 deaths. **(2)** (ref. **FDA-CBER-2021-5683-0000054**)

1.) **Nonclinical Evaluation Report BNT162b2 [mRNA] COVID-19 (COMIRNATY) Jan 2021 p. 4**
2.) **Cumulative analysis of post-authorization adverse event reports of PF-07302048 received through 28-Feb-2021 p. 7**

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A report from the Western Australian government (Western Australia Vaccine Safety Surveillance – Annual Report 2021) showed an alarming increase in AEFIs following the introduction of Covid19 vaccines. (see report referenced below) A statement in the report suggested Queensland (my own state) would have similar data. The data sets **"were similar to national rates reported by the Therapeutic Goods Administration (3)**

The TGA website suggests, **"It is important when looking for information about COVID-19 vaccines to consider whether the source of the information is credible and trustworthy."** This writer considers the W.A Department of Health, a "credible and trustworthy" source of information.

The data in the W.A. report a **twenty- four- fold** increase in AEFIs while the number of vaccinations following Covid increased more than **two fold**. (Covid-19 vaccinations were 3,948,000, of the 5,756,723 vaccinations administered) **(4)** The number of AEFIs was 10,600. (10,400 following Covid-19 vaccination) Of the AEFIs following Covid19 vaccinations more than 8,000 required medical assistance, (GP visit or Emergency Dept attendance) while 960 required admission to hospital **(5)** and there were 87 deaths. **(5)** The TGA reports 68 million doses of Covid-19 vaccines have been delivered in Australia. If the W.A. report is correct and "**were similar to national rates..**" the AEFI for Australia would total 181,333. Surely a figure of enormous concern for the medical regulator.

There has been no suggestion of a causal link, however, a temporal correlation exists between AEFI and Covid-19 vaccination and should be investigated. The AEFI rate for non Covid vaccinations was 1 in 7000, while with Covid vaccines, the rate of AEFIs was 1 in 263.7. Surely there should be questions asked about such a massive increase...State authorities denying it's citizens access to this data meant it was impossible for individuals to make an informed decision on whether to be immunised against Covid-19. As members of the inquiry would be aware, it is a requirement in law for individuals to give **"informed consent"** to receive any medical intervention. Without data it was simply not possible to give informed consent.

The TGA issued a warning of possible "rare" side effects of the MRNA vaccines. These AEFI's include Myocarditis and pericarditis. A recent active study conducted by the Department of Cardiology and Cardiovascular Research Institute in Basel found evidence of myocardium damage in one in 35 doses of mRNA vaccines. As this was an "active study", it tested participants in the days following vaccination and while many did not have symptoms, enzymes in blood tests confirmed minor myocardial damage in 1 in 35, with women being worst effected. **(7**)

While assurances were given by the TGA that "**The TGA will continue to actively monitor the safety of the Pfizer vaccine both in Australia and overseas", (8)** neither the Western Australian, nor the Basel study appear to have been acknowledged. This inquiry must ask the question, Is the TGA too close to the industry it is regulating to make unbiased decisions relating to "novel" medications particularly those without any long-term safety data?

3). Western Australian Vaccine Safety Surveillance-Annual Report 2021 p. 2

4) Ibid p.2

5) IBID Table 1 p.11

6) IBID Appendix 2 p.33

7) https://onlinelibrary.wiley.com/doi/epdf/10.1002/ejhf.2978

8) TGA website 12/12/2023

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At all stages of the government's public announcements during the pandemic we were bombarded with statements like "listen to the science", "follow the science". Why have we decided to stop looking at the science, the data, or worse still, simply bury the data.

In my own state Queensland it is simply not possible to find data supporting governments claim of Safe and Effective. Queensland was "covid free" until December 2021, all non-vaccinated individuals were effectively house bound. (denied access to theatres, music festivals, sporting events, clubs, pubs, restaurants, etc …) Visitors and returning residents of Queensland were required to be "fully vaccinated", yet by 15th January 2022, (a month after border openings) the ABC reported 19,000 new cases….clearly vaccination did not prevent transmission. Nevertheless, the Queensland Government pushed ahead with its policy of denying access to employment to anyone who was not vaccinated. Many corporations followed suit.

Clearly government's decision to mandate vaccination in many sectors was not based on science. So what was the basis of that decision?

Covid-19 is a disease which primarily effects the respiratory system, yet Australian Bureau of Statistics data from 2022 reports **"The mortality rate from respiratory diseases was 42.5 per 100,000 people. This was an increase of 8.4% from 2021, but remained lower than rates before 2020." (9)** Yet Australia experienced a 15% increase in deaths in 2022 (above the 5 year average) we need answers to these questions and the only way to have them answered is through a Royal Commission with broad terms of reference.

From the outset of the pandemic, the TGA, through its "provisional" approval of the Covid-19 vaccines, advised government on safety and efficacy without sufficient information to make that assertion. The "roll out" of the vaccine could have been a successful decision if it performed a simple risk/benefit analysis for individuals seeking immunisation. Instead, a "one size fits all" approach was adopted by medical authorities and governments rigidly enforced this policy.

In light of the vast number of AEFIs reported in the quoted report, the TGA should have sought or performed increased surveillance, even possible cessation, of the vaccination process in order to fully evaluate the impact of this novel vaccine. (Remember there is no long- term data available as this is a novel vaccine.) One is forced to ask, Is the funding arm of the TGA too close to the pharmaceutical industry it is supposed to be monitoring/regulating?

To summarise;

All health departments throughout the country must have data similar to the Western Australian vaccine safety surveillance report. So why is it not available to a scrutinising public or media? It seems government believes individuals cannot be trusted to make their own decisions with regard to their own health. Governments of all persuasions exclaim their belief in "transparency" of government. Where is this transparency?

9) Australian Bureau of Statistics (https://www.abs.gov.au/statistics/health/causes-death)

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Australians are reeling from the effects of lockdowns, mandates, curtailment of what many believed was their human rights and need reassurance from a body tasked to shine a light on the darkness of the pandemic period. This inquiry needs to ask authorising groups, starting with the TGA, what actions have been initiated, to seek understanding of why more than 150,000 Australians experienced AEFI. (a great number of whom are permanently damaged following vaccination with mRNA vaccines?)

The inquiry should lift the curtain of secrecy surrounding data relating to adverse events, it should demand bureaucrats release information it used to make the “safe and effective” statements, or at least admit that they “were just following orders”.

The responsibility of this inquiry, is to open up the pandemic wound, as painful as that might be, so that the truth is revealed.

Perhaps , while members may consider it is outside the terms of reference for the inquiry, call for the only chance to allow the truth to be told. Call for a Royal Commission!

Yours Sincerely

Brian Daley

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References:

FDA-CBER-2021-5683-0000054 (Pfizer's "Cumulative analysis of post-authorization adverse event reports of PF-07302048 received through 28-Feb-2021
Table 1 of this report noted 42,000 adverse events following immunisation (AEFI) including 1223 deaths.

Western Australian Vaccine Safety Surveillance-Annual Report 2021

Nonclinical Evaluation Report BNT162b2 [mRNA] COVID-19 (COMIRNATY) Jan 2021

Appendix 1

Therapeutic Goods Administration (TGA) has granted provisional approval to Pfizer Australia Pty Ltd for its COVID-19 vaccine, COMIRNATY, making it the first COVID-19 vaccine to receive regulatory approval in Australia.

Following a thorough and independent review of Pfizer's submission, the TGA has decided that this vaccine meets the high safety, efficacy and quality standards required for use in Australia.

COMIRNATY is provisionally approved and included in the Australian Register of Therapeutic Goods (ARTG) for active immunisation to prevent coronavirus disease 2019 (COVID-19), caused by SARS-CoV-2, in individuals 16 years of age and older.

Provisional approval of this vaccine is valid for two years and means it can now be legally supplied in Australia. The approval is subject to certain strict conditions, such as the requirement for Pfizer to continue providing information to the TGA on longer term efficacy and safety from ongoing clinical trials and post-market assessment.

Australians can be confident that the TGA's review process of this vaccine was rigorous and of the highest standard. The decision to provisionally approve the vaccine was also informed by expert advice from the Advisory Committee on Vaccines (ACV), an independent committee with expertise in scientific, medical and clinical fields including consumer representation.

The TGA will continue to actively monitor the safety of the Pfizer vaccine both in Australia and overseas and will not hesitate to take action if safety concerns are identified. As an extra check, the TGA laboratories will undertake batch assessment of each batch of the vaccine before it can be supplied in Australia.

The TGA has published a series of regulatory documents that relate to this decision, including the Australian Public Assessment Report (AusPAR) and the decision summary, which provide details about the evidence that the TGA reviewed to support the provisional approval of the vaccine. The Product Information, FAQs and information on labelling and batch testing are also available on the COVID-19 vaccines hub.

Further information on the COVID-19 vaccine rollout is available on the Department of Health website - external site.

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