Australian Government
Department of Health and Aged Care

**Secretary**

Senator Marielle Smith
Chair
Senate Standing Committees on Community Affairs
Parliament House
PO Box 6100
CANBERRA ACT 2600

Dear Senator

Thank you for the opportunity to respond to the concerns raised by Senator Rennick in his letter dated 11 April 2023 to the Senate Standing Committees on Community Affairs.

Firstly, I would like to advise that Adjunct Professor John Skerritt has recently retired as a Deputy Secretary of the Department of Health and Aged Care, after more than 11 years leading the Health Products Regulation Group that includes the Therapeutic Goods Administration. His extraordinary record of service and achievement during his career is testament to his demonstrative care and commitment to improving the health and well-being of all Australians through therapeutic regulation. This has been particularly apparent during the COVID-19 pandemic.

In relation to a number of allegations in Senator Rennick's letter, I would like to strongly assert that at no time did Adjunct Professor Skerritt mislead the Senate at the estimates hearing in February 2023. I have provided further information below which substantiates the statements made by Adjunct Professor Skerritt and also provides the relevant context in which they were made. Furthermore, I am unaware of such allegations ever being made against Adjunct Professor Skerritt while carrying out his duties and responsibilities as part of the Senior Executive team in the Department of Health and Aged Care.

Senator Rennick has provided a list of purportedly misleading statements attributed to Adjunct Professor Skerritt. The substance of these allegations has been addressed on a number of occasions before the Committee or in response to questions on notice. To assist the Committee, I have provided references to various responses that have already been provided to the Committee.

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## 1. Antiphospholipid syndrome

Adjunct Professor Skerritt's statements regarding the safety of COVID-19 vaccines in people with antiphospholipid syndrome (APS) were accurate and evidence-based. He referred to multiple studies of COVID-19 vaccines in patients with APS conducted early in the vaccine roll-out, and also referred to advice for APS patients from the UK.

The article quoted by Adjunct Professor Skerritt does refer to the Sinovac vaccine, but was only one of the studies referred to. There are other publications which support the statements made, including an earlier publication in the journal Rheumatology from June 2022:

- Pengo V, et al.; COVID-19 APS collaborators. ***Impact of COVID-19 and COVID-19 vaccination on high-risk patients with antiphospholipid syndrome: a nationwide survey***. Rheumatology (Oxford). 2022 Jun 28;61(SI2):SI136-SI142. doi: 10.1093/rheumatology/keac224. PMID: 35412604; PMCID: PMC9047199.

  This survey of APS patients at high risk of recurrent thrombotic events found mRNA vaccines were well tolerated with no thrombotic events reported. The study included 121 participants who received the Pfizer mRNA vaccine, 20 who received the Moderna mRNA vaccine and 5 who received the AstraZeneca vaccine.

- Sciascia S, et al. ***Safety and tolerability of mRNA COVID-19 vaccines in people with antiphospholipid antibodies.*** Lancet Rheumatol. 2021 Dec;3(12):e832. doi: 10.1016/S2665-9913(21)00320-9. Epub 2021 Oct 20. PMID: 34697607; PMCID: PMC8528471.

  This study was of patients with APS (n=52), or antiphospholipid antibodies without clinical features of the syndrome (n=50), who were at lower risk of thrombotic events. All received an mRNA COVID-19 vaccine (66% Pfizer, 34% Moderna). The vaccines were well-tolerated and there were no reports of thrombotic events after vaccination.

As such, it is clear that the statement that COVID-19 vaccines do not increase the risk of thrombotic events in patients with APS is well supported by published evidence covering different types of COVID-19 vaccines.

## 2. Comparison of deaths from paracetamol overdose versus COVID-19 vaccination related deaths

The statistics referred to by Adjunct Professor Skerritt were not based on data from the Database of Adverse Event Notifications (DAEN) – medicines. The data Adjunct Professor Skerritt quoted related to deaths from paracetamol overdose, which were drawn from an independent expert review conducted by leading medical and university experts, published on the TGA website on 14 September 2022. See: www.tga.gov.au/news/media-releases/independent-review-paracetamol-overdose

The independent review of paracetamol overdose found that there were 2 deaths per million people in Australia each year, indicating there would have been approximately 150 deaths in Australia since early 2020 when the COVID-19 pandemic began.

Vaccines can lead to death in extremely rare instances. However, most deaths that occur after vaccination are not caused by the vaccine. Since the beginning of the vaccine rollout to 14 May 2023, the TGA has identified 14 reports where the cause of death was linked to vaccination from 985 reports received and reviewed.

This illustrates that death from paracetamol overdose (150 deaths since early 2022) is more than ten times the number of deaths linked to COVID-19 vaccines (14 deaths since vaccines rollout to 14 May 2023).

Further information on the nature of the deaths from paracetamol overdose can be found in the report. It is not surprising that the number of deaths reported to the TGA, and as such included in the DAEN – medicines, is lower than that found by the independent review which was focussed on overdose.

The Department of Health and Aged Care stands by the statement made by Adjunct Professor Skerritt, as the available evidence clearly supports the statement that deaths from paracetamol are much higher than those linked to a COVID-19 vaccine.

**3. Effectiveness of the Moderna vaccine**

The quote provided by Senator Rennick from the transcript of the press conference announcing the regulatory approval of the Moderna vaccine removes the content immediately prior which included important context to the statements made. Specifically, it identified that the comments were being made in the context of the recent regulatory approval, the data for which is based on information from clinical trials, as shown below:

> **ADJUNCT PROFESSOR JOHN SKERRITT, HEAD OF THE THERAPEUTIC GOODS ADMINISTRATION:** *Thank you, Prime Minister, and thank you, Minister. So as the Prime Minister and Minister have said, we're delighted to have provided regulatory approval to the Moderna vaccine just within the last hour. It's also known as Spikevax (elasomeran), but like many things, the trade names will probably stick. And it's the fourth vaccine to receive regulatory approval in Australia. As many people will know, that regulatory approval is advised by a committee of external, medical and community experts, and they strongly supported its regulatory approval.*
>
> *Now, some of you may be aware that very recently Europe has authorised or at least recommended its use for children in over 12. We made the decision in conjunction with the company to do the adults first because that enabled us to reach a decision earlier, which can then start the whole process of access to the vaccine in Australia earlier. The data on the teenagers does look good and we should be able to make a decision, again, convening the expert advisory committee within the next three or four weeks on an application for use in 12 and over. It's highly efficacious. And of course, we can build on widespread global experience. So in the US alone, there has been over 140 million doses of Moderna used. The other really encouraging thing about Moderna is even after six months, it's proving to be 93 per cent efficacious against any infection, 98 per cent against severe disease and 100 per cent against death. And that's really exciting.*
> https://pmtranscripts.pmc.gov.au/release/transcript-43521

Once again, in the context of registration of a vaccine, efficacy is assessed by the TGA based on clinical trial data. In this instance, Adjunct Professor Skerritt was referring to clinical trial data when explaining efficacy outcomes against infection, severe

disease and death; only trial data was available at that time to draw such a conclusion. I acknowledge, however, that this statement could have been misunderstood in this instance as Adjunct Professor Skerritt also referred to 140 million doses of Moderna which had been administered in the UK.

## 4. Myocarditis and cardiac arrest

The Senator's letter states that Adjunct Professor Skerritt made a 'supposition that myocarditis does not lead to cardiac arrest'. It is important to consider the context in which the statements were made, noting that the discussion at Senate estimates was interrupted at times, with the focus of the discussion shifting frequently.

The discussion of cardiac arrest was initiated by a question from Senator Antic regarding two deaths reported in 7 and 9 year old children, neither of which have been assessed as being linked to COVID-19 vaccination (see page 52 of the Hansard). In his response, Adjunct Professor Skerritt stated that 'heart attack' is not a known adverse event of any COVID-19 vaccine. This statement is factually correct – neither the TGA nor any international regulator has identified heart attack, cardiac arrest or myocardial infarction as adverse events causally related to vaccination against COVID-19.[1]

In response to a later question "*Does myocarditis lead to cardiac arrest?*", Adjunct Professor Skerritt replied:

> "*There are cases where people who have had myocarditis have an increased prevalence of a range of other cardiac conditions. But to say that it leads to cardiac arrest is misleading, especially given that most myocarditis associated with vaccination – indeed, there's a recent publication in a top medical journal by Nordic scientists – is much milder than myocarditis after COVID infection or other forms of viral myocarditis*" [p54]

Adjunct Professor Skerritt acknowledged that in some cases myocarditis does lead to other cardiac conditions. While cardiac arrest can occur after myocarditis, it is not a common sequela of myocarditis in general and even less likely with the mild myocarditis associated with vaccination. A recent large Australian study (Circulation 2023;147:1309-1311) importantly showed no association between out of hospital cardiac arrest and COVID-19 vaccination.

As such, when these statements are considered in the context that they were made, it is clear that Adjunct Professor Skerritt did not mislead the Senate in his statements regarding the relationship between myocarditis and cardiac arrest.

## 5. Lipids used in the mRNA based COVID-19 vaccines

As has been indicated to the Senator on a number of occasions both at the Senate hearings and in responses to questions on notice, the lipid nanoparticles in the COVID-19 vaccines consist of four lipids. Two of these lipids are present in both the

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[1] The definitions of these medical terms have been provided to assist with the clarity of the response:

- 'cardiac arrest' is the cessation of the heartbeat, which may be temporary or permanent.
- 'heart attack' is a colloquial term for 'myocardial infarction' which is damage to the heart muscle, usually due to a disruption in blood supply, often caused by a clot.

Pfizer and Moderna mRNA-based vaccines - cholesterol and DSPC (1,2-distearoyl-*sn*-glycero-3-phosphocholine) - which are natural constituents of human cells and are found in bovine steak and even sausages. While the remaining two other lipids in the Pfizer vaccine are slightly different from the other two in the Moderna vaccine, all four lipids are also structurally similar to natural lipids found our body or food. (SQ22-000674).

The biodistribution and fate of lipid nanoparticles (LNP) were studied in animals and *in vitro*. The distribution of these LNPs was investigated by monitoring a radiolabelled lipid-marker in rats. The major update of this lipid-maker was noted at the injection site and in the liver, with lower levels distributed to the spleen, adrenal glands and ovaries. The LNP dose in this animal distribution study was considerably higher than the human dose. It is important to note that the radioactivity (lipid-marker) and not the actual lipid in the vaccine was measured in the rat distribution study. Therefore, the detected radioactivity could represent smaller pieces of the lipid from the vaccine's LNPs. It is a common practice to measure radioactivity in radio-labelled tissue distribution studies for pharmaceuticals because of the high sensitivity of radioactivity measurements s and the difficulty of detecting pharmaceuticals *per se* in tissues. (SQ22-000542)

The comment made by Adjunct Professor Skerritt is consistent with the findings from the nonclinical studies and how lipids in general are distributed throughout the body.

**6. The breakdown of the mRNA from vaccines.**

Proteins and mRNA are highly susceptible to breakdown in the human body. The scientific literature and studies demonstrate that the vaccine mRNA and spike protein are expected to be degraded by multiple endogenous pathways. The half-lives of native mRNA in mammalian cells range from minutes to hours, depending on many factors such as transcript function and cell type. Due to this rapid degradation of mRNA, vaccine mRNAs are delivered in lipid nanoparticles, which protect the mRNA from being broken down by nucleases and which help to deliver the mRNA into cells. The degradation of vaccine mRNA in these mRNA-LNP formulations is slightly slower than the decay of some native mRNAs. While there are no data specifically on the degradation of COVID-19 vaccine mRNAs in laboratory animals or humans, data from studies of an experimental flu vaccine and a cytomegalovirus vaccine indicated mRNA half-lives of 19 hours in mice and 15-60 hours in rats, respectively. (SQ22-000525).

As noted in previous advice in questions on notice, the biodistribution of the mRNA and the expressed antigen (spike protein) encoded by the mRNA component of the mRNA vaccines are expected to be dependent on the distribution of LNPs. To visualise the tissue distribution of the mRNA-LNP formulated vaccine, mRNA encoding luciferase was formulated in an LNP formulation identical to the Pfizer vaccine. Following intramuscular (IM) injection of the luciferase mRNA formulation in mice, luciferase was detected by whole body imaging mainly at the injection site, which declined to the background levels after 9 days. While luciferase was also seen in the liver, it had disappeared after 48 hours. Very low levels of mRNA or spike protein may be detectable for longer periods. (SQ22-000542). Irrespective of the

biodistribution studies in laboratory animals, repeat-dose toxicity studies in animals using high doses of the actual vaccine formulations that were ultimately administered to the population, did not raise safety concerns.

It is important to note that neither the mRNA nor the spike protein are pathogenic.

**7. The biodistribution of spike proteins following vaccination.**

As advised in SQ22-000555, *in vitro* studies using HEK293 cells (human embryonic cells) found that the expressed spike protein co-localised with an endoplasmic reticulum (ER) marker, suggesting that the spike protein is synthesised and processed within the ER for cell surface expression. This study did not show that the vaccine stimulates the human body to export the spike protein from the cell. On the contrary, the spike protein has a transmembrane anchor region that makes the protein attach to the cell membrane, and hence it is not secreted or releases in the blood stream from the cells due to the absence of a signal sequence for secretion. Additional information was also provided in that earlier advice citing a number of published papers specifically about spike protein Duan et al, 2020 (https://pubmed.ncbi.nlm.nih.gov/33117378/) and Heinz & Stiasny, 2021 (pubmed.ncbi.nlm.nih.gov/34400651/).

While the presence of spike proteins at very, very low levels in the bloodstream cannot be excluded, as per Adjunct Professor Skerrit's comments, if there are trace levels of any spike protein there is no evidence of any harm from the repeat-doses studies in laboratory animals.

I trust that the above information addresses the questions Senator Rennick has raised regarding the evidence provided by Adjunct Professor Skerritt.

Yours sincerely

Professor Brendan Murphy AC

24 May 2023