COMMONWEALTH OF AUSTRALIA

Proof Committee Hansard

SENATE

EDUCATION AND EMPLOYMENT LEGISLATION COMMITTEE

COVID-19 Vaccination Status (Prevention of Discrimination) Bill 2022 Fair Work Amendment (Prohibiting COVID-19 Vaccine Discrimination) Bill 2023

(Public)

THURSDAY, 3 AUGUST 2023

CANBERRA

BY AUTHORITY OF THE SENATE

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EDUCATION AND EMPLOYMENT LEGISLATION COMMITTEE

Thursday, 3 August 2023

Members in attendance: Senators Antic, Canavan, Grogan, Hanson, O'Sullivan, Payman, Rennick, Roberts and Sheldon

Terms of Reference for the Inquiry:

To inquire into and report on:

COVID-19 Vaccination Status (Prevention of Discrimination) Bill 2022

Fair Work Amendment (Prohibiting COVID-19 Vaccine Discrimination) Bill 2023

WITNESSES

HEWITT, Dr Brian, Head of Regulatory Sciences, Pfizer Australia [by video link]

THIRU, Dr Krishan, Country Medical Director, Pfizer Australia [by video link]

Committee met at 17:03

CHAIR (Senator Sheldon): I now declare open this hearing of the Senate Education and Employment Legislation Committee into COVID-19 Vaccination Status (Prevention of Discrimination) Bill 2022 and the Fair Work Amendment (Prohibiting COVID-19 Vaccine Discrimination) Bill 2023. I begin by acknowledging the traditional custodians of the land on which we meet and pay my respects to their elders both past and present. I extend that respect to Aboriginal and Torres Strait Islander peoples here today. The committee will be conducting today's hearing via video conference and in person. These are public proceedings being video streamed live via the parliament's website, and a *Hansard* transcript is being made.

I remind all witnesses that in giving evidence to the committee they are protected by parliamentary privilege. It is unlawful for anyone to threaten or disadvantage a witness on account of evidence given to a committee. Such action may be treated by the Senate as a contempt. It is also a contempt to give false or misleading evidence. Witnesses also have a right to request to be heard in camera. If a witness objects to answering a question, they should state the ground upon which the objection is made and the committee will determine whether it will insist on an answer having regard to the ground which is claimed. If the committee determines to insist on an answer, a witness may request that the answer be given in camera. I remind committee members and witnesses who are appearing via video conference who are not speaking to please mute their microphones.

I now welcome representatives from Pfizer Australia via video conference. I understand that information on parliamentary privilege and the protection of witnesses giving evidence to Senate committees has been provided to you. I now invite you to make a short opening statement. At the conclusion of any remarks, I'll invite members of the committee to ask questions. Over to you.

Dr Thiru: Thank you, Chair. Pfizer thanks the Senate Standing Committee on Education and Employment for the opportunity to appear at the hearing today. As has been communicated to the committee previously, Pfizer believes the debate on the prevention of discrimination based on COVID-19 vaccination status, which is at the core of both the bills that are subject to inquiry by this committee, is a policy matter for government. However, with our recent experience developing, manufacturing and supplying a COVID-19 vaccine, Pfizer is happy to share details of this experience.

With approximately 80,000 employees globally and one of the most sophisticated supply chains systems in the industry, Pfizer is one of the largest biopharmaceutical companies in the world. Pfizer is proud to have had operations in Australia since 1956. We have more than 1,000 employees in Australia and operate across two commercial sites in Sydney and Melbourne. We have a manufacturing facility in Melbourne that exports to over 60 countries worldwide. Pfizer is a proven, reliable, multinational vaccine producer, supplying vaccines that prevent a multitude of diseases and infections to 175 countries even prior to the pandemic, when we manufactured more than 200 million doses of Pfizer vaccines annually. Additionally, Pfizer is one of the largest sterile injectable suppliers in the word, producing more than one billion sterile units per year.

Last year, more than one out of every six people worldwide are estimated to have used a Pfizer medicine or vaccine. As of 4 June 2023, we have delivered more than 4.6 billion COVID-19 vaccine dozes to 181 countries and territories in every region of the world. These numbers represent real people around the world who are helped by what Pfizer scientists developed and brought to patients.

At the start of 2020, as the SARS-CoV-2 virus began rapidly spreading across the globe, Pfizer and our partner BioNTech recognised the urgency and need to play a leadership role in addressing the global public health crisis. On 17 March 2020, just six days after the World Health Organization declared COVID-19 a pandemic, Pfizer signed a letter of intent with BioNTech to codevelop a potential COVID-19 vaccine. We worked to safely accelerate the development, manufacture and distribution of an mRNA based coronavirus vaccine for active immunisation to prevent COVID-19 infection. In less than a year, it received emergency use approval from the US Food and Drug Administration, the first COVID-19 vaccine to be granted such authorisation.

In addition to the public health benefit, vaccine access has also had a tremendous economic benefit in Australia. A peer reviewed paper in the scientific journal *Vaccine* estimated the timely rollout of COVID-19 vaccinations to have reduced the impact of the pandemic on the Australian economy, resulting in a positive incremental benefit of $181 billion, contributing to significant positive effects for tourism exports, education exports, employment and government finances.

Pfizer has confidence in the safety of our vaccine. Given the urgent public health need to develop a vaccine in a safe and responsible way, we collaborated closely with independent regulatory and health authorities around the world to conduct key activities in parallel to allow us to significantly accelerate the vaccine development without compromising safety. The independent data monitoring committee for our landmark trial did not report any serious safety concerns related to the vaccine prior to licensing. The data demonstrates the vaccine is well tolerated across the authorised indications and across all age groups. The most common side effects reported have been local reactions at the injection site.

Since its FDA authorisation in 2020, Pfizer's COVID-19 vaccine has been administered to hundreds of millions of individuals globally and continues to be vigilantly monitored through trials and post-authorisation surveillance. The vaccine has received full regulatory approval in a variety of countries, including the United States, the EU and Australia, following earlier emergency use and conditional or provisional approvals. These authorisations are based on robust and independent evaluation of the scientific data on quality, safety and efficacy, including our landmark phase 3 trial. Data from real-world studies complement the clinical trial data and provide additional evidence that the vaccine provides effective protection against severe disease.

We take all adverse events that are potentially associated with our COVID-19 vaccine very seriously. We closely monitor all such events and collect relevant information to share with global regulatory authorities. Based on ongoing safety reviews performed by Pfizer, BioNTech and health authorities, the vaccine retains a positive benefit-risk profile for the prevention of COVID-19 infections. To date, hundreds of millions of people have been vaccinated with our vaccine. Pfizer and BioNTech have invested more than US$2 billion at risk to develop our COVID-19 vaccine. Within just 13 months from December 2020—

Senator CANAVAN: Sorry to interrupt. We have very limited time. I raise a point of order. Could we have an indication of how long to go? We could, of course, table any opening statement. That opportunity is there. I am sorry to interrupt. I am mindful of the clock.

CHAIR: It would be of assistance. It saves us having to have another hearing.

Dr Thiru: There is about one minute to go. I am happy to be guided by you, Chair.

CHAIR: If you can wrap up quickly, that would be great. If you get somebody from your office to email the opening statement, we might have it in front of us as well.

Dr Thiru: We would be happy to do that. Let me close. Vaccine manufacturing is a biological production that is extraordinarily complex under any circumstances. Pfizer's COVID-19 vaccine requires 280 components and relies upon 86 suppliers located in 19 different countries. As a result, the maintenance of strong and reliable global supply chains is crucial to the ongoing production and availability of the vaccine. Fundamental to Pfizer's ability to commit the R&D investment into vaccines and treatments are pro innovation policy settings, including a strong intellectual property system. Large-scale pandemics like COVID-19 are likely to occur again. Epidemiologists forecast that the frequency and scale of future pandemics may steadily increase. As such, near-term pandemic readiness efforts are critical to respond to future pandemic and/or public health emergencies at the domestic and global level. Pfizer is proud of its collaboration we've had with the Australian government. We look forward to continuing that partnership to ensure Australia is even better prepared for future threats to public health. Pfizer hopes that its appearance at this public hearing assists the Senate committee.

CHAIR: Thank you.

Senator CANAVAN: Thank you, gentlemen, for appearing today and your evidence. Did Pfizer test whether your COVID-19 vaccine could stop or reduce the transmission of the virus before its approval and rollout in late 2020?

Dr Thiru: To bring this vaccine to patients, we were required to show that the vaccine was safe and effective in preventing illness, in preventing severe disease and in preventing hospitalisations. The primary purpose of vaccination was, and remains, to protect the person who received the vaccine.

Senator CANAVAN: I will repeat the question. I appreciate that. There hasn't been an answer to it. I might add into the record that on 3 December 2020, your CEO, Mr Albert Bourla, when asked whether vaccinated people could carry and spread the virus, responded to NBC News:

I think this is something that needs to be examined. We are not certain about that right now.

Was Mr Bourla correct that, as of 3 December 2020, Pfizer did not know whether the vaccine could stop or reduce the spread of the virus?

Dr Thiru: Senator, as with all vaccines seeking regulatory authorisation, the requirement is to demonstrate in robust clinical programs that the vaccine is safe and effective in preventing the infection and, in this case, preventing severe disease and hospitalisation.

Senator CANAVAN: Sorry to interrupt, but I have very limited time. I have five minutes. Is it a yes or no? Did you test whether transmission would be reduced or stopped before the approval of the vaccine?

Dr Thiru: Senator, we designed our clinical programs in agreement with regulatory agencies, the purpose of which was to demonstrate the vaccine was safe and effective in preventing infections.

Senator CANAVAN: We might move on to another topic. On 14 January 2021, just six weeks after Mr Bourla's statement to NBC News, the official Pfizer Twitter account tweeted:

The ability to vaccinate at speed to gain herd immunity and stop transmission is our highest priority.

What evidence did Pfizer have to make that public statement to imply that vaccination could stop transmission?

Dr Thiru: I'm not familiar with the context or the details of those comments. Let me just say that the primary purpose of vaccination, the approved product label and the regulatory approvals in Australia and around the world were to prevent infection, prevent severe disease and prevent hospitalisation. That is what our clinical trial program sought to demonstrate. That is what was demonstrated. That was the evidence that was evaluated by regulatory agencies and by health authorities. That was the strong, robust clinical evidence that led to the approvals that were received in Australia and in many other countries.

Senator CANAVAN: I will ask you to take that on notice. The question is: what evidence did Pfizer have for their statement on Twitter on 14 January 2021?

Dr Thiru: Senator, I would be happy to take that question on notice—

Senator CANAVAN: Thank you.

Dr Thiru: and come back to the committee with what information we're able to provide.

Senator CANAVAN: So on 8 June 2021, the Pfizer CEO, Mr Albert Bourla, tweeted:

… vaccination is a critical tool to help stop transmission.

What evidence did Mr Bourla have by that stage, 8 June 2021, that vaccination could stop transmission?

Dr Thiru: Senator, it has been very clearly demonstrated that the robust efficacy of Pfizer's COVID-19 vaccine has been a centrally important tool in enabling societies to open up international borders, to reduce—

Senator CANAVAN: I'm asking for the evidence. What is the evidence? Can you point me to a study that an independent scientist has done to give grounds for Mr Bourla's statement that your vaccine stopped transmission?

Dr Thiru: Senator, I'm not familiar with the context of that statement. We've complied and worked very closely with the regulatory agencies around the world to probe the evidence that they required to approve this vaccine to prevent infection and severe disease and hospitalisations.

Senator CANAVAN: I will ask you to take on notice again the evidential basis for Mr Bourla's comments on 8 June 2021.

Dr Thiru: I am happy to take that on notice.

Senator CANAVAN: Thank you. Do you still believe that your COVID vaccine is a critical tool to help stop transmission?

Dr Thiru: Absolutely. It's a critical tool in preventing, as I said earlier, infections, severe disease and hospitalisation.

Senator CANAVAN: That wasn't my question. You did say, I think, absolutely. Just to be clear on that evidence, and if I could get you to clarify it, is it Pfizer's view that your COVID vaccine is a critical tool to help stop transmission?

Dr Thiru: Sorry, I may have misheard your question. I was—

Senator CANAVAN: That is why I re-asked it. I thought you might have misinterpreted it. Is your view that your vaccine is a critical tool to help stop transmission?

Dr Thiru: Pfizer's view is that the vaccine is a critical tool in protecting the health of individuals who are vaccinated and enabling society to operate normally as it is at the moment.

Senator CANAVAN: Okay. I'm taking from that you don't think it's a critical tool to help stop transmission. You haven't repeated Mr Bourla's statement today under oath, so it doesn't sound like you're that confident in it. What I'm concerned about here is that you have a statement from your CEO that obviously has huge weight for governments around the world on their regulatory settings, saying that the COVID vaccine could stop

transmission or was a critical tool to help stop transmission. Can you point me to any statements made by Pfizer officials—the Pfizer CEO, anything—that has somewhat moved away from that very strong statement of Mr Bourla in June 2021 that it is a critical tool to help stop transmission? Have you clarified the record since that time?

Dr Thiru: I am very confident that the evidence we have presented to regulatory agencies still stands and clearly demonstrates that the vaccine is safe and effective for its intended use.

Senator CANAVAN: That is not my question. I am very sorry to pull you up. I don't normally do this, but we have very limited time and you are being very shifty here. You are not answering the very clear questions.

Senator HANSON: Senator Canavan, can I just—

Senator CANAVAN: Hang on.

Senator HANSON: I would like see Dr Hewitt—

Senator CANAVAN: Can I—

Senator HANSON: I would like to see Dr Hewitt answer the question, because he is the scientist.

CHAIR: Senator Canavan has the floor. Any questions are through the chair. I do allocate time so people can have their train of questions before I allocate to others.

Senator CANAVAN: I will finish up now.

CHAIR: I will go to Senator Rennick next.

Senator CANAVAN: I'll finish with this. My point here is that, by late 2021 in this country, the Australian government and state governments imposed vaccine mandates on their own employees and required other employers to impose them on their employees. They definitely did that in part based on the evidence and advice from organisations like yours and the statements of Mr Bourla. We were constantly told by our leaders that your vaccine was necessary to stop the spread. I have pages and pages of quotes from those leaders saying that the vaccine would stop the spread. You have seen those statements. You are the head of regulatory services. You would have seen those statements. Is there any statement from Pfizer that clarified Mr Bourla's statement from June 2021 that responded to the very strong statements from premiers about your product? If not, what you are doing is effectively only reporting the good news that you have about your vaccine and not clarifying where there may be a shortcoming from your product that has led thousands of Australians to lose their jobs.

Senator ROBERTS: And livelihoods.

Senator CANAVAN: And their livelihoods. Why hasn't Pfizer clarified the record on transmission when governments have used that to mandate your product and provide you with billions of dollars of profits around the world by doing so?

Dr Hewitt: Perhaps I can make a comment. Pfizer was very clear in making an application to TGA that it sought an indication for active immunisation to prevent coronavirus disease caused by SARS-CoV-2.

Senator CANAVAN: But you said more than that. That's not what I am asking. I am asking about the public statements from your CEO. He said it was a critical tool to stop transmission. I can't find anything from him or anyone else of his employees that has moved back from that statement since, yet you won't repeat his statement on evidence today. So you obviously don't believe in it. Why haven't you clarified the public record since June 2021?

CHAIR: If you can answer that question, I will go to Senator Rennick.

Dr Hewitt: Senator, again, I can only repeat that in making an application to TGA, Pfizer sought active immunisation to prevent coronavirus disease caused by SARS-CoV-2. It was very clear in its application to the TGA.

CHAIR: Senator Rennick.

Senator RENNICK: I note that you've already stated today that the vaccine was designed to actually stop or prevent infection. This was also reiterated by your CEO, Albert Bourla, on 2 April 2021, when he posted a tweet,:

Excited to share that updated analysis from our Phase 3 study … showed that our COVID-19 vaccine was 100% effective in preventing #COVID-19 cases—

By September 2022, Australia had recorded 10 million cases of COVID despite having an adult population vaccinated to the tune of 95 per cent. Given those real-world figures in Australia, do you still stand by that statement you've just said to Senator Canavan that the vaccine was effective in preventing infection?

Dr Thiru: We strongly believe, and we reiterate, that the vaccine is safe and effective for its intended use. What changed was that the virus evolved. If we look at the clinical data from before the virus mutated into Delta, Omicron and subsequent variants, the vaccine maintained high levels of efficacy. If we look at the six-month data from the pivotal trial, efficacy for the prevention of serious—

Senator RENNICK: Sorry, I'm not referring to trials. I'm referring to the fact. I'm referring to the Omicron variant. That's a product of the nature of the vaccine. You have actually designed a vaccine that is an epitope on one spike protein and not the other 28 proteins in the vaccine. That is a design fault of yours, the fact that it can't cope with other variants. That is the nature of the way you have designed that vaccine.

Dr Thiru: Senator, I categorically reject your statement. The vaccine was carefully designed against the virus that was prevalent at the time, which was the original wild-type virus. It remained highly effective against preventing illness and preventing severe disease.

Senator RENNICK: Thank you. Can you define 'highly effective' in terms of a duration?

Dr Thiru: When the wild-type virus was prevent, efficacy of approximately or greater than 90 per cent was maintained at six months for both overall the illnesses and severe disease.

Senator RENNICK: The TGA non-clinical report on the Pfizer vaccine said that T-cells, antibodies and T-cells in monkeys declined quickly after five weeks after the second dose of the vaccine. So the best we've got here in animal studies was five weeks, 35 days, a bit over a month. Why are you saying six months when animal studies showed five weeks? In human studies, you cut them short after two months.

Dr Thiru: The human immune system doesn't rely on antibodies alone. Antibodies provide short-term protection against infection. T-cell and other immune responses, which are a bit more difficult to measure, provide longer lasting protection.

Senator RENNICK: Maybe you didn't hear what I just said. It said antibodies and T-cells declined quickly after five weeks. That's what the TGA Pfizer non-clinical report said—five weeks.

Dr Thiru: It is very difficult to measure the totality of the immune system's responses against the infection. What we need to rely on is—

Senator RENNICK: Okay. If that's the case—

CHAIR: Senator Rennick, Dr Thiru could finish his answer. Are you finished, Dr Thiru? By all means, if you have something else to say, say it. I'll then go back to Senator Rennick.

Dr Thiru: I will make one more comment. We then need to look to clinical outcomes. It's very clear that, even with the Omicron variant, with a virus that is now quite different to the original virus, efficacy against, in particular, severe disease, hospitalisation and people not surviving is maintained for significant durations.

Senator RENNICK: I'm referring to infection. For the bulk of the people, half the country was infected with COVID 10 months after. For healthy people of working age population, their risk from COVID was very low. I'm putting it into context here. These people were forced to take a vaccine that you said—you've said today—was effective in preventing infection. That is not the real-world data. The real-world data showed that almost 50 per cent of the population, despite being vaccinated twice, if not three times, caught COVID. You've just said it's very difficult to measure the duration. Are you going to retract the statement that the vaccine was effective, because you've basically contradicted yourself already?

Dr Thiru: Senator, the virus had approval for the prevention of infection, for the prevention of severe disease and the prevention of hospitalisation. Despite the fact that the virus had evolved, had mutated significantly, vaccination remained significantly effective against severe disease and hospitalisation for prolonged periods.

Senator RENNICK: I will move on. Thank you.

Dr Hewitt: May I say something? I actually reject your statement that people were forced to take the vaccine.

Senator RENNICK: We'll deal with that later. That's not your decision. That's not to do with today. According to the Pfizer non-clinical report, there were no carcinogenic tests, no genotoxicity tests, no immune toxicity tests, no interaction studies with other medicines and no longitudinal studies. I note that in regard to pregnancy and lactation, studies were conducted on rats. How can Pfizer say that the vaccine was unequivocally safe without qualifying any risks around the vaccine?

Dr Hewitt: I don't have that report in front of me so I'm afraid I can't talk to it. What I can say is that the TGA is one of the world's leading regulators.

Senator RENNICK: You can take my word for it. I'm happy to table this document. It clearly stated that a number of tests were not conducted. Those tests weren't conducted. I accept that we had a short time frame, but

that doesn't remove the fact that certain risks were not analysed. You never highlighted those risks when the vaccine was rolled out.

Dr Hewitt: I disagree with that statement. The Therapeutic Goods Administration is a very thorough and very competent authority perfectly able to reach a decision based on data that it reviews.

Senator RENNICK: Initially, when the vaccine was rolled out, myocarditis and pericarditis weren't recognised side effects. Does Pfizer understand why the vaccine causes myocarditis and pericarditis? If not, how can it guarantee that it is not also injuring other organs? Can you explain why the vaccine causes myocarditis and pericarditis?

Dr Thiru: I'll take that. Based on our clinical trials and pharmacovigilance data as well as real-world evidence following the distribution now of billions of doses of vaccine, we retain strong confidence in the safety profile of the vaccine.

Senator RENNICK: Chair, I raise a point of order. I have asked whether they understand why it causes these symptoms. I know that it is a low risk. I am asking whether you understand why it causes myocarditis. I want you to explain to me why it causes myocarditis. Do you understand why it causes myocarditis?

Dr Thiru: Pfizer is aware of very rare reports of myocarditis and pericarditis that have been temporarily associated with vaccination. However—

Senator RENNICK: Well, that's still ongoing for some people.

CHAIR: Senator Rennick, Dr Thiru should answer the question. Thank you, Dr Thiru.

Dr Thiru: According to public health experts and regulatory authorities around the globe, the number of reports of myocarditis remains small.

Senator RENNICK: I'm not referring to the number of reports. I want you to explain to me the mechanism of how the vaccine causes myocarditis. Do you or do you not understand the mechanism of why the vaccine causes myocarditis? It looks to me like you don't. If you don't understand it, why are you saying that the vaccine is safe without qualifying the risks?

CHAIR: Senator Rennick, I think Dr Thiru is actually about to get to that point. Whether people agree with his evidence is another question for others to make a judgement on. Dr Thiru, if you could again go to Senator Rennick's question.

Dr Thiru: All medicines, all therapeutic products and vaccines, have benefits and side effects as well. Looking at the totality of the evidence for Pfizer's COVID-19 vaccine, regulatory authorities, health authorities and experts globally, including in Australia within the department of health and the TGA, have maintained that the benefit-risk ratio—

Senator RENNICK: That's not the question I asked. I asked whether you can explain why the vaccine causes myocarditis. Yes or no?

Dr Thiru: The benefit-risk profile—

Senator RENNICK: Yes or no. You clearly don't understand the pathway, do you, because you can't explain it? I'm not referring to the cost-benefit analysis here. I'm referring to whether you understand the biochemical pathway as to why the vaccine causes damage to the heart.

Dr Thiru: Senator, I'm happy to take your question on notice and come back to the committee with whatever information we can provide. I might clarify that I was not referring to a cost-benefit analysis in my previous response. I was referring to the benefit-risk ratio. Health authorities around the globe continue to recommend the benefits of—

Senator RENNICK: This isn't the question I'm asking. Thanks, Chair.

CHAIR: Just so I can clarify as well, Dr Thiru, you have agreed to take the question on notice and give further response to that question. Is that correct?

Dr Thiru: That is correct, Chair. As I understand the question, it was about the mechanisms. We're happy to take that question on notice.

Senator ANTIC: I want to refer you to a recent study published in an Elsevier journal. It is a peer reviewed study, I believe, from late last year. I have copies here that I can tender, if you like. The cut and thrust of it, though, is that the study shows that the risks of these vaccines is greater than previously reported. It shows that, using your own publicly available data, there was one serious adverse event for every 800 vaccinations, which translates to about 1,250 serious events for every million vaccine recipients. Look at that in comparison to the rate for conventional vaccines. It is about, I think, one every one or two million. In fact, the 1976 swine flu vaccine

was withdrawn after it was associated with Guillain-Barre syndrome at a rate of about one in 100,000. But this is particularly difficult when you factor in that those at the lowest risk for hospitalisation were probably at the highest risk for serious vaccine reactions. Was Pfizer aware of these matters before it was approved in Australia? Did you alert the regulator, the TGA, to these risks?

Dr Hewitt: Senator, I'm not aware of the report that you are reading or, indeed, the article from which you are quoting. Could you just repeat your question? It was very complex. I'm not sure I fully understood it.

Senator ANTIC: Well, the question is: were you aware of the one in 800 rate of return on serious adverse events and the fact that the profile of those events damaged or affected those who are the least likely to be hospitalised prior to the drug being submitted for approval? Did you make the TGA aware of those risks?

Dr Hewitt: Again, I can't speak to that. I don't have that report in front of me. One thing I would note overall is that global regulators are continually assessing the vaccine safety data in their regions. The International Coalition of Medicines Regulatory Authorities, which is a coalition of 38 medicines regulatory authorities from every region in the world, recently released a statement. That statement was endorsed by the European Medicines Agency. It confirms the safety profile of COVID-19 vaccines. The regulators stated that the evidence from more than 13 billion doses of COVID vaccines administered worldwide showed that the vaccines have a very good safety profile in all age groups.

Senator ANTIC: Our therapeutic goods association derives something in the order of 96 per cent of its budget from industry fees. What amount of funding does Pfizer provide to therapeutic goods association per annum?

Dr Hewitt: The Therapeutic Goods Administration? Senator, yes, it's usually fee funded. So there are a couple of different ways in which the TGA is funded. There is a—

Senator ANTIC: The question is the dollar figure, not the rationale.

Dr Hewitt: I don't have that figure, Senator.

Senator ANTIC: You don't know that?

CHAIR: If you could take that on notice, it would be helpful.

Senator ANTIC: Thank you.

Dr Hewitt: We can.

Senator ANTIC: Another recent journal article in the *European Journal of Heart Failure* stipulates that the incidence and the mechanisms of myocardial injury following COVID mRNA booster vaccination was found to be more common than first thought and warranted further studies. Is Pfizer aware of this? If so, when is Pfizer going to remove this product from the market?

Dr Thiru: I might take this question. I don't have a copy of the research paper that you are referring to. It's not data that we have, so I can't comment on that specifically. What I can do is reiterate that we are aware of these very rare reports of myocarditis. We're aware that the Therapeutic Goods Administration has provided advice to vaccine administrators on how to manage that risk. We are aware that all the information available is in the approved product label. It is fully and transparently disclosed. That is a decision for individual vaccine providers to make. I might reiterate what my colleague Dr Hewitt just said. Based on the administration of over 13 billion doses of vaccine, regulatory agencies around the world have said that these vaccines remain safe in all age groups, including younger people, including people who are immune compromised and including people who have other medical conditions.

Senator ANTIC: I accept that you've been sent here to go the rope a dope like Ali and Frazier, the Thrilla in Manila, so we're not going to get proper answers out of this. I want you to answer this question. Did at any time your legal compliance teams look to the possibility that the lipid nanoparticle mRNA complexes satisfied the definitions for being properly deemed genetically modified organisms under the Australian legislation? The question is: did you examine that possibility?

Dr Hewitt: Senator, mRNA technology is not gene therapy. It does not alter human DNA.

Senator ANTIC: That is not an answer to the question. Was it examined or considered?

Dr Hewitt: Examined or considered? I'm not sure the nature of your question. Can you be more specific?

Senator ANTIC: I can't really be more specific. It was very specific. Did your legal compliance teams examine the possibility that these vaccinations satisfied the definitions for being properly deemed GMOs under the Australian legislation for the purposes of Australian legislation?

Dr Hewitt: Again, Senator, our commodity is not a genetically modified organism and does not—

Senator ANTIC: So your team did not consider that?

Dr Hewitt: Pfizer consulted with the Office of the Gene Technology Regulator and sought confirmation, in fact, that our vaccine did not fall under the Gene Technology Act 2000.

Senator ANTIC: Has Pfizer notified its underwriters of the potential for future litigation as a result of claims, or will those claims be offset pursuant to an indemnity given to the Australian government?

Dr Hewitt: I can't answer that one, Senator. I'll need to take that on notice.

Senator ANTIC: Thank you.

Senator RENNICK: Chair, I raise a point of order. I have a document here from Pfizer. I'm happy to table this. They actually state that manufacturing gene therapies in particular includes transfection, a process that uses HEK cells. So they admit on their own website that gene technology includes transfection. Transfection is a part of the COVID vaccine process. I table this document just to prove that these people are contradicting their own statements.

CHAIR: Firstly, pass it up here and we'll have a look at it. Can we just be mindful that Pfizer hasn't got a copy of this document for verification.

Senator RENNICK: Okay.

CHAIR: We've only got so much time. I would very much encourage that, if there are additional questions that may relate to this matter, we send them to Pfizer following this hearing.

Senator RENNICK: Absolutely, Chair. I'm happy to do that. I remind the witnesses to please not contradict statements on your own website.

CHAIR: The committee will circulate this and send it to Pfizer. We'll now go to another senator.

Senator HANSON: Thank you, gentlemen, for coming here. A recent peer reviewed paper in the establishment scientific journal *Vaccine* examined Pfizer's COVID vaccine randomised phase 3 clinical trial data. It used the World Health Organization framework made for this purpose. It is the Brighton Collaboration on adverse events of special interest. The authors are world leading virologist and pharmacology experts from the UCLA, Stanford, University of Baltimore and Queensland's Bond University. The paper concluded that Pfizer's vaccine was associated with a 36 per cent increase in serious adverse events. The most common were coagulation disorders, including thrombosis, and acute cardiac injury. In every 10,000 people injected, 18 will experience a life threatening or altering medical complication. Serious adverse events from the Pfizer COVID vaccine are four times higher than any benefit from the vaccine in reduced hospitalisation. The paper said that the product should never have been approved. Would you like to respond to that, please?

Dr Thiru: Senator, again, I do not have a copy of your paper. I have not examined it. I cannot comment on it specifically. What I can say is this. This benefit-risk ratio of vaccination in all age groups in all populations continues to be strongly positive. Vaccination continues to be encouraged by health authorities globally, including in Australia. The most common adverse events that are seen are local reactions—a painful arm, some redness or swelling, some muscle aches and pains, maybe a fever or some fatigue or tiredness. We take all reports of adverse events seriously. We collect that information. We analyse that information. We communicate it to regulatory agencies such as the TGA. They've pooled that data from the safety data that they receive from other sources, be it from health care professionals, patients directly or state departments of health. Their conclusion is very consistent with conclusions of other regulatory agencies around the world. That is, that the benefit-risk ratio for vaccination remains strongly positive in all indications and all age groups for which it has been approved.

Senator HANSON: Well, I want to know your response to the reported 1,476,227 adverse event reports up to December 2022, including 32,621 deaths.

Dr Hewitt: Senator, I'm not aware of the figures or the document from which you are reading.

Senator HANSON: In Australia. You don't know? You haven't read up much on all this, have you? You knew you were going to come this inquiry, yet you haven't done anything whatsoever to respond to our questions. I think it's very poor of you to not be able to answer these questions. You are a scientist. You are from science, Dr Hewitt, and you're a country doctor, Dr Thiru. I expected to have more of an answer here because we're going through dire straits. People in Australia have had adverse side effects. You say that the injection site is the main cause of adverse side effects. What I'm reading here in your figures is pages and pages of adverse side effects. You know what most of this comes up with? Nervous system disorders. There are thousands upon thousands of people affected, be it with lethargy or headache. You've got other problems here with them. Another one that really concerns me is to do with reproductive system and breast disorders. Did you state to the TGA the impact that this drug would have on pregnant women?

Dr Thiru: Senator, firstly, I reject the premise of your question in terms of those safety findings that you have communicated. It's very important to note the difference between an adverse event that has been reported and an adverse reaction that has been actually attributed to the product. The TGA carefully analyses all of the reports that it receives and makes a determination as to whether there is a causal link to therapeutic product or not. This is not something different for vaccines. This happens with all therapeutic products. In terms of your specific question about pregnancy, all of the information that we have has been communicated to the TGA. I draw your attention to the approved product label for the product. It says that there is limited clinical trial evidence in pregnant women and that it should be the subject of an informed decision between a woman and her physician or vaccine provider. That animal data has not suggested any untoward effects on pregnancy, on foetal development, on childbirth and on postnatal development. I might add that expert groups have said this about vaccination in pregnancy. The Australian Technical Advisory Group on Immunisation has recommended that if you are pregnant, you can get vaccinated with the Pfizer vaccine at any stage of pregnancy. They have also said real-world evidence has shown that the Pfizer vaccine is safe if you are pregnant and breastfeeding. If you are pregnant and unvaccinated, you have a higher risk of severe illness from COVID-19. Your baby may also have a higher risk of premature birth. That is one group of experts.

Another group of experts, and probably the most august authority in this area, is the Royal Australian and New Zealand College of Obstetricians and Gynaecologists. This is the peak body of obstetricians, the doctors who have spent their lives training and are specialised in the care of pregnant women. They have said that pregnant women in Australia are a priority group for COVID-19 vaccination and should be routinely offered the Pfizer vaccine Comirnaty or Moderna Spikevax at any stage of pregnancy. They have said there is no evidence of increased risk of miscarriage or teratogenic risk with mRNA or viral vaccines. It is very clear that experts who have spent their lives and are dedicated to examining this data in pregnant women have come to that conclusion.

We continue to take all reports of adverse events, whether pregnancy related or otherwise, very seriously. We work with the TGA and other regulators around the world to further characterise the vaccine. Based on the information that is available at the moment, that is the recommendation of expert authorities.

Senator HANSON: You are still on trial with this drug, aren't you? Any other drugs that are actually introduced into our society usually go through 10 years of testing. When the pandemic was announced by the World Health Organization, you said within six days you started doing trials into it. You started the vaccination, which you said came out a year later. It was passed. What trials had you done prior to that? What trials had you performed to ensure the full safety of this drug on the people of the world?

Dr Thiru: Before I hand over to my colleague Dr Hewitt, let me just correct the record. I did not say that any vaccination or clinical trial was done within six days. I said we signed—

Senator HANSON: No. I didn't say it wasn't done. You responded to the World Health Organization six days later. A year later, you produced the drug.

Dr Thiru: We signed a contract. We signed an agreement with another company BioNTech to research the vaccine. That proceeded over the year. I might ask my colleague Dr Hewitt to talk about the clinical trial program.

Dr Hewitt: Sure.

CHAIR: Dr Hewitt, just before you start answering, Senator Hanson, there's obviously an opportunity for a follow-up question after this.

Dr Hewitt: Given then urgent public health need to responsibly develop a vaccine with a favourable safety profile, we collaborated very closely with independent regulatory and health authorities around the world. That allowed us to conduct key activities in parallel to significantly accelerate vaccine development without compromising safety.

Senator HANSON: But—

Dr Hewitt: One of the reasons—

Senator HANSON: Go on.

Dr Hewitt: No, Senator. You go.

Senator HANSON: Right. This is the last question. You're both Australians. You live here. Were you in the country during COVID-19?

Dr Hewitt: Yes, Senator, I was.

Dr Thiru: Yes.

Senator HANSON: Okay. Dr Thiru, you made a comment that no-one was forced to have the vaccination. Who made the comment? Was it Dr Thiru?

Dr Thiru: I believe I made that comment.

Senator HANSON: You made that comment. You were in Australia during COVID-19. You must have been fully aware that people—nurses, doctors—to keep their jobs were forced to have the vaccination. Do you retract your statement that they were not forced?

Dr Thiru: No. I believe firmly that nobody was forced to have a vaccine. Mandates for vaccine requirement are determined by governments and health authorities. I believe everybody was offered an opportunity to get a vaccine or not get a vaccine. I don't believe that anybody was forced to take a vaccine.

Senator HANSON: A lot of Australians will disagree with you on that one.

Senator GROGAN: I appreciate that you have been presented with a range of extracts from reports. Are you aware of how many academic and situational reports have been published on COVID-19 since the beginning?

Dr Thiru: I'm not aware. I would imagine it would be a very large number.

Senator GROGAN: I had a quick search on Google. I got 23,500. That is an interesting point. Obviously, through that there are quite a lot of different perspectives, some of which have been fleshed out here. I understand that one of the great benefits of the mRNA technology is that you can quickly adapt the vaccine to respond to new variants. What other benefits could it present to vaccine development and medicine development in general?

Dr Thiru: Thank you, Senator. You are correct that the major benefit is that vaccines can be adapted very quickly. That is exactly what we're doing to respond to new variants that are emerging. For example, we were very quickly able to produce a BA.4 and BA.5 vaccine, which is now currently available and being used in Australia to provide protection against the Omicron variant. We are also now working on developing a vaccine against the XBB variant. There has been a request from regulatory agencies around the world for us to focus on that for our next vaccine. We've already commenced research. So processes that normally can take much longer can be now completed within some months. We can develop a new vaccine within 100 days of identifying an actual strain that we are targeting. So we are aiming to deliver that XBB variant vaccine by October in the United States and some time after that in Australia.

If we move potentially beyond vaccination, mRNA technology holds a tremendous amount of promise in other non-infectious diseases. That is whether we are talking about specific types of cancers or other autoimmune diseases, essentially where there's a protein that's missing or not functioning correctly and you can use the body's own protein factory to produce the desired protein. Potentially, it holds a lot of promise. Pfizer and many other companies are looking to see how this technology can be leveraged to address the immense unmet medical need in cancer, in autoimmune diseases as well as other infectious diseases at the moment.

Senator GROGAN: Thank you. I do have other questions. I'm going to put most of them on notice because we are tight on time. I would like to say since the workplace mandates have come into force—obviously, we are not looking at very much of that any more—Pfizer has developed an antiviral to treat COVID infection. Is that correct?

Dr Thiru: That is correct. We were proud to develop an effective antiviral agent for people who are most at risk of severe disease. Vaccination remains the primary first-line defence against severe disease or hospitalisation. There are people who are particularly at risk of a poorer outcome should they contract a COVID infection. That could be due to age—being over 50, 60 or 70 years—having chronic health conditions with heart, lung, kidney, liver disease or diabetes, being in a residential care facility or having a disability or other complex health needs. Those people can be treated early with an antiviral agent such as Paxlovid, which is Pfizer's agent. It's essentially a take home pack, a five-day course of pills similar to an antibody. It substantially reduces the risk of the disease progressing to severe disease that may require hospitalisation. The pivotal clinical trial that was submitted to the TGA that led to that organisation authorisation for distribution in Australia demonstrated a 90 per cent reduction in the risk of hospitalisation and death. So that has immense potential to mitigate the burden of disease of COVID-19 that is still ever-present in our community.

Senator GROGAN: Does it provide sufficient protection for people who are hesitant or antivaccine?

Dr Thiru: I said at the start that vaccination remains the primary first line of defence against severe COVID-19 and hospitalisation. This is a second line defence or another option for people potentially who weren't able to be vaccinated. It has demonstrated that it has a substantial effect on improving or mitigating that risk of severe disease and hospitalisation.

Senator GROGAN: Thank you very much. I'll put the rest of my questions on notice.

Senator O'SULLIVAN: I have a quick question. Dr Hewitt, I looked at all the information before me, as every other Australian had the opportunity to do, to get vaccinated. I decided that getting vaccinated was the right thing for me. I am fully vaccinated. There are many Australians who, looking at that information, didn't believe the vaccination was right for them. I'm from Western Australia. In Western Australia, vaccines were mandated essentially across the entire population. There were a few exceptions. There were very few exceptions. If you wanted to go to work and earn a living and provide for your family, you had to be vaccinated. Based on your evidence, I'm staggered that was the response you gave earlier to questions in relation to whether or not people were forced to have vaccines. If you had to make a choice between paying your mortgage and putting food on the table for your family, you can hardly say that those people were not forced. They were making choices. There were plenty of people who were forced to do it. There were some in Western Australia—I've had so many who have contacted me—who had to go without because they chose not to be vaccinated. The state government forced them to be vaccinated, frankly. What do you have to say to that?

Dr Hewitt: Mandates or vaccine requirements are determined by governments and health authorities. As a company, we were not involved in the development of any government vaccine mandates.

Senator O'SULLIVAN: But they didn't have the same opportunity. You said that they had the opportunity to be vaccinated. Well, there were people who had the opportunity to not pay their mortgage and they chose to not be vaccinated.

Dr Hewitt: Is there a question there, Senator?

Senator O'SULLIVAN: Do you still stand by your original statement that you made a few minutes ago?

Dr Hewitt: The mandates for vaccine requirements are determined by governments and health authorities. I don't believe that the mandates actually forced individuals to get vaccinations.

Senator ROBERTS: Thank you, Dr Hewitt and Dr Thiru, for being here. You have repeatedly refused to provide evidence. You've dodged questions on evidence from Senator Canavan and from Senator Rennick. You have relied instead on appeals to authority and other logical fallacies, including an appeal to authority. Let's talk about one of your experts, the health minister. The former health minister in this country said, 'We're engaged in the world's largest clinical vaccination trial.' It's experimental, in his view. He was the health minister that introduced these things. Let's go to the first question. What we've seen during the COVID mismanagement and malfeasance was the largest transfer of wealth in our nation's history from we the people to big pharma via big government that lied repeatedly during the COVID mismanagement. My question is: did you ask the minister to introduce vaccine mandates for employment?

Dr Thiru: Senator, I reject the premise of your question. We have—

Senator ROBERTS: Did you or did your company ask the minister to introduce vaccine mandates for employment?

Dr Thiru: Senator, I reject your question and your accusation. We had no involvement.

Senator ROBERTS: I made no accusation, Dr Thiru. I asked you a question.

Dr Thiru: I was referring to your previous comments as well when you mischaracterised the evidence base for the vaccine. We have covered that previously. What I can confirm is that we have had not had any discussions. We have not been involved with any governments or any other organisations in relation to vaccine mandates. That is a matter for government. That is a matter for law makers. That is not a matter for Pfizer.

Senator ROBERTS: Did you ask the health department or one of their agencies for vaccine mandates?

Dr Thiru: I believe I have clearly communicated the position on that. Pfizer had no involvement and has no involvement in the imposition of vaccine mandates.

Senator ROBERTS: Did you ask anyone in or near a government or a department to ban Ivermectin?

Dr Thiru: Pfizer has had no involvement and no—

Senator ROBERTS: Thank you.

Dr Thiru: discussion in relation to Ivermectin.

Senator ROBERTS: Does the indemnity you have with the government extend to providing you with indemnity in a situation where an employee is forced by their employer to undergo vaccination and then experiences harm? If you do have indemnity, I want the proof.

Dr Thiru: Any indemnity agreements between Pfizer and the Australian government are confidential. We are not able to discuss that in this forum.

Senator ROBERTS: Why are they confidential? As a taxpayer, I paid for those injections even though I didn't take any. Why are they confidential from 26 million Australians? What are you hiding?

Dr Thiru: Indemnity agreements between the Australian government and private organisations such as Pfizer are confidential. We are not at liberty to discuss that.

Senator ROBERTS: Why are they confidential? The people who paid for these injections cannot see what they've actually bought. Why are they confidential? Why are you hiding?

Dr Thiru: Those indemnity agreements—indeed, contractual arrangements, as is always the case, between the Australian government and external parties—are confidential. I don't have any information today that might assist the committee in relation to that.

Senator ROBERTS: Did Pfizer have COVID vaccine mandates for your own employees in Australia?

Dr Thiru: At the height of the pandemic and consistent with guidance from health authorities from the New South Wales and Victorian governments, Pfizer did have a colleague vaccination program for its employees.

Senator ROBERTS: Do you still have it?

Dr Thiru: That vaccine requirement for colleague vaccination for Pfizer employees is currently present. We introduced a colleague vaccination program in the interests of protecting the health and safety of our colleagues and the communities in which we operate.

Senator ROBERTS: We've read that your vaccine mandate was using your own batch of vaccine especially imported for Pfizer which was not tested by the TGA. Is that correct?

Dr Hewitt: Pfizer undertook to import our batch of vaccines specifically for the employee vaccination program. That was so that no vaccine would be taken from government stocks. It was being delivered to clinics as needed.

Senator ROBERTS: Thank you. Did you enforce your mandate on your colleagues, your employees? Did you enforce it? Did you sack anyone or refuse to pay anyone who refused to take the injection?

Dr Thiru: We aligned with the public health guidance. We permitted accommodations or exemptions for people who had specific medical or religious reasons that they did not or could not be vaccinated. A small number of colleagues departed the company.

Senator ROBERTS: Thank you. Does your contract with the government for the supply of COVID injections include a clause that negates your indemnity in the event of Pfizer committing a crime such as fraudulent treatment of trial data?

Dr Thiru: Pfizer always abides by all of the laws and regulations of the markets in which it operates. It abides by the highest standards for clinical trials and all its operations.

Senator ROBERTS: Does your contract with the government for supply of COVID injections include a clause that negates your indemnity in the event of Pfizer committing a crime such as fraudulent treatment of trial data?

Dr Thiru: I hadn't—

Senator ROBERTS: The question is simple. What is the answer? Yes or no?

Dr Thiru: As I have mentioned previously, the contents of Pfizer's contract with the Australian government remains confidential. I don't have any information that I can provide to the committee in relation to that.

Senator ROBERTS: Is it true that Pfizer COVID-19 vaccines were developed initially as countermeasures for the American Department of Defense?

Dr Thiru: Our sole focus from the start of this pandemic has been to discover, develop and supply a safe and effective vaccine—

Senator ROBERTS: I didn't ask you about your focus. I asked you whether it is true that Pfizer's COVID-19 injections of vaccines were developed initially as countermeasures for the American Department of Defense, as experts have told us. Is it true?

Dr Thiru: The vaccine was developed to address the dire global public health emergency that became rapidly apparent in the early part of 2020. That was the only reason for which the Pfizer vaccine was developed. We're very proud of the role that the Pfizer vaccine has demonstrated clearly in protecting the health of hundreds of millions of people around the world and enabling countries, borders and societies—

Senator ROBERTS: There you go again—another appeal to authority, another appeal to consensus and an appeal to numbers. That's not what I asked. Have you had any association during the development of these vaccines with the Department of Defense?

CHAIR: Just before you answer that, Dr Thiru, there is a follow-up question after this answer.

Dr Thiru: I have no information on that. I'm happy to take it on notice. Let me confirm again that the sole purpose of developing the vaccine was to protect global public health.

Senator ROBERTS: Isn't it true that many standard steps and procedures otherwise required before receiving approval for use were omitted or circumvented entirely to achieve this accelerated time period of development that you talked about of 12 months?

Dr Hewitt: The evidence that was gathered and presented not just to the Therapeutic Goods Administration but to regulators worldwide was thorough and comprehensive. It was assessed by those regulators, who made independent decisions on the benefit-risk profile of the vaccine.

Senator ROBERTS: I notice that you have repeatedly transferred the responsibility for these injections to the TGA. Repeatedly you've done that. Did Pfizer research the long-term effects and risk profile of its COVID-19 vaccine prior to release? Long-term?

Dr Hewitt: Again, as part of an application to any regulatory authority, the data that we gather and present are used to determine whether or not the regulatory authority feels that the medicinal product may be licensed and supplied to patients.

Senator ROBERTS: Again, you have failed to answer my question. You are shifting responsibility to the TGA. I will be asking the TGA.

CHAIR: If there's another answer to that, please proceed. I don't think there was a question in that. If there are further questions, you can give them on notice. I know that Senator Payman said that she will put her questions on notice in light of the time. I know there is a quick follow-up question from Senator Antic.

Senator ANTIC: You can take this on notice if you would like. I remind you that providing correct evidence to the Australian Senate is critical. I want to know whether or not Pfizer had any communications with any Australian government department or social media company in relation to the censorship of Australians' social media posts.

Dr Thiru: Senator, I have no information in relation to your question.

Senator ANTIC: You may not, but I would like you to take that on notice.

Dr Thiru: We will take it on notice and come back to the committee with any information of relevance that we can provide.

Senator ANTIC: Thank you.

CHAIR: Thanks very much. Dr Thiru and Dr Hewitt, thank you for—

Senator CANAVAN: I have one more question.

CHAIR: If it's a quick follow-up.

Senator CANAVAN: Very quickly. I want to ask a quick question about the Doherty modelling, which was crucial in convincing Australian governments to impose mandates in late 2021. In that modelling—I'm sure you are familiar with the Doherty modelling—they concluded:

High vaccine coverage can reduce transmission and health impacts in urban and remote communities.

Was Pfizer consulted by any of the modellers that compiled the Doherty modelling report for the Australian national cabinet?

Dr Hewitt: I can't answer that question. I will need to take that on notice.

Senator CANAVAN: Take that on notice. In particular, can you take on notice whether you provided any advice to Doherty modelers around the effectiveness of your vaccine in reducing transmission?

Dr Hewitt: Noted.

Senator CANAVAN: Thank you. Thank you, Chair.

CHAIR: Thanks very much. Thank you for joining us this evening and having a robust engagement. If you have taken any questions on notice, please return the answers to the secretariat by 17 August 2023. Have a good evening. Thank you.

Dr Hewitt: Thank you, Senator.

Dr Thiru: Thank you, Senators.

CLARKE, Dr Chris, Director, Scientific Leadership, Moderna [by video link]

DAWSON, Dr Rachel, Executive Director, Medical Affairs, Respiratory Vaccines, Moderna [by video link]

LEONG, Dr Jane, Vice President, Medical Affairs, Moderna [by video link]

[18:12]

CHAIR: I now welcome representatives from Moderna Australia via video conference. I understand that information on parliamentary privilege and the protection of witnesses giving evidence to Senate committees has been provided to you. I now invite you to make a short opening statement. At the conclusion of any remarks, I'll invite members of the committee to ask questions.

Dr Leong: Thank you, Chair and members of the committee. Moderna values the opportunity to participate in this inquiry and to highlight the critical role that vaccines have played in preventing severe illness and death throughout the COVID-19 pandemic. Since 2020, the COVID-19 pandemic has claimed an estimated seven million lives worldwide. These deaths are not simply statistics. They represent far-reaching loss and suffering for much loved parents, grandparents, colleagues and friends. The pandemic at its outset and still today continues to have profound and long-term impacts on families, communities and economies. In fact, this year alone, 4½ thousand Australians have lost their lives to COVID-19, a staggering figure. However, without the development of vaccinations against COVID-19, the situation could have been significantly worse. Worldwide, it is estimated that over 13 billion COVID vaccine doses have been administered and that over 72 per cent of the world's population has received at least one dose. So 1.5 billion of those vaccines have been a Moderna mRNA vaccine.

Recent global modelling on the impact of COVID-19 vaccination has shown that, based on officially reported COVID-19 deaths, these vaccines prevented an estimated 20 million deaths from COVID-19 in 185 countries between December 2020 and December 2021. In Australia, 68 million COVID-19 vaccine doses have been administered since they became available. Over six million Moderna Spikevax original or Spikevax Bivalent vaccines have been administered. Moderna is proud of the contribution we have made, and continue to make, towards reducing the toll of COVID-19 on the community.

Following the declaration of COVID-19 as a global pandemic by the World Health Organization in March 2020, developing vaccines was the top priority of governments, medical researchers and the wider global community because it was promptly recognised that control of the pandemic would require safe and efficacious vaccines. Moderna was able to leverage its decade of research and investment in the mRNA platform to develop a vaccine that would activate the body's immune response and prevent severe illness and death from the virus. Prior to its approval by regulatory agencies around the world and subsequent delivery to the community, our vaccine underwent rigorous and comprehensive clinical trials to demonstrate that it met internationally agreed benchmarks for safety and efficacy. These trials involved tens of thousands of participants and followed well-established protocols and guidelines to assess the safety, efficacy and side effects of the vaccine. The data from these trials has been assessed by regulatory agencies around the world, including the US Food and Drug Administration, the European Medicines Agency and Australia's Therapeutic Goods Administration, all of which have authorised the Moderna COVID-19 vaccine for use.

Once authorised for use, all vaccines are monitored continuously by the regulatory authority and by the sponsor. Monitoring is conducted to assure that health care authorities, providers and patients have up-to-date information about product safety. Measures such as updates to product labelling are implemented when appropriate and serve to provide accurate information about vaccine safety. This is true for all authorised vaccines. In addition, every single batch of Moderna's COVID-19 vaccine that arrives in the country is firstly tested by the TGA for quality to ensure that it meets expected standards before it can be released and delivered to the community.

CHAIR: Dr Leong, we are quite short on time. Have you got less than 30 seconds?

Dr Leong: Yes, I have.

CHAIR: If there are other words in the statement, we're happy to take the statement and put it on record.

Dr Leong: I'm happy to conclude. In terms of the bills the committee is inquiring into, as a company that is focused on developing and producing vaccines, Moderna believes the issue of vaccine administration policy is for policy makers. However, we are able to provide senators with information about the development and production of our vaccine which may be relevant to this inquiry. On issues relating to the development of public health measures during the pandemic, departments of health at the federal, state and territory levels are best positioned to address these questions. Moderna thanks the committee for its interest and welcomes the opportunity to highlight

the role of vaccines in overcoming this global crisis and creating a safer world that is healthier for us and future generations. Thank you, Chair.

CHAIR: Thank you.

Senator RENNICK: My first question is about the weight of Moderna. The dose was 100 microns. Is that correct?

Dr Clarke: Yes. That's correct. It is a 100 microgram dose.

Senator RENNICK: Thank you. Can you explain why that is almost three times bigger than the Pfizer weight of 30 microns? Pfizer used 30 microns and Moderna used 100. Why the difference in weight?

Dr Clarke: I cannot speak to the dose selected by Pfizer for their vaccine. I can tell you that we studied a variety of doses in early phase clinical trials. We selected the optimal dose based on the results of those early studies.

Senator RENNICK: If you have the optimal dose, what has Pfizer got, then?

Dr Clarke: I can't comment on other companies' products. They obviously have access to information about their products that I don't have.

Senator RENNICK: Does Moderna use the same mRNA sequence as the Pfizer mRNA sequence? I'm led to believe that Moderna used two stop codons and Pfizer used three stop codons. Is that correct?

Dr Clarke: I think the sequence is very similar.

Senator RENNICK: But there were differences, weren't there?

Dr Clarke: There are differences in the overall vaccine composition.

Senator RENNICK: Tell me this: how is it that you're both coding for the same spike? You're clearly not coding for the same spike protein, then, are you, if you are using a different code to what Pfizer is. The alpha variant has a specific genetic sequence. One of you two aren't coding to that sequence, if not both of you.

Dr Clarke: Again, I can't speak for the Pfizer product. We are aware that the sequence we have used corresponds to the spike protein of the ancestral strain of the virus. I refer you to Pfizer to ask about the sequence that they used.

Senator RENNICK: Does the Moderna mRNA use uridine or methylpseudouridine?

Dr Clarke: Methylpseudouridine.

Senator RENNICK: That is not mRNA, is it? That's modified RNA?

Dr Clarke: It's modified RNA; that's correct.

Senator RENNICK: Because everyone called it mRNA, but it's not really, is it?

Dr Clarke: It is a modified mRNA, so it is messenger RNA.

Senator RENNICK: That's right. And Pfizer say that they used that particular nucleotide to increase the expression of the actual vaccine. So that would make the vaccine stronger, not weaker, than the virus. Is that correct?

Dr Clarke: I can't comment on Pfizer's products. I suggest—

Senator RENNICK: Let me put it another way. Why did you use methylpseudouridine and not the natural substance uridine?

Dr Clarke: Moderna spent 10 years optimising the use of different types of RNAs. It was found that methylpseudouridine has improved properties.

Senator RENNICK: You can take this on notice. Did you do distribution and degradation studies on that methylpseudouridine?

Dr Clarke: I will have to take that on notice.

Senator RENNICK: I know Pfizer didn't do that. One of the side effects of the Moderna vaccine is myocarditis. I didn't have much luck with Pfizer. Can you explain why the Moderna vaccine causes myocarditis in young people? I want to understand the pathway.

Dr Clarke: What we do know is that myocarditis has been reported in rare circumstances after—

Senator RENNICK: I realise that. That's not my question. Do you understand why it causes the injury?

Dr Clarke: I just want to explain that myocarditis is observed after RNA vaccines and non-RNA COVID-19 vaccines as well as after COVID infection. In fact, it's much more frequent after COVID infection. That does give

some clues towards what the mechanism might be. We have put in place a number of studies to further investigate the cases of myocarditis that occur after vaccinations with Spikevax.

Senator RENNICK: So do you think there's a risk that the vaccine could induce a killer T-cell response that attacks healthy cells in the heart?

Dr Clarke: That is a speculation. I couldn't comment on that.

Senator RENNICK: Isn't that the point of the whole vaccine—to induce antibodies and T-cell responses?

Dr Clarke: Indeed, it has been demonstrated that the vaccine does induce a strong neutralising antibody response to this spike protein. We also see cellular immunity.

Senator RENNICK: Are you saying that the Moderna doesn't cause a T-cell response, because the Pfizer one does?

CHAIR: Just before you answer, Senator Rennick, you have one more question after this.

Senator RENNICK: Thanks, Chair.

Dr Clarke: No. I did state that neutralising antibodies and a cellular immune response—

Senator RENNICK: What percentage of profits does Moderna plough back into helping people who are injured by the vaccine?

Dr Leong: We are aware that there is an indemnity for COVID-19 suppliers. But indemnity is a policy matter for government to decide. I can't comment.

Senator RENNICK: So Moderna doesn't put any of its profits back into helping the victims of injuries from the Moderna vaccine. Is that correct?

Dr Leong: Moderna is a company that is focused on manufacturing vaccines. The matter of indemnity for vaccine suppliers is a matter for government. I can't comment.

Senator RENNICK: So you're not prepared to underwrite the risk of your own vaccine? You're not prepared to actually put money where your mouth is when it comes to the safety of your vaccines. Is that correct?

CHAIR: Just before you answer this question, Senator Rennick, I will have to go to Senator Antic after this answer is given.

Senator RENNICK: That is the last question.

CHAIR: Back to you.

Senator RENNICK: Just yes or no. You're not prepared to underwrite the safety of your own vaccine?

Dr Leong: We take the safety of our vaccines very seriously. We have a very good pharmacovigilance process in place. In fact, it is a comprehensive one. However, I would only reiterate that indemnities are a matter for policy makers.

Senator RENNICK: What about a moral and social conscience of putting some of your profits back into helping victims of the vaccine? Is it zero dollars?

CHAIR: Dr Leong, just before you answer that, I appreciate—

Senator RENNICK: It's just that she's not answering, Chair.

CHAIR: I respect your asking the questions. I want to make sure we can get to Senator Antic and keep to our timetable.

Senator RENNICK: I will take that as a zero. Thank you.

Senator ANTIC: I referred earlier to a report from an Elsevier journal and tabled it. It was a recent report from the end of last year. It found that serious adverse reactions are occurring at a rate of one in 800 people vaccinated. According to your own clinical trial data, do you accept that is the rate? If not, how does your overall rate of serious adverse events compare with routine traditional vaccine products such as flu vaccines and the like?

Dr Clarke: I'm not aware of the report to which you are referring.

Senator ANTIC: This is the report of a prominent medical journal. You are not aware of it?

Dr Clarke: I'm not aware of it.

Senator ANTIC: Do you think you should be aware of it?

Dr Clarke: I think if you provide that report, we could provide—

Senator ANTIC: This is part of the frustration of this process. If you were here, we could provide you with it. This has been widely reported. You are a manufacturer of vaccines. I find it difficult to think that you wouldn't be aware of this report.

Dr Clarke: One thing I can say is that, as a company, as part of our pharmacovigilance activities we do routine screens of the literature to look particularly for publications that include adverse events. We do review those publications and those adverse events. We do include them into our global pharmacovigilance database. That manuscript would have been assessed by our pharmacovigilance department. The information from it would have been taken into account in evaluating the benefit-risk profile of our vaccine.

Senator ANTIC: What is Moderna's overall rate of serious adverse events? How does it compare with routine vaccinations? That is the question.

Dr Clarke: I don't have the actual rate of adverse events.

Senator ANTIC: You don't have the rates of adverse events in front of you?

Dr Clarke: I can refer to the product information. What I can tell you is that the rate of serious adverse events in our very large randomised control trials was actually in a similar range to what was observed in the placebo.

Senator ANTIC: But you can't tell me the rates of serious adverse events. You realise that you've come to a Senate hearing today for the purposes of exactly that question and you can't tell me the rates of serious adverse reactions to your product, which I find extraordinary.

Dr Clarke: What I can tell you is that on the TGA website it reports there are 1.2 reports per—

Senator ANTIC: That is the TGA. I'm not asking about the TGA. I'm asking about Moderna. You must have that information. You are a multinational company. You are before a Senate inquiry. You cannot tell me the rates of serious adverse events. It is quite extraordinary what you are telling me. Nobody can tell me that?

CHAIR: Dr Clarke—

Dr Clarke: I can provide that information on notice. What I can tell you is that in our clinical trials we observed no safety concerns. There were no imbalances of serious adverse events of special interest or deaths between the vaccine group and the placebo group.

Senator ANTIC: Chair, I think we're wasting our time here. Thank you. You can have the call back.

CHAIR: Thank you, Dr Clarke, for taking that on notice as well.

Senator PAYMAN: Thank you for appearing before us tonight. I am curious to know whether you have any specific modelling to show how many lives have been saved during the pandemic from the vaccination.

Dr Dawson: Yes. I can respond to that. The evidence of the benefits of the vaccination demonstrated that there were 13 billion doses of vaccines administered worldwide, of which 1.5 billion were Moderna vaccines, with an estimated 20 million lives saved in the first year alone.

Senator PAYMAN: Thank you. In the interests of time, I will put the rest of my questions on notice. Thank you.

Senator HANSON: How long before you released your vaccine on the public did you go into trials?

Dr Dawson: Your question is how long? Can you repeat the first part of the question?

Senator HANSON: How long since the invention of the vaccine did you go through trials before it was actually released on the public?

Dr Dawson: First of all, it was over a decade of Moderna research into mRNA platform. This allowed the vaccine to be developed within 11 months due to the culmination of the years of research and government agencies and researchers coming together to make vaccines that saved millions of lives during the pandemic.

Senator HANSON: You are talking about 10 years or 11 years before COVID-19 was a new virus released on the world. How could you actually do that? When were your trials on this actual vaccine that you produced as Moderna that was given to the public? How could you have possibly known that 10 years beforehand?

Dr Dawson: What I actually stated is that there is over a decade of Moderna research into the mRNA platform that allowed us to develop the COVID-19 vaccine.

Senator HANSON: What tests were done on people with that specific vaccination before it was released on the public? That is regardless of what you started 10 years ago or prior to that. With regard to the vaccine given to the public, when were your trials conducted and over what period of time?

Dr Dawson: The trials were conducted worldwide over the course of the 11 months that I mentioned, with over 30,000 individuals having received the vaccine in that time period.

Senator HANSON: Usually when you bring a new vaccine on to the market, here in Australia, it is actually between seven to 10 years that it must be trialled and tested before it is actually allowed to be given to the public. Why was yours passed in such a short period of time, over 11 months, to be released on the public?

Dr Dawson: That is because of my first comment. The fact is that the mRNA platform was studied for over a decade. This allowed this vaccine to be made within the 11-month time period. I remind you of the culmination of the years of research of government agencies and researchers, who came together to make the vaccines that saved millions of lives.

Senator HANSON: There are thousands upon thousands of people. I have pages and pages of adverse side effects from people having Moderna. What is very disturbing is people who have reproductive system and breast disorders. What tests were done there?

Dr Dawson: Dr Clarke?

Dr Clarke: As Dr Dawson has said, we conducted very large randomised control trials. There were more than 40,000 people together in the studies. And 25,000 of those people did receive the vaccine during those studies. We collected all of the adverse events during those studies. Subsequently, in post marketing, we continued to collect data through our pharmacovigilance network. We are also aware that the TGA collects those events as well. We reconcile them to make sure that none of them are missed. We have a safety signal detection system when both we and the TGA do this kind of activity. When we identify safety signals, we do update them into the product information. At this point in time, we haven't identified any safety signals with regard to what you are asking.

Senator HANSON: Senator Rennick asked you whether there was any compensation paid from Moderna to the people of Australia who have been affected with adverse side effects and death. What do you say to those people who have had adverse side effects from your Moderna or those who have actually died?

Dr Leong: Indeed, it is a matter of public record that the Australian government provided indemnities to vaccine suppliers.

Senator HANSON: I'm not asking about what the Australian government did. What do you personally say to these people in Australia who have had adverse side effects or miscarriages? They've had ongoing health problems and possibly will for the rest of their life. I am pulled up constantly when I'm out in the public with people telling me about the problems they've had after being forced to have these injections. People have also lost their loved ones. I have a 21-year-old who died after having the Moderna and a Pfizer vaccinations. I will be truthful that she had both of them. What do you say to those people?

Dr Leong: Firstly, in any circumstances of loss or death, we clearly convey our condolences to the families. I would only say that indemnities are a matter of policy for the government. I can't provide further comment on that.

Senator HANSON: People in this country are still being forced to have the vaccination in order to work. There are people who are out of work and won't be employed because they've been forced to have the vaccination. Do you believe that today, when we are past the pandemic, people should be forced to have this vaccination?

Dr Leong: Moderna is the manufacturer of vaccines. We focus on manufacturing vaccines. We do not have a view on decisions taken by public health agencies or governments in relation to vaccine mandates. This is purely a matter for policy makers.

Senator HANSON: Do you back your product to the hilt that it should be given to people in order to work? Do you support your product that it will not have any adverse side effects or death on the Australian people?

Dr Leong: Our product has been tested extensively and has been reviewed. All the data has been reviewed by the Therapeutic Goods Administration. Again, I reiterate that we make vaccines. We are focused on making vaccines. We do not have a view on vaccine mandates.

Senator HANSON: Thank you, Chair.

Senator ROBERTS: Thank you for appearing today. In Australia, there was a significant rise in excess deaths. At April 2023, it was 27 per cent in excess of the normal level. That is a likely 30,000 excess deaths per year, mostly not due to COVID. As the injections increased, the deaths increased. As the injections decrease, the deaths decrease. Can you suggest an explanation?

Dr Clarke: I'm not sure what data you are referring to.

Senator ROBERTS: The Australian Bureau of Statistics.

Dr Clarke: I read the report from the Australian Bureau of Statistics that looks at deaths and excess mortality up to the end of the first quarter of 2023. When I read that report, I noted that in 2020 and 2021 excess mortality was either within the normal range or slightly below. In 2022, we do see that there is excess mortality outside the normal range. In fact, it does appear to be actually due to the SARS-CoV-2 infections because the period of excess mortality does correlate with spikes in disease activity. The ABS did an additional analysis where they subtracted the number of COVID deaths from the total number of deaths. When they did that, the mortality rate was actually within the expected range. So it suggests very clearly that the excess mortality that we observed in 2022 was actually due to the virus.

Senator ROBERTS: I notice that in 2021 after the injections were introduced there is a growing increasing trend in deaths. Thank you for that answer.

Senator RENNICK: I raise a point of order, Chair.

CHAIR: I will go to Senator Canavan, who has some questions.

Senator CANAVAN: How many doses of the Moderna vaccine have been delivered in Australia this calendar year?

Dr Clarke: I would have to take that on notice.

Senator CANAVAN: Could you take on notice how many were delivered last year as well for the full calendar year 2022?

Dr Clarke: Yes.

Senator CANAVAN: Finally, has Moderna done any studies on the effectiveness of your vaccine in stopping or reducing the transmission of the COVID-19 virus?

Dr Dawson: I can respond to that. As mentioned earlier, COVID-19 vaccines were primarily designed to protect individuals from COVID-19 infection, so the disease, hospitalisations and deaths. They have actually very effectively done so. However, I can add that the COVE study, which was our large phase 3 study used for licensure of Spikevax early in the pandemic, demonstrated that vaccination with the primary series not only helped to prevent severe infections and mortality but also prevented milder and even asymptomatic infection. The importance of that is that prevention of asymptomatic infections can make an important contribution to reducing viral transmission.

Senator CANAVAN: When was that study completed?

Dr Dawson: This was the phase 3 study early on. It was the very first study that led to the licensure of the vaccine.

Senator CANAVAN: Excuse my ignorance, but what does 'early on' mean? Late 2020? Early 2021?

Dr Dawson: In 2020.

Senator CANAVAN: Have you done any further studies with real-world data?

Dr Dawson: The real-world data, there has been a systematic review and metanalysis evaluating the spread of infection to family members, which is called the secondary attack route by vaccination status. It found evidence of a reduction in infectiousness from breakthrough cases of fully vaccinated individuals. Actually, our studies have investigated viral load and viral shedding in breakthrough cases. The exploratory analysis suggested that viral load was around a hundredfold lower and the duration of shedding was shorter in vaccinated individuals.

Senator CANAVAN: When was that study completed?

Dr Dawson: This was in 2021.

Senator CANAVAN: When in 2021?

Dr Dawson: I would have to get back to you with that answer.

Senator CANAVAN: Are you doing any ongoing investigations on this matter?

Dr Dawson: Moderna continues to do ongoing investigation on this topic.

Senator CANAVAN: On the transmission?

Dr Dawson: Yes.

Senator CANAVAN: Will that be publicly released? On notice, can you provide us the most recent findings that you have on that?

Dr Dawson: Yes.

Senator CANAVAN: To me, as a layperson, it just doesn't seem to stack up. We were told by the experts that when we reached 70 per cent to 80 per cent vaccination, it would have a significant impact on the spread. It would stop the spread. Our politicians told us it would stop the spread. Clearly, that hasn't happened. Do you have a simple explanation for why very high rates of vaccination—higher than anyone expected; over 90 per cent in this country—has clearly not stopped the spread of coronavirus?

Dr Dawson: As a reminder, the goal of vaccination is to prevent severe infection, hospitalisation and deaths.

Senator CANAVAN: That is not my question. The witnesses here today have been extremely underwhelming. Instead of answering a question, they take it back to a completely irrelevant matter. My question is: how can you explain to the Australian public, some of whom were forced to take this vaccine, the claims in your studies and the statements of our political leaders that your vaccine would stop the spread? That's what they said. They said it would stop the spread. It hasn't happened. Why hasn't it happened?

Dr Dawson: As a reminder, the virus has changed over time as well. Again, COVID-19 vaccinations, and vaccination programs in general, are primarily designed to protect individuals against infection, severe disease, hospitalisation and deaths.

Senator CANAVAN: Thank you.

CHAIR: If you have taken any questions on notice, could you please return the answers to the secretariat by 17 August 2023. Thank you again for joining us this evening and for the robust conversation. Thank you.

Dr Dawson: Thank you, Senators.

Dr Clarke: Thank you.

Dr Leong: Thank you.

HENDERSON, Mr Nick, Acting First Assistant Secretary, Medicines Regulation Division, Therapeutic Goods Administration

LAWLER, Professor Anthony, Deputy Secretary, Health Products Regulation Group, Therapeutic Goods Administration

PENGILLEY, Dr Andrew, Medical Officer 5, Medicines Regulation Division, Therapeutic Goods Administration

[18:43]

CHAIR: I now welcome representatives of the Therapeutic Goods Administration, with officers appearing both in person and via videoconference. The Senate has resolved that an officer of a department of the Commonwealth or a state shall not be asked to give opinions on matters of policy and should be given reasonable opportunity to refer questions asked of the officer to superior officers or to a minister. This resolution does not preclude questions asking for explanations of policies or factual questions about when and how policies were adopted. Commonwealth officers appearing today are also reminded of the Senate order specifying the process by which a claim of public immunity should be raised. A copy of the order is available from the secretariat. I understand that information on parliamentary privilege and the protection of witnesses giving evidence to Senate committees has been provided to you.

Senator ROBERTS: Thank you for appearing today. A recent peer reviewed paper in the establishment scientific journal *Vaccine* examined Pfizer's COVID vaccine randomised phase 3 clinical trials data. That's Pfizer's own trial. It used the World Health Organization's framework made for this purpose, the Brighton Collaboration on adverse events of special interest. Authors included virologist and pharmacology experts from UCLA, Stanford, University of Baltimore and Queensland's Bond University. The paper concluded that Pfizer's vaccine, its injection, was associated with a 36 per cent increase in serious adverse events. The most common were coagulation disorders, including thrombosis and acute cardiac injury. In every 10,000 people injected, 18—that is, two in 1,000—will experience a life threatening or altering medical complication. Serious adverse events from Pfizer's COVID vaccine are four times higher than any benefit from the vaccine in reduced hospitalisation. The paper said the product should never have been approved. These world leading virologists spent 18 months reviewing the data, Pfizer's patient level data, and peer reviewing their paper. The department reviewed the data in a matter of weeks and made a finding that is the reverse of this paper's findings. Who got it wrong—these world leading virologists or the politically compromised advisory panel? Who got it wrong?

Prof. Lawler: Thank you very much for the question, Senator. Can I clarify that you are talking about the article by Fraiman et al that was published in the *Vaccine* journal in December 2022?

Senator ROBERTS: I don't have it with me.

Prof. Lawler: Without the article in front of me, I'm going to assume that you are talking about the article by Fraiman et al, including Peter Doshi and a number of other journalists. There were findings that called upon the list assembled by the Brighton Collaborative, which includes adverse events of special interest. You highlighted that there are multiple adverse events there, including serious adverse events to do with clotting disorders. There are also others to do with a chilblain-like effect. There has been a significant discussion around the rigour of that article in the scientific press. It has been challenged on a number of grounds. One of those is particularly the fact that this is a re-analysis of an initial randomised controlled trial some 21 months after the effect. That is an unusual undertaking in its own respect. One of the challenges about it, of course, is that it is relying on data that was collected at the very start of the pandemic as opposed to, as has been highlighted in the hearing already, significant real-world evidence that has been assembled since then, including the administration of 12 billion vaccine doses worldwide and, indeed, about 68 million vaccine doses in Australia up until 23 June this year.

The TGA undertakes a number of actions to ensure the safety, efficacy and quality of the medications that are entered on to the Australian register of therapeutic goods. These include, obviously, premarket assessment. You would be fully aware, I'm sure, Senator, of the provisional approval pathway undertaken for these vaccines. We also undertake significant pharmacovigilance activities in the post market surveillance. This includes being fully aware and apprised of literature of varying levels of scientific rigour and incorporating them into our post market surveillance, as we search for signals. It also includes our significantly well-developed and well-subscribed reporting of adverse event process in Australia.

To 23 July 2023, there have been 139,270 adverse event reports for COVID-19 vaccines, which gives us a rate of two per 100,000. I think it is important to note that a number of features do hamper our ability to take those numbers as overall evidence of serious adverse events that are vaccine related. These include such issues as

reporting capture. Obviously, it goes to the inclination of individuals to report those events. I want it to be very clear, Senator, that at the TGA we very much encourage the reporting by consumers or health professionals of adverse events that they believe follow a vaccination whether there is evidence or not that they are actually caused by the vaccine. That's very interesting.

Senator ROBERTS: Professor Skerritt, as I understand it, admitted, in answering a question of mine in the last Senate estimates sessions, that the TGA did no testing and relied on the FDA. The FDA, in turn, I'm advised, did no testing and relied on Pfizer's trials, the same trials that I just discussed. On what scientific basis did you mandate the untested injections? Professor Skerritt said that they didn't do it because the FDA has $8 billion in annual budget and 15,000 employees so you relied on the FDA. The FDA relied on Pfizer. No-one in the TGA, as I understand it, reviewed the patient level data?

Prof. Lawler: I will start by saying that I am not in a position to answer for Professor Skerritt. There was a question in the middle that I understood to be on what basis did we mandate the vaccinations. Is that correct?

Senator ROBERTS: No. I didn't say that.

Prof. Lawler: Sorry, I misheard, then.

Senator ROBERTS: I'm sorry if I said that. On what basis did you provisionally approve?

Prof. Lawler: Thank you. Apologies for misunderstanding you, Senator. As you would be aware, the Therapeutic Goods Administration does have the responsibility for assessing and approving medications to go on to the Australian register of therapeutic goods on the basis of safety, quality and efficacy. All the COVID-19 vaccines have been approved via our provisional registration pathway, which enables earlier access to promising new medicines while data on longer term efficacy and safety are still being gathered. I think it is important to—

Senator ROBERTS: Sorry, what was that last bit?

Prof. Lawler: While data on longer term efficacy and safety are still being gathered.

Senator ROBERTS: So you provisionally approved them and now you are collecting the data?

Prof. Lawler: No. It is the role of the TGA to undertake the assessment of medication prior to entry on the Australian register of therapeutic goods. We always have an ongoing role in continuing to collect data, including through our pharmacovigilance activities, which includes maintenance of adverse event reporting and surveillance for the development of signals both in Australia and elsewhere.

Senator ROBERTS: I have asked three times about your adverse events reporting. Professor Skerritt failed to reply the first two times. It took me months to get it out of him. What is your process for reviewing the adverse events reports, especially doctors' reports of death? Doctors have reported about 1,000 deaths. That has been wiped down to about 14, with no objective criteria in the assessment process. How can you call that decent adverse event reporting, with deaths just wiped?

Prof. Lawler: If I understand correctly, you are asking two questions, Senator. One is about the process we undertake for provisional reporting. The other is the process we undertake for adverse event notification and monitoring. Am I correct?

Senator ROBERTS: That's correct. Changing it from reported deaths to—

CHAIR: Senator Roberts, I know you have a follow-up question. After the follow-up question, there is one more question.

Senator ROBERTS: Okay.

Prof. Lawler: So before the provisional approval of vaccines within Australia, we establish the acceptable safety, quality and efficacy of the vaccine based on a comprehensive evaluation of a wide range of information. That includes leveraging our significant global partnerships with other regulators. It's important to note that we undertake, through a team of clinical and scientific experts at the TGA, a careful review of this data. We seek advice as well from the statutory advisory committee on vaccines prior to a senior medical officer making a regulatory decision within the statutes of the Therapeutic Goods Act 1989. The vaccine is only provisionally approved by the TGA if this rigorous process is completed and the benefits of the vaccine are considered to be much greater than any potential risks.

On the second question that you asked, Senator, I think you were suggesting that there was a wiping or removal of deaths that have been reported. I think it is important to note, as I was saying previously, that there are a number of reasons why we encourage adverse event reporting. But the numbers that come through to our database of adverse event notification are not and should not be taken on face value as an indication that there are—

Senator ROBERTS: Excuse me. Doctors are charged with the responsibility of writing out a death certificate and signing it. They know the cause. There were close to 1,000 of them, but they have been wiped by the TGA. They were reviewed, without objective criteria, down to 14. How can you justify that?

Prof. Lawler: Well, I don't think that it's accurate for you to characterise it—

Senator ROBERTS: Doctors reported deaths.

Prof. Lawler: I appreciate that the determination of the cause of death is a coronial activity. Dr Pengilley, would you like to reflect on it?

Dr Pengilley: I won't reflect on therapeutic goods—

Senator ROBERTS: How many of these have gone to the coroner?

CHAIR: Following this answer, I will have to go to Senator Antic.

Senator ROBERTS: How many have gone to the coroner?

Dr Pengilley: I won't answer the question regarding the 1,000 reports. I think Professor Lawler is saying that when we get a report, and obviously the report is of somebody who has died, we try to determine whether that is actually related to the vaccine or to any product. That is a determination which has to be made by further examination of the circumstances and, with temporality, whether there were other causes. That means that a large number of the reports eventually are found not to be associated. There are a whole range of criteria you can use for them. I won't go into them. We can provide more information on notice.

Senator ROBERTS: Can you put it on notice? I want to know the objective criteria you use for changing a doctor's report, who knows the patient.

Dr Pengilley: We're not changing a doctor's report.

Senator ROBERTS: The doctor reported death attributed to a vaccine and you are not accepting it.

Dr Pengilley: Senator, with respect, we're not saying the patient didn't die.

Senator ROBERTS: I didn't say that. You are misleading.

Dr Pengilley: Well, I am accurately—

CHAIR: Can I just interrupt?

Prof. Lawler: We're happy to take that on notice.

CHAIR: Yes.

Senator ROBERTS: I want the objective criteria by which you change a doctor's reported death due to a vaccine back to not associated with the vaccine.

Prof. Lawler: We're very happy to provide the senator with information on the process that is followed—

Senator ROBERTS: Thank you.

Prof. Lawler: following the report of a death following vaccination.

CHAIR: Thanks, Professor Lawler. We appreciate that.

Mr Henderson: We provided, via questions on notice through Senate estimates, responses to that question. We are happy to table those responses as well.

CHAIR: That would be helpful. Thank you, Mr Henderson. I'm mindful of the time. Some people have flights to run to.

Senator ANTIC: Yes, absolutely. Of the six leading regulators in Australia, Canada, Europe, Japan, the UK and the US, Australia's TGA has the highest proportion of budget from industry fees at 96 per cent. In 2020 to 2021, the TGA approved nine out of every 10 drug company applications. Does the TGA consider that it is horribly conflicted by virtue of that industry funded model?

Prof. Lawler: No.

Senator ANTIC: What percentage of current members of the TGA executive of the health products group, the advisory panel or any of the other advisory bodies under the executive arm of the Therapeutic Goods Administration are prior employees of big pharmaceutical companies?

Mr Henderson: I don't have an answer to that question, Senator Antic. I will take that on notice.

Senator ANTIC: Can you take that on notice?

Mr Henderson: Yes. Of course, we do have detailed processes around managing conflicts of interest within the TGA and our committees, so I am happy to provide them as well.

Senator ANTIC: Is it not a problem, though, that something like $170 million worth of pharmaceutical money comes towards the TGA and it represents 96 per cent of your funding?

Prof. Lawler: Thank you for the question, Senator. I would highlight that the proportion of our funding by industry is not 96 per cent. It is somewhat lower than that. I also appreciate the comment that a high proportion of those medicines and devices that come to us for review and for authorisation pass. That is, I think, in large part a testament to the fact that as a regulator we are complying with best practice regulation, which obviously has a significant part of its focus on compliance and enforcement that is undertaken on a risk based and data driven basis. We also significantly invest both time and resources in collaboration and engagement in order to ensure our engagement with all of our key stakeholders, which includes health professionals, consumers, the community, indeed, jurisdictions and, it has to be said, sponsors applying to have their products reviewed. It is undertaken in such a way that education about, and the establishment of, effective codes of practice means that the quality of applications coming to us is very high. We—

Senator ANTIC: This is ultimately a big cosy club, though, is it not?

Prof. Lawler: No.

Senator ANTIC: It's not?

Prof. Lawler: No. It's not unusual in the regulatory world for the activities of the regulator to be undertaken on a cost recovery basis. It is undertaken on a cost recovery basis. I would also indicate that we established the fees and charges to undertake the work. We communicate that to industry. The work we undertake all the way from the assessment of applications for authorisation and entry on to the Australian register of therapeutic goods through to the inspection that we undertake for manufacturing and product quality are all undertaken in a way that is absolutely in line with effective codes of practice and—

Senator ANTIC: The TGA is not going to bite the hand that feeds it?

Prof. Lawler: I reject the statement that we are not undertaking our responsibilities with due diligence and appropriate certitude our responsibility as a regulator.

Senator RENNICK: Can I table some documents? Is that alright?

CHAIR: Yes. Certainly.

Senator RENNICK: They should know them, but I'm going to ask questions. I was told they didn't have the documents, so I just want to make sure they've got the documents.

CHAIR: Also, Senator Rennick, I'm mindful of the time. There's a capacity for questions on notice where it's appropriate. I'll leave that to your very good judgment.

Senator RENNICK: Thank you very much, Chair. Guys, could I refer you to the *Western Australian vaccine safety surveillance—annual report 2021*, page 28. I'd like to think you're up to speed with this already, but that's why I provided the documents. There's a table there, 8.1 on page 28, that says the rate of adverse events per 100,000 doses is 264.1 for COVID-19 vaccines versus 11.1 for non-COVID-19 vaccines. That's per dose, so that effectively means that the rate of adverse events for COVID vaccines is 24 times higher than for non-COVID vaccines. This is the Western Australian safety data from 2021, and that's per dose. I note that in order to be up to speed with the COVID vaccine you needed either two or three doses. Assuming you need three doses a year, that's at least a 60 to 75 times higher rate of an event than for non-COVID vaccines. Given the higher rate of injury, do you think that the COVID vaccine has a much higher risk of adverse events than normal vaccines, based on this real-world data from the Western Australian government?

Prof. Lawler: There are a couple of features that I had intended to explain in my previous answer around adverse event reporting, and I think that they're relevant to this answer. There are issues of causality. Obviously, one is that we do frequently see adverse events after vaccination of any kind, and that does not necessarily mean that there is a causal link. It can be a temporal link.

Senator RENNICK: I'm well aware of that.

Prof. Lawler: Secondly, I think it's important to note that many of the adverse events that were reported in the *Western Australian vaccine safety surveillance* report—which, again, as I mentioned previously, is one of a number of different surveillance mechanisms that we use to identify signals—were quite mild and expected—

Senator RENNICK: Okay. Could I ask you to refer to the table on page 11, now that you've seen that figure—go to the bottom set of figures, please—because I dispute that. If you actually look at the figures in 2021 down the bottom right-hand side, you will see that 48 per cent of people who reported an adverse event to the COVID vaccine went to the emergency department, and nine per cent were admitted to hospital. That's 57 per

cent of people who reported an adverse event who actually went to hospital. That's twice as high, if not higher, than in prior years for non-COVID vaccines, so I think it's not fair to say that these are mild events.

Prof. Lawler: I appreciate that. I understand that there has been discussion around the use of the term 'mild events' previously, and I absolutely appreciate the fact that those who've experienced vaccine injury would find that a diminishing term, and it has certainly not been intended in that way. What I'm saying is that there are a proportion of injuries that are to be expected following COVID or any other vaccination. The other element—

Senator RENNICK: Sorry to interrupt you there, but my point is that the rate of injury is much higher with the COVID vaccines. That's what these figures prove, because they're real-world figures of a population of 2½ million people. It's significantly higher.

Prof. Lawler: Again, I appreciate that. I think it's also important to note, and it was noted within the report itself, that those undertaking the survey and the collection of data did not specifically ask patients or participants why they accessed medical care in the days following treatment. I think it's also important to note as well—

Senator RENNICK: Can I say that that's the fault of the reporting system. We're rolling out a novel vaccine here. So that's not my fault; that's their fault for not tracking—

Prof. Lawler: It's absolutely not your fault. I do find it, though—and I'm sorry; I don't mean to interrupt—challenging to rely on one part of the report as representative of a problem with a vaccine and then to dismiss another part of the report as a fault of reporting.

Senator RENNICK: It's a signal, and a very large sample.

Prof. Lawler: And it's one of the many signals that we look at. It's one of the many signals that we incorporate in terms of our determination.

The other thing I would indicate is that there is what we call the Hawthorne effect, which is that there will be a change in the reporting when there is a significant focus on a disease. I think it's very important to note. And this is in part why we encourage both health professionals and the community to report adverse events, because we want to be picking up those signals. But it actually says on page 28, as you highlighted, that the surveillance of routine vaccines was a small component of the workload.

Senator RENNICK: That's right.

Prof. Lawler: People expect, to a certain extent, to have vaccine after-effects. Whether we characterise them as adverse events or injuries, they expect to have vaccine after-effects after a routine vaccine.

Senator RENNICK: Okay. Thank you.

Prof. Lawler: There is a more prompt pick-up after—

Senator RENNICK: Thank you. Sorry, but I've got to keep moving on. I've asked both of the two manufacturers tonight, Pfizer and Moderna, whether they can explain the process by which the vaccine causes myocarditis. I don't want to talk about benefits and risks; I want to know why the vaccine causes myocarditis. It damages heart cells. Okay?

Prof. Lawler: Yes.

Senator RENNICK: Can you explain why the vaccine damages heart cells?

Prof. Lawler: I'll ask Dr Pengilley to respond.

Dr Pengilley: This is an issue of some ongoing discussion in the medical literature, and I think it is fair to say that the absolute, definitive mechanism has not been isolated yet.

Senator RENNICK: Thanks for that.

Dr Pengilley: But I'll caveat those comments by saying that myocarditis is generally an autoimmune phenomenon where antibodies are formed against cells, in this case of the heart. It occurs after COVID at a higher rate than it does after vaccination, and it occurs in relation to a number of other infections, such as coxsackieviruses. It's something which is observed whenever there is an immune response. It is therefore likely that it is somewhat related to the immune response, and I guess there is a similarity between the immune response to COVID and—

Senator RENNICK: Okay. Thank you. Fantastic answer. I appreciate that.

Dr Pengilley: Well, perhaps I—

Senator RENNICK: So, given that this wasn't identified before the rollout and, as you said, it's an ongoing area of concern and investigation, how can you then rule out—and you've admitted it's potentially an autoimmune issue—that other body organs aren't also being damaged by the vaccine, but they're subclinical issues because the

heart is obviously something that has a higher pain threshold, or sends a greater signal? How can you rule out other issues or side effects from the vaccine? When you're saying that it's not necessarily causal, could the vaccine be causing other autoimmune issues in other body organs? Is that a potential risk? Do you accept that that's a risk?

Dr Pengilley: Senator, as Professor Lawler has pointed out, the TGA maintains an ongoing surveillance of potential risks and potential adverse events as they're reported to us. The fact of the matter is that with all medical products more information becomes available as they are used. However—

Senator RENNICK: I accept there's a risk, but my issue is that you never outlined those risks at the start.

Dr Pengilley: Well—

Senator RENNICK: It's always, 'The vaccine is safe and effective,' without any qualification.

Dr Pengilley: I think if you look at the statement regarding provisional registration the basis on which they're approved is pretty clear. But it's also the case that there is a risk-benefit. I realise you said you don't want to discuss it, but if you're trying to prevent myocarditis then preventing COVID is the best way to do it. So you do look at the—

Senator RENNICK: Well, we had 10 million people, I will dispute, that caught COVID.

Dr Pengilley: You do look at what you're doing in terms of the rate of adverse events. And, since it is also an adverse event of COVID infection, the overall benefit, even for that adverse event, is likely to be positive. Whether there is an unknown adverse event is purely speculative. It goes to proving a negative, and that's not something that—

Senator RENNICK: You're playing with people's lives. You can't say that's speculative. You're risking people's health here. We're not speculating in the casino or at a football—

Dr Pengilley: I would say, though, Senator—

CHAIR: Sorry to interrupt, Dr Pengilley. Senator Rennick, I was trying not to interrupt you as you were asking the question, but I will need to go to Senator Canavan. We are over time.

Prof. Lawler: I think the 'speculative' comment probably relates more to some of the physiological and virological thoughts around organs and how organ systems are affected. Moving away from the speculative position: as we've mentioned a couple of times, we undertake significant adverse event notification and monitoring. In the context of 16 million doses having been developed, the reported rate—and we rely very much on the reported rate—of adverse events of myocarditis and pericarditis has been in the region of two to three per 100,000. As Dr Pengilley has highlighted, we rely on the growing body of real-world evidence in our ongoing assessments—

Senator RENNICK: It's per thousand, not 100,000.

Prof. Lawler: No, it's per 100,000 doses.

Senator RENNICK: The reporting injuries, as per your regular reports, are two per thousand.

Prof. Lawler: I'm wanting to make a clear distinction between the specific diagnosis of myocarditis and pericarditis versus—

Senator RENNICK: And I'm talking about the other 998. If it can happen to the heart, it can happen to other body organs; that's my point. You're talking about two in 100,000, yet your own weekly report talks about two in a thousand reported injuries. I'll leave that as a comment.

Senator CANAVAN: Did Pfizer, Moderna or even AstraZeneca provide you any evidence about the effectiveness of their vaccine in reducing or stopping transmission?

Dr Pengilley: Thank you for the question. I know this has been an issue of some discussion tonight. You can look at transmission broadly in two ways. You can look at it as the effectiveness of the vaccine in preventing somebody getting COVID; if you do that, then you've prevented transmission to that person. Both in the clinical studies that have been submitted for registration and moreover in the literature now, there is an abundance of evidence that vaccination has the ability to prevent people from acquiring an infection of COVID however that is defined, whether you define it with symptomatic infection, serious infection or just—

Senator CANAVAN: Can I just stop you there, given the time. I am more interested in the second definition you're going to raise. I know this committee inquiry has been wide-ranging, which is fine, but we are here to discuss a bill about ending vaccine mandates. It's really that other form of transmission: being vaccinated, do I stop spreading it? That's what I want to know. We were often told that we should get the vaccine to protect our grandma, not necessarily ourselves. I am more interested in getting evidence on whether, by getting the vaccine, I would reduce my propensity to spread the disease.

Dr Pengilley: Fair point. I would just say that one way you can prevent spreading it is: don't get the disease.

Senator CANAVAN: I get it.

Dr Pengilley: That's the point I'm making. I don't believe it was in the original regulatory dossiers, because, as I think most companies have said, the initial purpose was to prevent disease in individuals. However, there are a number of studies, and we'll be happy to provide these—

Senator CANAVAN: Maybe you can provide those on notice.

Dr Pengilley: which have subsequently done those studies—

Senator CANAVAN: About stopping the spread?

Dr Pengilley: Yes—looking at the reduction in the spread by vaccinated people in households, in prison communities, in healthcare facilities. These are secondary transmissions. They're not as frequent because they're harder studies to do, but they certainly have been done.

Senator CANAVAN: I was wholly unconvinced—Pfizer tonight wouldn't stand behind their own statements as a company. When you check their official statements, they haven't made any statements since mid-2021 about the effectiveness of transmission, yet we still have mandates today. Finally, getting back to the bill: does the TGA have a position on whether or not companies should mandate the vaccine?

Prof. Lawler: Thank you for the question. The TGA has a role in approving medications and other products to go onto the—it is the role of ATAGI and other appropriate bodies to make—

Senator CANAVAN: Fair enough. I just note the Secretary of the Department of Health and Aged Care, at the last Senate estimates, said he didn't see a justification for mandates continuing, but I recognise the position you're in. Thank you very much.

CHAIR: I just have one question: what role, if any, has the pharmaceutical companies had in policy formulation by the TGA?

Prof. Lawler: The TGA is a regulator that sets its own regulatory settings. It interacts with industry, in that industry sponsors bring medications and other devices to the TGA for registration on the approval. We have a role as a contemporary regulator in collaboration and engagement, but it's very clear in that relationship that we undertake the regulatory role.

CHAIR: That's independent of the pharmaceutical companies? The decisions are made by the TGA?

Prof. Lawler: Absolutely—and delegates within the TGA, that's right.

CHAIR: I just want to be very clear for the *Hansard*. Thank you. If you've taken any questions on notice, could you please return the answers to the secretariat by 17 August 2023. That concludes today's hearing. Thank you to all the witnesses who appeared and to Hansard and Broadcasting for their assistance. The committee has agreed that responses to questions on notice should be provided by Thursday 17 August 2023.

Committee adjourned at 19:15