PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health and Aged Care

Education and Employment Legislation Committee

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

03 August 2023

PDR Number: IQ23-000058

Doctor reported deaths

Spoken

Hansard page number: 24

Senator: Malcolm Roberts

Question:

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.

Answer:

Several statements made by Senator Roberts regarding the deaths reported to the Therapeutic Goods Administration (TGA) were incorrect. To clarify:

- Since the beginning of the vaccine rollout to 6 August 2023, the TGA has received 996 adverse event reports with a fatal outcome. Of these:
    - 122 were reported to the TGA directly by a health professional, of which 43 were from a medical practitioner, 23 were from a nurse or pharmacist, and 56 did not specify the type of health professional.
    - 90 were from a coroner
    - 609 were reported by a state or territory health department
    - 129 were reported directly by members of the community
    - 46 were reported by a pharmaceutical company
    - over one third have been referred to a coroner based on the information available to the TGA.
    - the TGA has identified 14 reports where the cause of death was linked to vaccination.

- The TGA has not 'wiped' any reports of deaths – all reports remain in the TGA's database and are used in the TGA's ongoing safety monitoring activities. In addition, these reports remain available to the public via the Database of Adverse Event Notifications (DAEN) – Medicines, available at: daen.tga.gov.au/medicines-search/ The TGA also continues to report on these deaths in the COVID-19 vaccine safety report, available at: www.tga.gov.au/news/covid-19-vaccine-safety-reports

As previously outlined in SQ22-000105 (published 20 June 2022), the TGA does not determine the medical condition that caused the death of an individual, nor does it 'overrule' the cause of death included on the death certificate. Treating health professionals, hospitals and coroners are best placed to investigate and identify the medical conditions that caused death.

The TGA encourages reporting of all significant health events after vaccination, even if there is only a small chance that they were caused by the vaccine. In some cases, the reporter may state that they do not believe there is a link to vaccination, or other information provided in the report indicates that the vaccine is very unlikely to have contributed to the death. Nevertheless, as described above, these reports are retained in the TGA's adverse event database to contribute to safety monitoring.

The TGA applies a structured and objective approach to assessing fatal cases, using an internationally accepted method for causality assessment recommended by the World Health Organization (WHO). The approach considers the evidence for a causal link between the vaccine and the diagnosis made by the relevant health professional who examined the patient. The same approach is used by Vaccine Safety Investigation Groups, which are panels of experts convened by the TGA to undertake causality assessments of individual cases that may have an impact on the benefit risk balance of a vaccine. Further information regarding the assessment process and current templates for the assessment of fatal reports have been released under Freedom of Information (FOI) requests. This includes documents released under FOIs 4029 (published January 2023) and 4302 (published May 2023), which are available on the TGA's FOI disclosure log at: www.tga.gov.au/foi-disclosure-log

Regardless of the outcome of the individual causality assessment, the TGA includes fatal adverse event reports in analyses to identify and investigate signals that may not be apparent through individual case review. This approach is consistent with the approach recommended by the WHO.

The TGA's regulatory assessment is focused on identifying new medical conditions that may be associated with the vaccine. Detailed information on the processes used by the TGA to assess reports of death in people who have been vaccinated has previously been provided in:

- SQ21-001136 (published 7 April 2022)
- SQ21-001181 (published 21 June 2022)
- SQ21-001218 (published 22 June 2022)
- SQ22-000096 (published 21 June 2022)
- SQ22-000099 (published 28 June 2022)
- SQ22-000104 (published 30 June 2022)
- SQ22-000105 (published 20 June 2022)
- SQ22-000527 (published 16 December 2022)
- SQ23-000140 (published 30 March 2023)
- SQ23-000545 (published 2 June 2023)

Additionally, the COVID-19 Vaccine Safety report is published by the TGA and is available at www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-weekly-safety-report-02-12-2021

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health and Aged Care

Education and Employment Legislation Committee

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

03 August 2023

PDR Number: IQ23-000060

Studies on COVID-19 vaccines preventing disease in individuals

Spoken

Hansard page number:28

Senator: Matthew Canavan

Question:

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.

Answer:

- Responses supporting the transmission effects of the COVID-19 vaccines which have been provided to questions on notice from previous Senate Estimates Rounds are attached as follows:
    - Attachment A: SQ22-000421 - Q2a (published 16 December 2022)
    - Attachment B: SQ22-000485 (published 16 December 2022)
- Additionally, the Therapeutic Goods Administration (TGA) specifically draws your attention to the following three articles:
    - An article published in Nature Medicine in January 2023 by Tan *et al*: *Infectiousness of SARS-CoV-2 breakthrough infections and reinfections during the Omicron wave* (doi.org/10.1038/s41591-022-02138-x). This study underscored the benefit of vaccination to reduce, but not eliminate, transmission.
    - An article published by Meyer *et al* in Influenza and Other Respiratory Viruses in September 2022: *BNT162b2 vaccination reduced infections and transmission in a COVID-19 outbreak in a nursing home in Germany, 2021* (onlinelibrary.wiley.com/doi/epdf/10.1111/irv.13051). This study demonstrated that vaccination reduced the risk for SARs-CoV-2 infection, viral load and transmission in a German nursing home.
    - An article published in the International Journal of Infectious Diseases in 2023 by Maeda *et al*: *Effect of COVID-19 vaccination on household transmission of SARS-CoV-2 in the Omicron era: The Vaccine Effectiveness, Networking, and Universal Safety (VENUS) study* (doi.org/10.1016/j.ijid.2023.06.017). This study demonstrated that COVID-19 vaccination effectively reduced household transmission in Japan.

Senate Committee: Community Affairs Committee

QUESTION ON NOTICE

Budget Estimates 2022-2023
Outcome: 1 - Health Policy, Access and Support

PDR Number: SQ22-000421

Question Subject: TGA's legal permissions for COVID-19 vaccines

Type of Question: Written

Senator: Alex Antic

Question:

1. The U.S.'s FDA approval of modified Pfizer COVID vaccines to be used as boosters for people aged over 18 was based on data collected from testing on 8 mice, and was not tested on humans.
   a.) Are these boosters being used here? In other words, are any COVID vaccines being approved based on animal data rather than human data in Australia?
2. The Public Assessment Report for the Pfizer vaccine, dated January 2021, reads, "In addition to the unknown longer-term safety and unknown duration of vaccine protection, there are other limitations with the submitted data. The following questions have not yet been addressed:
   a.) Vaccine efficacy against asymptomatic infection and viral transmission.
   b.) The concomitant use of this vaccine with other vaccines.
   c.) Vaccine data in pregnant women and lactating mothers.
   d.) Vaccine efficacy and safety in immunocompromised individuals.
   e.) Vaccine efficacy and safety in paediatric subjects (under 16 years old)." This indicates that as early as January 2021, before the rollout began, the TGA knew that the Pfizer vaccine's impact on viral transmission was unknown, that its safety profile for pregnant women, immunocompromised individuals, and under 16 year olds was unknown.
   f.) Is this correct?
3. Pfizer representative Janine Small has admitted to the European Parliament that Pfizer did not test their vaccine for its effect on viral transmission.
   a.) Was the TGA aware of this fact prior to approving the Pfizer vaccine?

4. The TGA Website provides that: “In 2019, the TGA issued a permission that allows advertising of vaccines (including COVID-19 vaccines) that is, or forms part of a Commonwealth or state or territory health campaign (the 2019 permission). Under this permission, any party can use material produced by the Australian Government or an Australian state or territory government to promote COVID-19 vaccines.”

   a.) Why was this permission issued in 2019, before the COVID-19 pandemic was declared in 2020?

5. The TGA Website provides that: “In recognition of the importance of responsible communications regarding the COVID-19 vaccination program, the TGA has issued a subsequent legal permission (the 2021 permission) that allows advertisers such as health professionals, participating vaccination sites, corporate entities, media outlets and others to develop their own materials to communicate publicly about COVID-19 vaccines subject to the conditions below.

   Those conditions include the following:

   “the advertisement must: …

   d) not contain any statement to the effect that the therapeutic goods cannot cause harm or have no side effects; and

   e) not contain any statement regarding the therapeutic goods that is false or misleading”

   a. Would advertising a COVID-19 vaccine as “safe” be a breach of the condition referred to at paragraph d above?

   b. Would advertising the COVID-19 vaccines as being useful in preventing transmission of COVID-19 be “false” or “misleading”?

   c. Would advertising the COVID-19 vaccines as not putting one at risk of developing myocarditis be “false” or “misleading”?

Answer:

Question 1

No. In law, under section 25(d) of the *Therapeutic Goods Act 1989,* clinical data (studies in humans) is required to be submitted to the Therapeutic Goods Administration (TGA) for evaluation under the provisional registration pathway before a regulatory decision can be made about the vaccine. So no vaccines in Australia have been approved based on studies in mice only. Therefore, these boosters are not being used in Australia at present.

Question 2

a.) All COVID-19 vaccines continue to have at least 60% efficacy, in many cases much higher of significantly reducing the risk of severe COVID-19, including hospitalisation and death, particularly in older adults. Since the publication of the Public Assessment Report almost two years ago, a number of articles in major medical journals demonstrating the efficacy of COVID-19 vaccines have been published. Examples of reports from the US Centres for Disease Control and Prevention (CDC) include:

- In March 2022, the CDC published Effectiveness of mRNA Vaccination in Preventing COVID-19–Associated Invasive Mechanical Ventilation and Death — United States, March 2021–January 2022 (Tenforde *et al*, 2022) (available at: www.archive.ph/lMg77#selection-647.0-647.150).

- In July 2022, the CDC published Effectiveness of two, three, and four COVID-19 mRNA Vaccine Doses Among Immunocompetent Adults During Periods when SARS-CoV-2 Omicron BA.1 and BA.2/BA.2.12.1 Sublineages Predominated — VISION Network, 10 States, December 2021–June 2022 (Link-Gelles *et al*, 2022) (available at: www.cdc.gov/mmwr/volumes/71/wr/mm7129e1.htm?s_cid=mm7129e1_w).
- In August 2022, the CDC published Laboratory-Confirmed COVID-19–Associated Hospitalizations Among Adults During SARS-CoV-2 Omicron BA.2 Variant Predominance — COVID-19–Associated Hospitalization Surveillance Network, 14 States, June 20, 2021–May 31, 2022 (Havers *et al*, 2022) (available at: www.cdc.gov/mmwr/volumes/71/wr/mm7134a3.htm?s_cid=mm7134a3_w).
- In August 2022, the CDC updated information on the Benefits of Getting a COVID-19 vaccine (available at: www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html).

Transmission effects are not an approved indication of any COVID-19 vaccine. However, over the course of the pandemic numerous studies have been published which show that the vaccines have an effect on the transmission on earlier variants:

- In August 2021, Harris *et al*, 2021 (available at: www.nejm.org/doi/full/10.1056/nejmc2107717)
- In October 2021, Shah *et al*, 2021 (available at: www.nejm.org/doi/full/10.1056/NEJMc2106757)
- In October 2021, Nordström *et al*, 2021 (available at: www.jamanetwork.com/journals/jamainternalmedicine/fullarticle/2785141)
- In March 2022, Salo *et al*, 2022 (available at: www.nature.com/articles/s41467-022-28825-4).

In September 2022, Nature Communications published Lyngse et al, 2022 (available at: www.nature.com/articles/s41467-022-33498-0). This study found there was an increased transmission for unvaccinated people, and a reduced transmission for booster vaccinated people, compared to those who had completed their primary vaccination course.

b.) Post approval, a number of studies have been published:

- In March 2022, the Australian Technical Advisory Group on Immunisation published advice on seasonal influenza vaccines in 2022 and co-administration with COVID-19 vaccines (available at: www.health.gov.au/resources/publications/atagi-advice-on-seasonal-influenza-vaccines-in-2022) and in October 2022, the US Centers for Disease Control and Prevention published updated advice on getting a flu vaccine and a COVID-19 vaccine at the same time (available at: www.cdc.gov/flu/prevent/coadministration.htm).

In relation to pregnancy, post-market global surveillance data from large numbers of pregnant people have not identified any significant safety concerns with mRNA COVID-19 vaccines given at any stage of pregnancy. There is no evidence of decreased fertility, increased risk of miscarriage or teratogenic risk. For example, in June 2021, (Shimabukuro *et al*, 2021) (available at: www.nejm.org/doi/full/10.1056/nejmoa2104983). This study of more than 35,000 pregnant people showed no difference in side effects or pregnancy outcomes between those who were pregnant and those who were not.

In relation to immunocompromised individuals, in March 2022 the BMJ published (Lee *et al*, 2022) (available at: www.bmj.com/content/376/bmj-2021-068632) which found that seroconversion rates improved across all patient groups, including immunocompromised patients after a second dose of a COVID-19 vaccine and that for immunocompromised patients a third (booster) dose, should be performed.

IT would have been nonsensical to discuss the safety of the vaccine in children under 16 in Public Assessment report that was specifically for an approval for this vaccine in the 16 years and over age group. The vaccine was not approved for under 16-year-olds until somewhat later. However, a number of peer-reviewed clinical trials on the safety of the Pfizer vaccine in children have been published, including:

- www.nejm.org/doi/full/10.1056/NEJMoa2107456?query=featured_coronavirus
- www.nejm.org/doi/full/10.1056/NEJMoa2116298, and
- www.nejm.org/doi/full/10.1056/NEJMoa2209367.

Since these vaccines were granted provisional approval more than five billion people have received COVID-19 vaccines worldwide. Data on real-world use of the COVID-19 vaccines approved in Australia provides reassurance about their safety in the subpopulations of concern. This is supported by reviews of safety data by international medicines regulators in countries with extensive COVID-19 vaccine experience who have found no new safety concerns associated with the use of COVID-19 vaccines in these populations.

c.) See response to Question 2b.

d.) See response to Question 2b.

e.) See response to Question 2b.

Question 3

See response to Q2a. The TGA did not receive an application, nor did it approve the vaccines for reduction of transmission. However, the TGA was aware that at the time of approval in January 2021 a number of studies on the impact on transmission were underway, and these have since been published.

Question 4

The Therapeutic Goods (Restricted Representations - Government Health Campaigns) Permission 2019 was made so that TGA registered vaccines could be promoted in the context of Commonwealth or state or territory government public health campaigns. The permission predates COVID-19 and COVID-19 vaccines and was issued so that governments could prepare and conduct public health campaigns about TGA approved vaccines. Government promotion of registered COVID-19 vaccines is subsequently covered by this permission.

Question 5

a.) The Senator has misquoted the content of this legislative instrument. The Therapeutic Goods (Restricted Representations - Government Health Campaigns) Permission 2019 does not impose a condition that advertisements for registered vaccines not contain any statement to the effect that the therapeutic goods cannot cause harm or have no side effects.

Advertising prepared under the Therapeutic Goods (Restricted Representations – COVID-19 vaccines) Permission 2021 with a reference to 'safe' needs to be reviewed in the context of the entire advertisement to determine whether it is in breach of the permission. Commonwealth health messaging reflects that for most individuals, the benefits of the COVID-19 vaccine outweigh its risks.

b.) An advertising claim to the effect that COVID-19 vaccines are 'useful in preventing transmission of COVID-19' would not be false or misleading. Such a claim is not inconsistent with Commonwealth health messaging in relation to measures for 'slowing the spread' of COVID-19 which include vaccination, social distancing, mask wearing in certain circumstances and hygiene measures.

c.) An express claim in advertising to the effect that COVID-19 vaccines 'do not put one at risk of developing myocarditis' would very likely be misleading. However, the absence of this information in advertisements would not be considered misleading.

The Department of Health and Aged Care has produced the document 'Guidance on Myocarditis and Pericarditis after COVID-19 vaccines'. This guidance states that the "overwhelming benefits of vaccination in protecting against COVID-19 greatly outweigh the rare risk of myocarditis and/or pericarditis."

Senate Committee: Community Affairs Committee

QUESTION ON NOTICE

Budget Estimates 2022-2023
Outcome: 1 - Health Policy, Access and Support

PDR Number: SQ22-000485

Question Subject: Articles providing scientific evidence that vaccines prevent transmission of COVID-19

Type of Question: Spoken, Hansard page 64, 10 November 2022

Senator: Alex Antic

Question:

Senator ANTIC: Can I ask you this? At the previous Senate estimates hearing, Professor Kelly, you said to me that, in relation to my suggestion that the COVID vaccines don't prevent transmission—which, of course, is a key plank of the mandates—that was 'not a true statement'. It actually was a true statement, though, wasn't it?

Prof. Kelly: No, it was not a true statement, in my view.

Senator ANTIC: In your view or according to the science?

Prof. Kelly: That would be my view based on the science. There is an effect on transmission—

Dr Skerritt: There are several publications on transmission.

Senator ANTIC: There are many publications which say that they have no impact on transmission, so it's not—

Dr Skerritt: And there are many publications that say there's an impact on transmission.

Senator ANTIC: But what is that impact? We went through this last time. What is it in real-world terms?

Dr Skerritt: It decreases. It is lower now with omicron and lower with delta. With the original ancestral and first couple of strains the impact on transmission was significantly greater. It wasn't as great as the impact on infection. On notice, I'm happy to give you a list of seven or eight articles.

Answer:

- Information is provided in SQ22-000421.
- Over the course of the pandemic, numerous studies have been published which show that the vaccines did have an effect on transmission on earlier variants:
    - In August 2021, the New England Journal of Medicine published Effect of Vaccination on Household Transmission of SARS-CoV-2 in England (Harris *et al*, 2021) (available at: www.nejm.org/doi/full/10.1056/nejmc2107717)
    - In October 2021, the New England Journal of Medicine published Effect of Vaccination on Transmission of SARS-CoV-2 (Shah *et al*, 2021) (available at: www.nejm.org/doi/full/10.1056/NEJMc2106757)
    - In October 2021, the JAMA Network published Association Between Risk of COVID-19 Infection in Nonimmune Individuals and COVID-19 Immunity in Their Family Members (Nordström *et al*, 2021) (available at: www.jamanetwork.com/journals/jamainternalmedicine/fullarticle/2785141?guestAccessKey=b1c447e0-09a7-4171-92ff-4b129431de51&utm_source=silverchair&utm_medium=email&utm_campaign=article_alert-jamainternalmedicine&utm_content=olf&utm_term=101121)
    - In March 2022, Nature Communications published The indirect effect of mRNA-based COVID-19 vaccination on healthcare workers' unvaccinated household members (Salo *et al*, 2022) (available at: www.nature.com/articles/s41467-022-28825-4).
- Since these studies were published the Omicron subvariants have become more prevalent, and these have been shown to be more transmissible than the initial subvariants.
    - In September 2022, Nature Communications published Household transmission of SARS-CoV-2 Omicron variant of concern subvariants BA.1 and BA.2 in Denmark (Lyngse et al, 2022) (available at: www.nature.com/articles/s41467-022-33498-0). This study found there was an increased transmission for unvaccinated people, and a reduced transmission for booster vaccinated people, compared to those who had completed their primary vaccination course (first and second dose).