From: s22
To: GILL, Tony; s22 ; s22
Subject: RE: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]
Date: Tuesday, 7 February 2023 1:02:58 PM
Attachments: image003.png
image004.png
image005.png

Yes, Tony,
there are published data relating to effectiveness of bivalent boosters as mentioned in previous brief (D23-5034224).
PB can get info relating to "Pfizer Bivalent vaccines causing stroke in people aged 65 and older".
Regards,
s22

From: GILL, Tony
Sent: Tuesday, 7 February 2023 11:54 AM
To: s22 ; s22 ; s22
Subject: FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]
I have attached the orfit article mentioned in MINCORRO.
Hopefully we have information already re "efficacy of bivalent boosters"
Note need by COB today
Tony

From: s22 @health.gov.au>
Sent: Tuesday, 7 February 2023 11:48 AM
To: KAY, Elspeth <Elspeth.Kay@health.gov.au>; GILL, Tony <Tony.Gill@health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]
Dear Elspeth and Tony
Grateful for any input that you can provide, noting that John will want to consider and clear this before it is returned to PIPCRD.
They were hopeful of receiving this input by COB today because it appears that they have been holding the PDR for two weeks and it is due tomorrow, and so we'll aim to meet this deadline.
Cheers
s22

From: s22 @health.gov.au>
Sent: Tuesday, 7 February 2023 10:58 AM
To: HPRG Parliamentary s22 @health.gov.au>
Cc: s22 @health.gov.au>
Subject: FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]
Hi Team,
We have just been allocated the below corro for an M response. The response is due to MO tomorrow.
As such, can you please provide input addressing the concerns raised with regards to the efficacy of bivalent boosters and Pfizer Bivalent vaccines causing stroke in people aged 65 and older, by COB today.
Many thanks in advance and apologies for the tight timeframes.
Kind regards
s22
A/g Assistant Director - Intergovernmental Engagement Section

Vaccine Policy & Transition Branch

National COVID-19 Vaccine Program Division | Health Resourcing Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: Scarborough House 10.210
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

s22

Senator **GERARD RENNICK**
LNP Senator for **Queensland**

The Hon. Mark Butler MP
Minister for Health & Aged Care
PO Box 6022
Parliament House CANBERRA ACT 2600
Minister.butler@health.gov.au

24th January 2023

Dear Minister,

Cease the rollout of ineffective Bivalent Covid-19 Booster vaccines

I note the recent advice from renowned vaccinologist, immunologist, and advisory committee member for both the CDC and FDA, Paul A. Offit, M.D published in the reputable New England Journal of Medicine, January 15, 2023.

Dr Offit's states, *"I believe we should stop trying to prevent all symptomatic infections in healthy, young people by boosting them with vaccines containing mRNA from strains that might disappear a few months later".* Dr Offit went on to say, "*neither research group found bivalent boosters to elicit superior immune responses"* compared to the monovalent booster group.

I also note that Pfizer's bivalent Covid-19 vaccine has shown a potential link to stoke in people 65 and older in a safety database monitored by the FDA. Given the low risk: reward ratio, will the Health Department suspend the rollout the Pfizer Covid bivalent vaccine until investigations can be concluded to better understand both the risks and benefits of the new vaccine.

Your prompt reply is greatly appreciated.

Kind regards,

Gerard Rennick
LNP Senator for Queensland

From: s22
To: s22
Subject: FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]
Date: Tuesday, 7 February 2023 1:16:33 PM
Attachments: image004.png
image005.png
image006.png
image007.png

FYI – this is PB's input (to be cleared).

From: PBPMA
Sent: Tuesday, 7 February 2023 12:24 PM
To: KAY, Elspeth
Cc: GILL, Tony ; PMAB Coordination ; s22 ; PBPMA
Subject: RE: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]

Hi Elspeth,

Suggested input (having spoken with Tony I understand PMAB are addressing the efficacy question):

> The TGA is aware of the United States Centers for Disease Control (CDC) and Food and Drug Administration (FDA)'s article dated 13 January 2023, which states that a preliminary safety signal has been detected for stroke in people ages 65 and older who received the Pfizer bivalent COVID-19 Vaccine. This preliminary signal was identified in the CDC's Vaccine Safety Datalink (VSD), which is one of their safety monitoring systems.
>
> The detection of a data signal does not automatically mean that the adverse event was caused by the vaccine. The article states that the CDC and FDA continue to evaluate this signal further and that to date, no other safety systems have shown a similar signal, multiple subsequent analyses have not validated this signal, and that the totality of the data currently suggests that it is very unlikely that this signal represents a true clinical risk. Notably, FDA and CDC recommend no change in the current vaccination practice.
>
> In Australia, the TGA has not observed any safety signal for stroke following administration of bivalent mRNA COVID-19 vaccines (Pfizer and Moderna), noting the number of doses of bivalent vaccines administered has been proportionally lower than monovalent vaccines. The TGA continues to closely monitor the safety of bivalent COVID-19 vaccines, including updates on this preliminary signal that may arise from the FDA, and will take appropriate regulatory action if necessary.

Thanks,
Grant

From: s22 @health.gov.au>
Sent: Tuesday, 7 February 2023 11:51 AM
To: PBPMA s22 @Health.gov.au>
Cc: KAY, Elspeth <Elspeth.Kay@health.gov.au>
Subject: FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]

Hi Grant for your input pls and back to EK asap

Regards

s22

Phone: s22

From: HPRG Parliamentary [redacted]@health.gov.au>
Sent: Tuesday, 7 February 2023 11:48 AM
To: KAY, Elspeth <Elspeth.Kay@health.gov.au>; GILL, Tony <Tony.Gill@health.gov.au>
Cc: [redacted]@health.gov.au>; [redacted]@health.gov.au>; [redacted]@health.gov.au>; [redacted]@health.gov.au>; [redacted]@health.gov.au>
Subject: FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]

Dear Elspeth and Tony

Grateful for any input that you can provide, noting that John will want to consider and clear this before it is returned to PIPCRD.

They were hopeful of receiving this input by COB today because it appears that they have been holding the PDR for two weeks and it is due tomorrow, and so we'll aim to meet this deadline.

Cheers

[redacted]

From: [redacted]@health.gov.au>
Sent: Tuesday, 7 February 2023 10:58 AM
To: HPRG Parliamentary [redacted]@health.gov.au>
Cc: [redacted]@health.gov.au>
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Many thanks in advance and apologies for the tight timeframes.

Kind regards

[redacted]
A/g Assistant Director - Intergovernmental Engagement Section
Vaccine Policy & Transition Branch
National COVID-19 Vaccine Program Division | Health Resourcing Group
Australian Government, Department of Health and Aged Care
T: [redacted] | E: [redacted]@health.gov.au
Location: Scarborough House 10.210
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[redacted]

s22

From: GILL, Tony
To: s22 s22
Cc: PMAB Coordination; s22
Subject: RE: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]
Date: Tuesday, 7 February 2023 4:04:20 PM
Attachments: image001.png
image002.png
image003.png
image004.png
image005.png

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s22
Cleared input is

> Provisional determination applications for COVID-19 vaccines or treatments are not required to demonstrate comparison to other medicines that are registered in the Australian Register of Therapeutic Goods (ARTG), or justification of a major therapeutic advance. This is to facilitate potential availability of a range of COVID-19 vaccine and treatment options through the provisional registration pathway, noting the seriousness of the pandemic. To be clear, comparison to other vaccines was not required or evaluated. Rather, each provisionally approved vaccine met the TGA's requirement that benefit outweighed risk for safety, quality and efficacy.
>
> In any case the TGA notes that data continues to emerge in relation to comparative vaccine efficacy on variants of concern.

NOTE any comment on advice on whether to use or not is not for TGA
Regards
Tony

From: s22
Sent: Tuesday, 7 February 2023 3:56 PM
To: GILL, Tony
Cc: PMAB Coordination ; s22 ; PBPMA ; s22 ; KAY, Elspeth ; s22
Subject: RE: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]

Hi Tony
PMAB input for your clearance.
s22

> Provisional determination applications for COVID-19 vaccines or treatments are not required to demonstrate comparison to other medicines that are registered in the Australian Register of Therapeutic Goods (ARTG), or justification of a major therapeutic advance. This is to facilitate potential availability of a range of COVID-19 vaccine and treatment options through the provisional registration pathway, noting the seriousness of the pandemic. To be clear, comparison to other vaccines was not required or evaluated. Rather, each provisionally approved vaccine met the TGA's high standard for safety, quality and efficacy.
>
> In any case the TGA notes that data continues to emerge in relation to comparative vaccine efficacy on variants of concern.
>
> *OPTIONAL (for further info)*
>
> *COMIRNATY Original/Omicron BA.1 (tozinameran and riltozinameran)*
>
> ¡¤Approval of the Pfizer BA.1 bivalent vaccine was supported by immunogenicity and safety data from the C4591031 trial. Participants aged >55 years received Pfizer

bivalent (BA.1) vaccine as their second booster dose (fourth dose), 5 to 12 months following a Pfizer original primary course (30mcg) and Pfizer original first booster dose (30mcg).

- The trial included 305 people who received the Pfizer bivalent (BA.1) vaccine and 305 people who received the Pfizer original vaccine as a second booster dose.
- Against the Omicron BA.1 variant, the Pfizer bivalent vaccine provided 1.6 times higher neutralising antibodies compared to the original vaccine, in people without prior infection. Against the original virus, neutralising antibody titres were similar for the Pfizer bivalent and Pfizer original vaccine.
- While immunogenicity data was not available for people aged ≤55 years for the bivalent version of the product, the C4591031 trial included a cohort of participants aged 18 to 55 years who received the Pfizer monovalent Omicron BA.1 vaccine (30mcg) as a second booster – that is, the vaccine contained the active ingredient designed to target BA.1 only.
- The trial included 263 people receiving the Pfizer monovalent Omicron BA.1 vaccine and 280 people receiving the Pfizer original vaccine. Against the Omicron BA.1 variant, neutralising antibodies for the Pfizer monovalent BA.1 vaccine were higher compared to the Pfizer original vaccine (unpublished company data) by a similar degree to that seen in the Pfizer bivalent study above.
- Initial results demonstrated that this vaccine produces neutralising antibodies against BA.4/5, though to a lesser extent than BA.1.

COMIRNATY ORIGINAL/OMICRON BA.4-5 COVID-19 VACCINE (tozinameran and famtozinameran)

The following studies demonstrate the effectiveness of bivalent boosters (in some cases against the monovalent):

- On January 25 2023, the *New England Journal of Medicine (NEJM)* published a study on the effectiveness of bivalent booster against severe Omicron infection. The study found the bivalent vaccine to be 58.7% effective against hospitalisation compared to 25% for the monovalent; its effectiveness against infection was 61.8% compared to 24.9% for the monovalent. Scientists noted that this study covered a period when Omicron subvariants BQ.1 and BQ.1.1. were also circulating, which suggests the updated vaccine is more effective against those strains in addition to the ones it was designed to target. Effectiveness of Bivalent Boosters against Severe Omicron Infection | NEJM
- A study from the US CDC, published on 25 January 2023, assessed the bivalent vaccine's effectiveness against the most recent Omicron subvariants, XBB and XBB.1.5, in people who had previously received two to four monovalent vaccine doses, and found it to be similar in efficacy as it is against BA.5 for at least the first three months after vaccination. The CDC's study was based on COVID-19 tests performed in the pharmacy, and it found effectiveness against symptomatic infection varied by age: in ages 18 to 49, it was 49% against the XBB strains versus 52% against the BA.5 viruses; in ages 50 to 64, it was 40% compared to 43% for BA.5; and in people 65 and older, 43%, compared to 37% for the BA.5 viruses. Early Estimates of Bivalent mRNA Booster Dose Vaccine Effectiveness in Preventing Symptomatic SARS-CoV-2 Infection Attributable to Omicron BA.5– and XBB/XBB.1.5–Related Sublineages Among Immunocompetent Adults — Increasing Community Access to Testing Program, United States, December 2022–January

2023 | MMWR (cdc.gov)

- A recent study (Arbel *et al*, Lancet preprints 2023) posted by Lancet Preprints on **3 January 2023**, indicated that a booster dose of a bivalent mRNA vaccine significantly reduced the risk of COVID-19-associated hospitalisation and death by **81% and 86%,** respectively. Amidst the rising number of breakthrough infections from emergent Omicron subvariants, these findings highlight the importance of making the bivalent vaccine available to those at high risk of COVID-19, such as the older section of the population and individuals with comorbidities. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4314067

From: s22 [redacted] @health.gov.au>
Sent: Tuesday, 7 February 2023 1:38 PM
To: KAY, Elspeth <Elspeth.Kay@health.gov.au>; s22 [redacted] @health.gov.au>
Cc: GILL, Tony <Tony.Gill@health.gov.au>; PMAB Coordination s22 [redacted] @Health.gov.au>; s22 [redacted] @health.gov.au>; PBPMA s22 [redacted] @Health.gov.au>; s22 [redacted] @health.gov.au>
Subject: RE: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]

Thanks Elspeth,

I won't send up 'til I have PMAB's cleared input too, saves confusion

Cheers,

s22 [redacted]
s22 [redacted] (Ms/ she/ her)
Executive Officer to Nick Henderson, A/g First Assistant Secretary

Medicines Regulation Division | Health Products Regulation Group
(comprising the Therapeutic Goods Administration and the Office of Drug Control)
Australian Government, Department of Health and Aged Care
☎: s22 [redacted] | 💻: s22 [redacted] @health.gov.au
Location: Fairbairn 1.S.221
📫: PO Box 100, Woden ACT 2606, Australia
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From: KAY, Elspeth <Elspeth.Kay@health.gov.au>
Sent: Tuesday, 7 February 2023 1:35 PM
To: PBPMA s22 [redacted] @Health.gov.au>; s22 [redacted] @health.gov.au>
Cc: GILL, Tony <Tony.Gill@health.gov.au>; PMAB Coordination s22 [redacted] @Health.gov.au>; s22 [redacted] @health.gov.au>
Subject: RE: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]

Thanks v much Grant. s [redacted], this input is cleared for Nick's review.

From: KAY, Elspeth
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Cc: GILL, Tony <Tony.Gill@health.gov.au>; PMAB Coordination s22 [redacted] @Health.gov.au>; s22 [redacted] @health.gov.au>
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Cc: GILL, Tony <Tony.Gill@health.gov.au>; PMAB Coordination s22 @Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
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Sent: Tuesday, 7 February 2023 11:51 AM
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Cc: KAY, Elspeth <Elspeth.Kay@health.gov.au>
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Regards
s22
Phone: s22

From: HPRG Parliamentary s22 @health.gov.au>
Sent: Tuesday, 7 February 2023 11:48 AM
To: KAY, Elspeth <Elspeth.Kay@health.gov.au>; GILL, Tony <Tony.Gill@health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]
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From: s22 @health.gov.au>
Sent: Tuesday, 7 February 2023 10:58 AM
To: HPRG Parliamentary s22 @health.gov.au>
Cc: s22 @health.gov.au>
Subject: FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]

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Many thanks in advance and apologies for the tight timeframes.
Kind regards

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A/g Assistant Director - Intergovernmental Engagement Section
Vaccine Policy & Transition Branch
National COVID-19 Vaccine Program Division | Health Resourcing Group
Australian Government, Department of Health and Aged Care
T s22 | E s22 @health.gov.au
Location: Scarborough House 10.210
GPO Box 9848, Canberra ACT 2601, Australia
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s22

s22

From: KAY, Elspeth
To: HENDERSON, Nick; s22 GILL, Tony
Cc: s22 ; s22 ; s22 HPRG Parliamentary; s22 ; s22 ; s22 ; s22 ; PSAB Co-ord Inbox; PMAB Coordination
Subject: RE: URGENT ACTION - CLEARANCE - FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]
Date: Tuesday, 7 February 2023 5:22:19 PM
Attachments: image001.png
image002.png
image003.png
image004.png

Thanks s22 no concerns about the content.

From: HENDERSON, Nick
Sent: Tuesday, 7 February 2023 4:57 PM
To: s22 ; KAY, Elspeth ; GILL, Tony
Cc: s22 ; s22 ; s22 ; HPRG Parliamentary ; PBPMA ; s22 ; s22 ; s22 ; PSAB Co-ord Inbox ; PMAB Coordination
Subject: RE: URGENT ACTION - CLEARANCE - FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]

Perfect thanks s22
Nick

From: s22 @health.gov.au>
Sent: Tuesday, 7 February 2023 4:52 PM
To: HENDERSON, Nick <Nick.Henderson@health.gov.au>; KAY, Elspeth <Elspeth.Kay@health.gov.au>; GILL, Tony <Tony.Gill@health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; PBPMA s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; PSAB Co-ord Inbox s22 @Health.gov.au>; PMAB Coordination s22 @Health.gov.au>
Subject: RE: URGENT ACTION - CLEARANCE - FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]
Importance: High

Hi Nick,

I've updated BPB 1 with the information about comparative efficacy below:

	D23-5032371	COVID-19 vaccines – *This stays as a general brief with more details about the approval timelines and more stats than is in the HIB.* *NEW*

And in BPB 3 I've added the info below about stroke in 65 yrs and over (last pg):

3.	D23-5034216	COVID-19 Vaccines - Adverse Effects *NEW*

Are you happy with this? @GILL, Tony@KAY, Elspeth any concerns/ additions?

Cheers,

s22
s22 (Ms/ she/ her)
Executive Officer to Nick Henderson, A/g First Assistant Secretary

Medicines Regulation Division | Health Products Regulation Group
(comprising the Therapeutic Goods Administration and the Office of Drug Control)
Australian Government, Department of Health and Aged Care
☎: s22 | 💻: s22 @health.gov.au
Location: Fairbairn 1.S.221
📫: PO Box 100, Woden ACT 2606, Australia
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From: HENDERSON, Nick <Nick.Henderson@health.gov.au>
Sent: Tuesday, 7 February 2023 4:42 PM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; HPRG Parliamentary s22 @health.gov.au>
Subject: RE: URGENT ACTION - CLEARANCE - FW: MC23-001915 - FW: Correspondence from Senator Rennick

[SEC=OFFICIAL]
Thank you cleared, and can the BPBs be updated to reflect the below

From: s22 @health.gov.au>
Sent: Tuesday, 7 February 2023 4:07 PM
To: HENDERSON, Nick <Nick.Henderson@health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; HPRG Parliamentary s22 @health.gov.au>
Subject: URGENT ACTION - CLEARANCE - FW: MC23-001915 - FW: Correspondence from Senator Rennick
[SEC=OFFICIAL]
Importance: High

Hi Nick,

Elspeth and Tony have cleared the below input to the attached MC from Sen Rennick that PIPCRD are responding to (noting any comment on advice on whether to use or not is not for TGA) – it only came to us this morning and is due today:

> Provisional determination applications for COVID-19 vaccines or treatments are not required to demonstrate comparison to other medicines that are registered in the Australian Register of Therapeutic Goods (ARTG), or justification of a major therapeutic advance. This is to facilitate potential availability of a range of COVID-19 vaccine and treatment options through the provisional registration pathway, noting the seriousness of the pandemic. To be clear, comparison to other vaccines was not required or evaluated. Rather, each provisionally approved vaccine met the TGA's requirement that benefit outweighed risk for safety, quality and efficacy.
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For your urgent review and clearance ASAP today please.

Cheers,

s22
s22 (Ms/ she/ her)
Executive Officer to Nick Henderson, A/g First Assistant Secretary

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(comprising the Therapeutic Goods Administration and the Office of Drug Control)
Australian Government, Department of Health and Aged Care
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Location: Fairbairn 1.S.221
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Kind regards

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A/g Assistant Director - Intergovernmental Engagement Section

Vaccine Policy & Transition Branch

National COVID-19 Vaccine Program Division | Health Resourcing Group

Australian Government, Department of Health and Aged Care

T s22 | E: s22 @health.gov.au

Location: Scarborough House 10 210

GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connect on to land, sea and comm. n ty. We pay o. r respects to them and the r c. lt. res, and to all Elders both past and present.

s22

s22

From: s22
To: s22
Cc: s22 ; HPRG Parliamentary; GILL, Tony; s22 ; s22
Subject: RE: URGENT ACTION - CLEARANCE - FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]
Date: Tuesday, 7 February 2023 6:12:22 PM
Attachments: image001.png
image002.png
image003.png
image004.png

Hi s22 ,

Apologies it was BPB 8C I updated, not BPB 1, with the comparative words:

8C	D23-5057563	COVID-19 Vaccines – Treatments- *NEW*

Cheers,

s22
s22 (Ms/ she/ her)
Executive Officer to Nick Henderson, A/g First Assistant Secretary

Medicines Regulation Division | Health Products Regulation Group
(comprising the Therapeutic Goods Administration and the Office of Drug Control)
Australian Government, Department of Health and Aged Care
☎: s22 | 💻: s22 @health.gov.au
Location: Fairbairn 1.S.221
📫: PO Box 100, Woden ACT 2606, Australia
The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22
Sent: Tuesday, 7 February 2023 5:00 PM
To: s22
Cc: s22 ; HPRG Parliamentary
Subject: FW: URGENT ACTION - CLEARANCE - FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]

Hi s22 ,

As discussed Nick has cleared updates to the following 2 BPBs based on the input we are providing to PCPID re Sen Rennick's corro (which is w John for clearance). These changes are in tracked:

I've updated BPB 1 with the information about comparative efficacy below:

1.	D23-5032371	COVID-19 vaccines – *This stays as a general brief with more details about the approval timelines and more stats than is in the HIB.* *NEW*

And in BPB 3 I've added the info below about stroke in 65 yrs and over (last pg):

3.	D23-5034216	COVID-19 Vaccines - Adverse Effects *NEW*

Cheers,

s22
s22 (Ms/ she/ her)
Executive Officer to Nick Henderson, A/g First Assistant Secretary

Medicines Regulation Division | Health Products Regulation Group
(comprising the Therapeutic Goods Administration and the Office of Drug Control)
Australian Government, Department of Health and Aged Care
☎: s22 | 💻: s22 @health.gov.au
Location: Fairbairn 1.S.221
📫: PO Box 100, Woden ACT 2606, Australia
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From: HENDERSON, Nick <Nick.Henderson@health.gov.au>
Sent: Tuesday, 7 February 2023 4:57 PM
To: s22 @health.gov.au>; KAY, Elspeth <Elspeth.Kay@health.gov.au>; GILL, Tony <Tony.Gill@health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22

s22 @health.gov.au>; HPRG Parliamentary s22 @health.gov.au>; PBPMA s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; PSAB Co-ord Inbox s22 @Health.gov.au>; PMAB Coordination s22 @Health.gov.au>

Subject: RE: URGENT ACTION - CLEARANCE - FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]

Perfect thanks s2

Nick

From: s22 @health.gov.au>

Sent: Tuesday, 7 February 2023 4:52 PM

To: HENDERSON, Nick <Nick.Henderson@health.gov.au>; KAY, Elspeth <Elspeth.Kay@health.gov.au>; GILL, Tony <Tony.Gill@health.gov.au>

Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; HPRG Parliamentary s22 @health.gov.au>; PBPMA s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; PSAB Co-ord Inbox s22 @Health.gov.au>; PMAB Coordination s22 @Health.gov.au>

Subject: RE: URGENT ACTION - CLEARANCE - FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]

Importance: High

Hi Nick,

I've updated BPB 1 with the information about comparative efficacy below:

	D23-5032371	COVID-19 vaccines – *This stays as a general brief with more details about the approval timelines and more stats than is in the HIB.* *NEW*

And in BPB 3 I've added the info below about stroke in 65 yrs and over (last pg):

3.	D23-5034216	COVID-19 Vaccines - Adverse Effects *NEW*

Are you happy with this? @GILL, Tony@KAY, Elspeth any concerns/ additions?

Cheers,

s22
s22 (Ms/ she/ her)
Executive Officer to Nick Henderson, A/g First Assistant Secretary

Medicines Regulation Division | Health Products Regulation Group
(comprising the Therapeutic Goods Administration and the Office of Drug Control)
Australian Government, Department of Health and Aged Care
☎: s22 : s22 @health.gov.au
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: PO Box 100, Woden ACT 2606, Australia
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From: HENDERSON, Nick <Nick.Henderson@health.gov.au>

Sent: Tuesday, 7 February 2023 4:42 PM

To: s22 @health.gov.au>

Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; HPRG Parliamentary s22 @health.gov.au>

Subject: RE: URGENT ACTION - CLEARANCE - FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]

Thank you cleared, and can the BPBs be updated to reflect the below

---

From: s22 @health.gov.au>

Sent: Tuesday, 7 February 2023 4:07 PM

To: HENDERSON, Nick <Nick.Henderson@health.gov.au>

Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; HPRG Parliamentary s22 @health.gov.au>

Subject: URGENT ACTION - CLEARANCE - FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]

Importance: High

Hi Nick,

Elspeth and Tony have cleared the below input to the attached MC from Sen Rennick that PIPCRD are responding to (noting any comment on advice on whether to use or not is not for TGA) – it only came to us this morning and is due today:

> Provisional determination applications for COVID-19 vaccines or treatments are not required to demonstrate comparison to other medicines that are registered in the Australian Register of Therapeutic Goods (ARTG), or justification of a major therapeutic advance. This is to facilitate potential availability of a range of COVID-19 vaccine and treatment options through the provisional registration pathway, noting the seriousness of the pandemic. To be clear, comparison to other vaccines was not required or evaluated. Rather, each provisionally approved vaccine met the TGA's requirement that benefit outweighed risk for safety, quality and efficacy.
>
> In any case the TGA notes that data continues to emerge in relation to comparative vaccine efficacy on variants of concern.
>
> The TGA is aware of the United States Centers for Disease Control (CDC) and Food and Drug Administration (FDA)'s article dated 13 January 2023, which states that a preliminary safety signal has been detected for stroke in people ages 65 and older who received the Pfizer bivalent COVID-19 Vaccine. This preliminary signal was identified in the CDC's Vaccine Safety Datalink (VSD), which is one of their safety monitoring systems.
>
> The detection of a data signal does not automatically mean that the adverse event was caused by the vaccine. The article states that the CDC and FDA continue to evaluate this signal further and that to date, no other safety systems have shown a similar signal, multiple subsequent analyses have not validated this signal, and that the totality of the data currently suggests that it is very unlikely that this signal represents a true clinical risk. Notably, FDA and CDC recommend no change in the current vaccination practice.
>
> In Australia, the TGA has not observed any safety signal for stroke following administration of bivalent mRNA COVID-19 vaccines (Pfizer and Moderna), noting the number of doses of bivalent vaccines administered has been proportionally lower than monovalent vaccines. The TGA continues to closely monitor the safety of bivalent COVID-19 vaccines, including updates on this preliminary signal that may arise from the FDA, and will take appropriate regulatory action if necessary.

For your urgent review and clearance ASAP today please.

Cheers,

s22
s22 (Ms/ she/ her)
Executive Officer to Nick Henderson, A/g First Assistant Secretary

Medicines Regulation Division | Health Products Regulation Group
(comprising the Therapeutic Goods Administration and the Office of Drug Control)
Australian Government, Department of Health and Aged Care
☎: s22 | 💻: s22 @health.gov.au
Location: Fairbairn 1.S.221
📫: PO Box 100, Woden ACT 2606, Australia
The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: HPRG Parliamentary s22 @health.gov.au>
Sent: Tuesday, 7 February 2023 11:48 AM
To: KAY, Elspeth <Elspeth.Kay@health.gov.au>; GILL, Tony <Tony.Gill@health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]

Dear Elspeth and Tony

Grateful for any input that you can provide, noting that John will want to consider and clear this before it is returned to PIPCRD.

They were hopeful of receiving this input by COB today because it appears that they have been holding the PDR for two weeks and it is due tomorrow, and so we'll aim to meet this deadline.

Cheers

s22

From: s22 @health.gov.au>
Sent: Tuesday, 7 February 2023 10:58 AM
To: HPRG Parliamentary s22 @health.gov.au>
Cc: s22 @health.gov.au>
Subject: FW: MC23-001915 - FW: Correspondence from Senator Rennick [SEC=OFFICIAL]

Hi Team,

We have just been allocated the below corro for an M response. The response is due to MO tomorrow.

As such, can you please provide input addressing the concerns raised with regards to the efficacy of bivalent boosters and Pfizer Bivalent vaccines causing stroke in people aged 65 and older, by COB today.

Many thanks in advance and apologies for the tight timeframes.

Kind regards

s22

A/g Assistant Director - Intergovernmental Engagement Section
Vaccine Policy & Transition Branch

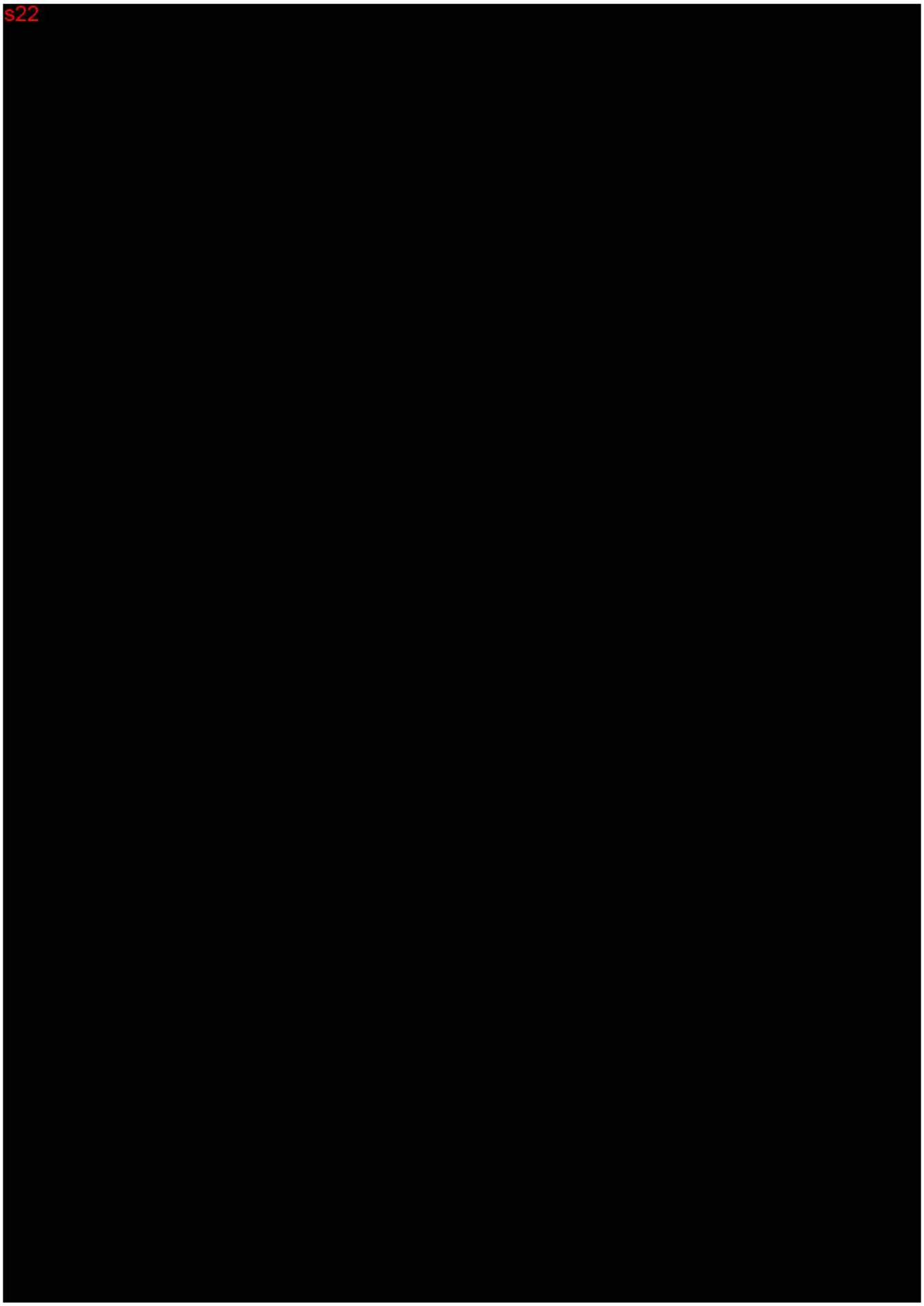
National COVID-19 Vaccine Program Division | Health Resourcing Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: Scarborough House 10 210
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing

s22

HPRG Senate Estimates Brief

s22



s22

s22

s22

s22

[redacted]

Stroke in people aged 65 or older

- The TGA is aware of the United States Centers for Disease Control (CDC) and Food and Drug Administration (FDA)'s article dated 13 January 2023, which states that a preliminary safety signal has been detected for stroke in people ages 65 and older who received the Pfizer bivalent COVID-19 Vaccine. This preliminary signal was identified in the CDC's Vaccine Safety Datalink (VSD), which is one of their safety monitoring systems.
- The detection of a data signal does not automatically mean that the adverse event was caused by the vaccine. The article states that the CDC and FDA continue to evaluate this signal further and that to date, no other safety systems have shown a similar signal, multiple subsequent analyses have not validated this signal, and that the totality of the data currently suggests that it is very unlikely that this signal represents a true clinical risk. Notably, FDA and CDC recommend no change in the current vaccination practice.

- In Australia, the TGA has not observed any safety signal for stroke following administration of bivalent mRNA COVID-19 vaccines (Pfizer and Moderna), noting the number of doses of bivalent vaccines administered has been proportionally lower than monovalent vaccines. The TGA continues to closely monitor the safety of bivalent COVID-19 vaccines, including updates on this preliminary signal that may arise from the FDA, and will take appropriate regulatory action if necessary.

Division:	Medicines Regulation Division
Contact Officer:	Elspeth Kay
Date:	6 February 2023

From: s22
To: s22 ; s22 ; VUCKOVIC, George
Cc: SIMPSON, Andrew; HENDERSON, Nick; s22
Subject: RE: **URGENT REVIEW: Request for instructions by 12pm on 8 February 2023 - Parry & Ors v Secretary, Department of Health (S162/2022) - High Court matter [SEC=OFFICIAL, ACCESS=Legal-Privilege]
Date: Wednesday, 8 February 2023 9:52:12 AM
Attachments: image001.png
image002.png
image003.png
image004.gif
image005.jpg
image006.jpg
image007.jpg

Hi s2 ,
Also found this from the April SQoNs

COVID vaccines and OGTR

Added 13 April 2022 from SQ22-000134

The Office of Gene Technology Regulator (OGTR) regulates genetically modified organisms (GMOs). A GMO is defined as a plant, animal or other organism whose genetic material has been modified using gene technology or an organism that has inherited modified traits from a GMO.

The Therapeutic Goods Administration (TGA) did not seek advice or analysis from the OGTR before approving the Pfizer vaccine, nor was authorisation required from OGTR. This is because messenger RNA (mRNA) vaccines, such as the Pfizer and Moderna COVID-19 vaccines, are not considered to be GMOs.

mRNA vaccines contain fragments of mRNA that give our cells instructions about how to make the coronavirus' antigenic protein, the spike protein. When our body has made the protein encoded by the mRNA vaccine, it then recognises that the spike protein is foreign and mounts an immune response against it. The mRNA is broken down quickly by the body. It never enters the cell nucleus and cannot affect or combine with our DNA in any way to change our genetic code.

The viral vector COVID-19 vaccines, including the AstraZeneca (Vaxzevria) and Janssen COVID-19 vaccines, contain genetically modified material so do fall under the OGTR's remit.

Viral vector vaccines use a genetically modified, non-pathogenic, weakened virus that contains the genetic code for the coronavirus' unique spike protein (Vaxzevria uses an animal virus, Janssen uses a human virus). When this enters our body, the genetic material contained in the viral vector instructs our cells to make the copies of the coronavirus spike protein. Our body then recognises the spike protein as being foreign and mounts an immune response against it. As with mRNA vaccines, the genetic material from viral vector vaccines does not change, or interact, with our DNA in any way.

Subsection 30C(2) of the *Therapeutic Goods Act 1989,* states that the TGA must provide written notice to the OGTR stating that an application to register a therapeutic good containing a GMO has been made and requesting that the OGTR provide advice about the application. Accordingly, the OGTR did provide an analysis to the TGA about the AstraZeneca and Janssen COVID-19 vaccines.

OGTR assessed and issued a licence to AstraZeneca and Janssen for the importation, transport, storage and disposal of their COVID-19 vaccines.

- The AstraZeneca COVID-19 vaccine licence is available at: www.ogtr.gov.au/gmo-dealings/dealings-involving-intentional-release/dir-180
- The Janssen COVID-19 vaccine licence is available at: www.ogtr.gov.au/gmo-dealings/dealings-involving-intentional-release/dir-182

In addition, the TGA have several dozen scientific and regulatory staff with extensive experience in gene technology.

s22
Engagement and Coordination Officer, Application Entry, Support and Exports Section
Prescription Medicines Authorisation Branch
Medicines Regulation Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: Fairbairn Business Park, Level 1 North
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22
Sent: Wednesday, 8 February 2023 9:51 AM
To: s22 ; s22 ; VUCKOVIC, George
Cc: SIMPSON, Andrew ; HENDERSON, Nick ; s22
Subject: RE: **URGENT REVIEW: Request for instructions by 12pm on 8 February 2023 - Parry & Ors v Secretary, Department of Health (S162/2022) - High Court matter [SEC=OFFICIAL, ACCESS=Legal-Privilege]
Importance: High

Hi s22 and George,

I've had a look at the SQoNs from November and can't see we answered any q's on this then directly, however SEB provided input into the attached SQoN about how many people we have reviewing genotoxicity of vaccines.

There isn't anything I can find from Feb or April SE last year either.

Not sure the above is of any assistance, but please let me know if you need anything to draft the input Nick is after.

Cheers,

s22
s22 (Ms/ she/ her)
Executive Officer to Nick Henderson, A/g First Assistant Secretary

Medicines Regulation Division | Health Products Regulation Group
(comprising the Therapeutic Goods Administration and the Office of Drug Control)
Australian Government, Department of Health and Aged Care
☎: s22 | 💻: s22 @health.gov.au
Location: Fairbairn 1.S.221
📫: PO Box 100, Woden ACT 2606, Australia

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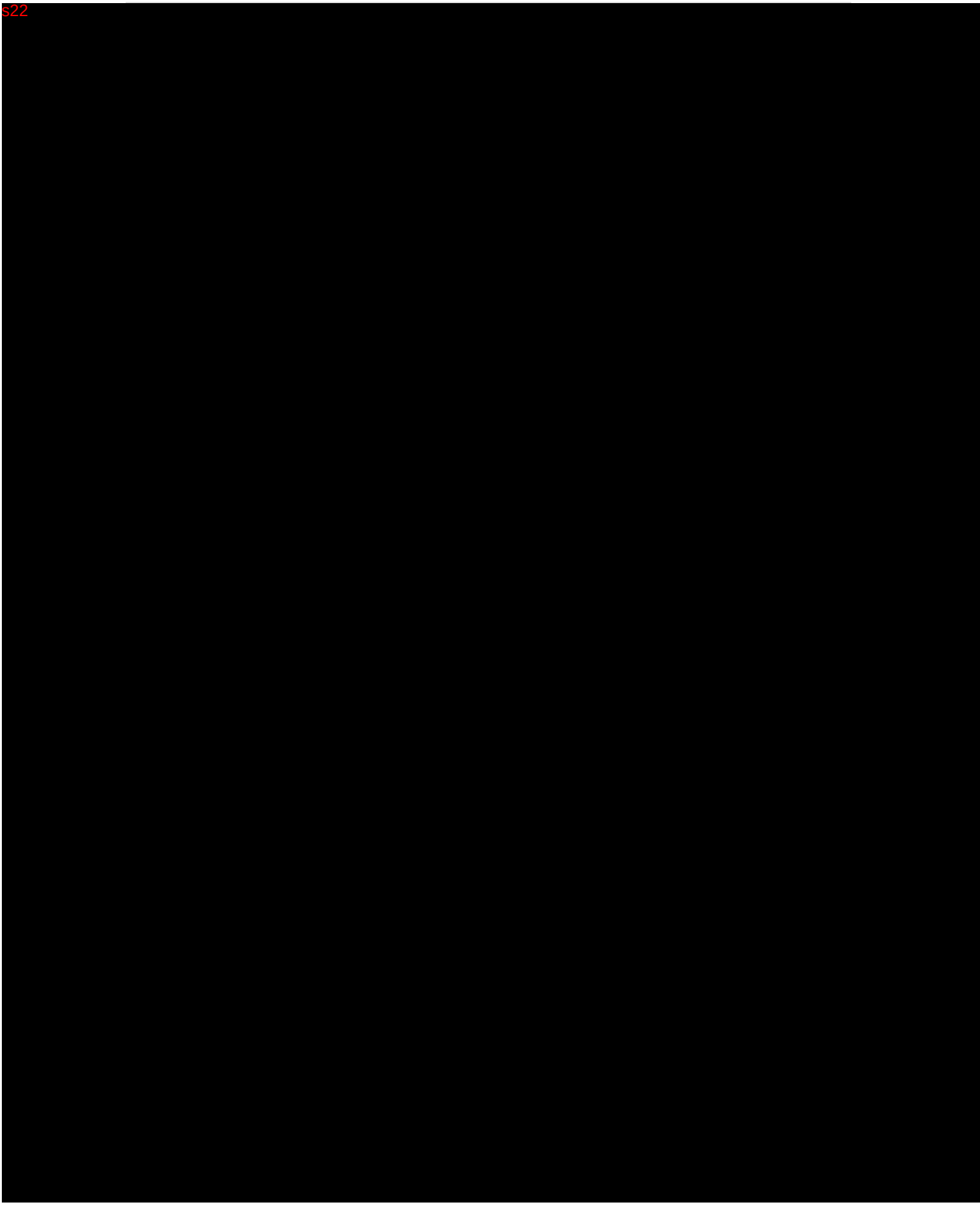
From: HENDERSON, Nick <Nick.Henderson@health.gov.au>
Sent: Wednesday, 8 February 2023 9:37 AM
To: s22 @health.gov.au>; s22 @health.gov.au>
Cc: SIMPSON, Andrew <Andrew.Simpson@health.gov.au>
Subject: FW: **URGENT REVIEW: Request for instructions by 12pm on 8 February 2023 - Parry & Ors v Secretary, Department of Health (S162/2022) - High Court matter [SEC=OFFICIAL, ACCESS=Legal-Privilege]

Hi s2 and s2

Based on the issues in these proceedings, could I get some wording on mRNA vaccines not being a

GMO and therefore no need to get OGTR approval. I remember this line of questioning was asked at the previous Senate Estimates to the OGTR and they said not their issue its TGA, but Sentor Rennick didn't get back to it when we were up
Nick

s22



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s22 [redacted]

Document 7

From: s22 [redacted]
Sent: Friday, 3 February 2023 12:40 PM
To: GILL, Tony <Tony.Gill@health.gov.au>
Cc: s22 [redacted] @health.gov.au>
Subject: **ADVICE - BPBs PMAB [SEC=OFFICIAL]

Tony – draft below for your consideration. Please cc s2 [redacted] when you send

Hello John

As requested, PMAB has drafted the below back pocket briefs relating to COVID for estimates (currently with Nick for clearance). We have suggested some name changes to better align with content of the briefs and to avoid confusion and duplication.

1	COVID-19 vaccines and treatments - approvals - *This stays as a general brief with more details about the approval timelines and more stats than is in the HIB.*
67	Review of TGA Decisions - Types of review and trends
7	COVID-19 vaccine - Efficacy and saftey in Children
8	COVID-19 Vaccines – mRNA Vaccine Translation structure, lab tests, characteristics and storage
8C	COVID-19 ~~Vaccines~~ – Treatments (including efficacy of monoclonal antibodies)
6	COVID-19 Efficacy of vaccines ~~and treatments~~ (including impact of vaccines on transmission) and boosters

You also requested a brief on *COVID-19 Vaccines – Administrative / Legal*, could you please provide advice on what you would like to be captured in this brief? As per the attached, we note that QoNs relevant to this brief relate to ACV, a meeting with Senator Rennick and COVID FOI requests. We are happy to provide further info on these matters but want to clarify that this is indeed the information that your are after.

Many thanks

s22

[redacted]

Document 8

From: s22 [redacted] @health.gov.au>
Sent: Monday, 6 February 2023 8:30 PM
To: HENDERSON, Nick <Nick.Henderson@health.gov.au>; GILL, Tony <Tony.Gill@health.gov.au>
Cc: s22 [redacted] @health.gov.au>; PMAB Coordination
s22 [redacted] @Health.gov.au>
Subject: RE: ADVICE - BPBs PMAB [SEC=OFFICIAL]

Happy to talk you through it.

Essentially we've just pulled out let's of the QoNs which John referred as relevant (see below).

Without further direction it's very difficult to know what John wants, noting the rest of the major issues relating to COVID are covered in the remaining briefs.

s2 [redacted]

8B (10) QoN	D23-5057561 TRIM	COVID-19 Vaccines – Administrative / Legal (other) Title
66	SQ22-000637	Lodgement of complaint to TGA regarding vaccine
84	SQ22-000674	Misleading information by Professor Kelly and Adjunct Professor Skerritt
86	SQ22-000534	FOI requests to TGA

Sent from Workspace ONE Boxer

On 6 February 2023 at 6:19:06 pm AEDT, HENDERSON, Nick <Nick.Henderson@health.gov.au> wrote:

> Thanks s2 [redacted], the request is a little confusing. I'll go through in the morning using my QoN folder

From: GILL, Tony <Tony.Gill@health.gov.au>
Sent: Monday, 6 February 2023 6:09 PM
To: s22 @health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
Cc: s22 @health.gov.au>; PMAB Coordination s22 @Health.gov.au>
Subject: RE: ADVICE - BPBs PMAB [SEC=OFFICIAL]

s2
Happy to go with this as a start!
Tony

From: s22 @health.gov.au>
Sent: Monday, 6 February 2023 6:02 PM
To: HENDERSON, Nick <Nick.Henderson@health.gov.au>; GILL, Tony <Tony.Gill@health.gov.au>
Cc: s22 @health.gov.au>; PMAB Coordination s22 @Health.gov.au>
Subject: RE: ADVICE - BPBs PMAB [SEC=OFFICIAL]

Hi Nick/Tony

Draft as requested.

D23-5057561

Thanks
s2

From: s22 @health.gov.au>
Sent: Monday, 6 February 2023 3:15 PM
To: s22 @health.gov.au>
Cc: HENDERSON, Nick <Nick.Henderson@health.gov.au>; s22 @health.gov.au>; GILL, Tony <Tony.Gill@health.gov.au>; s22 @health.gov.au>
Subject: RE: ADVICE - BPBs PMAB [SEC=OFFICIAL]

Hi s22

As I wasn't copied in on this email – I have not been able to follow up with John about it. I did discuss it with Tony Gill and provided him with John's view and a suggested course of Action (write the brief as requested – copying from QoN responses and other BPBs as needed.)

John is not back in the office until tomorrow and travelling at the moment, so I won't be able to follow up with him – as he has several other priorities he is dealing with.

As the BPBs are due to John today – it would be good to get a draft at least done. Then John can review and provide advice if he wants something further.

Thanks

s22
Executive Office Manager to Deputy Secretary John Skerritt
Health Products Regulation Group
(comprising the Therapeutic Goods Administration and the Office of Drug Control)
T: s22 | E: s22 @health.gov.au
Location: Fairbairn Level 2 North - 2.N.461

From: s22 @health.gov.au>
Sent: Monday, 6 February 2023 2:55 PM
To: s22 @health.gov.au>
Cc: HENDERSON, Nick <Nick.Henderson@health.gov.au>; s22 @health.gov.au>; GILL, Tony <Tony.Gill@health.gov.au>; s22 @health.gov.au>
Subject: RE: ADVICE - BPBs PMAB [SEC=OFFICIAL]
Importance: High

Hi s22,

Tony Gill has just asked me to follow up the below email he sent to John on Friday afternoon, as he's not yet heard back. In particular we are seeking urgent guidance on:

You also requested a brief on *COVID-19 Vaccines – Administrative / Legal, linking the following QoNs*

8B (10)	D23-5057561	COVID-19 Vaccines – Administrative / Legal (other)
QoN	TRIM	Title
66	SQ22-000637	Lodgement of complaint to TGA regarding vaccine
84	SQ22-000674	Misleading information by Professor Kelly and Adjunct Professor Skerritt
86	SQ22-000534	FOI requests to TGA

we note that QoNs relevant to this brief relate to AEs and ACV, a meeting with Senator Rennick and COVID FOI requests.
Qon 66 has been covered in a PB brief
QoN 84 information is in other briefs
QoN 86 was about FOI disclosures etc which sits with RLSB.
I also note the High Court case is covered in another brief.
Could you please provide advice on what you would like to be captured in this brief or if there is still a need for this BPB?

Appreciate it if you could please bring this to John's attention.

Cheers,

s22

s22 (Ms/ she/ her)

Executive Officer to Nick Henderson, A/g First Assistant Secretary

Medicines Regulation Division | Health Products Regulation Group
(comprising the Therapeutic Goods Administration and the Office of Drug Control)
Australian Government, Department of Health and Aged Care
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From: GILL, Tony <Tony.Gill@health.gov.au>
Sent: Friday, 3 February 2023 4:30 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>
Cc: HENDERSON, Nick <Nick.Henderson@health.gov.au>; s22 s22 @health.gov.au>; s22 <s22 @health.gov.au>
Subject: ADVICE - BPBs PMAB [SEC=OFFICIAL]

John

As requested, PMAB has drafted the below back pocket briefs relating to COVID for estimates. We have suggested some name changes to better align with content of the briefs and to avoid confusion and duplication.

1	COVID-19 vaccines and treatments - approvals - *This stays as a general brief with more details about the approval timelines and more stats than is in the HIB.*
67	Review of TGA Decisions - Types of review and trends
7	COVID-19 vaccine - Efficacy and saftey in Children
8	COVID-19 Vaccines – mRNA Vaccine Translation structure, lab tests, characteristics and storage
8C	COVID-19 ~~Vaccines~~ – Treatments (including efficacy of monoclonal antibodies)
	COVID-19 Efficacy of vaccines ~~and treatments~~

6	(including impact of vaccines on transmission) and boosters

You also requested a brief on *COVID-19 Vaccines – Administrative / Legal, linking the following QoNs*

8B (10)	D23-5057561	COVID-19 Vaccines – Administrative / Legal (other)
QoN	TRIM	Title
66	SQ22-000637	Lodgement of complaint to TGA regarding vaccine
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Qon 66 has been covered in a PB brief
QoN 84 information is in other briefs
QoN 86 was about FOI disclosures etc which sits with RLSB.
I also note the High Court case is covered in another brief.
Could you please provide advice on what you would like to be captured in this brief or if there is still a need for this BPB?
Regards
Tony

[SEC=OFFICIAL]

COVID-19 Vaccines – Administrative/Legal

SQ22-00637 (folder reference QoN 66) - Lodgement of Complaint to TGA regarding vaccine (key issue: hard to lodge AEs)

- Almost 140,000 COVID-19 vaccine adverse event reports have been lodged since early 2021.
- The TGA has multiple channels available for reporters to submit an adverse event report.
  - Consumers and health professionals can report to the TGA via email, through the TGA website and even by mail and fax.
  - Consumers can call the Adverse Medicines Event telephone line which is staffed by pharmacists who assist consumers in reporting adverse events to the TGA.
  - Consumers can also report to the TGA via their health professional, such as their pharmacist or GP.
- For an adverse event report to be valid, information on only four elements is required:
  - patient
  - medicine or vaccine
  - adverse event experiences
  - the reporter of the event.
- The TGA has made templates available for GPs to integrate into some prescribing software, reducing the time to report as information is transferred from their system into the form.
- Acknowledgment letters are sent to members of the public who submit reports. This letter includes the TGA identifier for their report, which can be used by reporters if they wish to provide further information about their event.
- Reporters are not routinely given feedback about their adverse event report beyond the acknowledgement letter. However, in some cases reporters are contacted if further information is required to either complete or assess the adverse event report.

SQ22-000674 (folder reference QoN84) – Misleading information by Prof Kelly and Prof Skerritt (key issue transmission and lipid nanoparticles)

Effectiveness against Transmission – Prof Kelly's claim vaccines stopped transmission

- Transmission effects are not an approved indication of any COVID-19 vaccine. However, over the course of the pandemic, numerous studies have been published that report a positive effect of vaccination on transmission of the various subvariants. *(Back Pocket Brief 6 contains details of the studies supporting effectiveness against transmission*).
- Research is ongoing to directly assess the impacts of the more recent variants of concern on transmission, noting that vaccines to address viral variants continue to be developed. It is important to note that whilst dampening transmission of COVID-19 is important, the purpose and approved indication of COVID-19 vaccines is to prevent serious illness and death.

Lipid Nanoparticles

The spike protein in the mRNA vaccine has a transmembrane anchor region that makes the protein attach to the cell membrane and, in the absence of a signal sequence for secretion, will not be secreted or released into the blood stream from the cells (available at: www.pubmed.ncbi.nlm.nih.gov/33117378 and https://pubmed.ncbi.nlm.nih.gov/34400651/).

Therefore while the presence of spike proteins at very low levels cannot be excluded, - if there are trace levels of any spike proteins there is no evidence of any harm to the human body. Nonclinical animal toxicity studies, conducted at very high vaccine doses, and human data demonstrated the safety of the provisionally approved mRNA vaccines.

A whole-body imaging study with a surrogate mRNA expressing luciferase protein encapsulated in the lipid nanoparticles used in the Pfizer vaccine indicated that the expressed protein was mainly localised at the injection site and distributed to liver. Spike protein expression was detected in antigen presenting cells in draining lymph nodes and spleen in mice after injection of the Moderna mRNA vaccine. The spike protein expressed by COVID-19 mRNA vaccines in blood circulation was not measured in nonclinical animal studies.

In a recent publication (https://academic.oup.com/cid/article/74/4/715/6279075), very low levels (in pg/mL) of a fragment (S1 subunit) of the spike protein were detected in the plasma of 11 out of 13 human subjects from one day to nine days after the first injection. The full-length spike protein was only detected in three out of 13 subjects from day nine to 29. The S1 protein rapidly disappeared, associated with the induction of anti-S1 and anti-spike antibodies. After the second vaccine dose, no S1 or spike protein was detected.

Information on lipids was explained in detail in Adjunct Professor (Prof) Skerritt's verbal testimony at the Senate Estimates hearings on 10 November 2022.

As explained by Prof Skerritt, lipid nanoparticles in the COVID-19 vaccines consist of four lipids. Those in both the Pfizer and Moderna vaccines contain cholesterol and DSPC (1,2-distearoyl-*sn*-glycero-3-phosphocholine) which are natural constituents of human cells and are found in bovine steak. The other two lipids in the Pfizer vaccine are slightly different from those in the Moderna vaccine but all four lipids are also structurally similar to natural lipids in our body system or food. Nonclinical and clinical studies demonstrated that the lipid nanoparticles in the vaccines are safe.

SQ22-000534 (folder reference QoN86) – FOI Requests to TGA (key issue: TGA is not disclosing all FOI requests that have been grated (and not granted) to the disclosure log)

TGA processing of FOI requests

- The TGA provides public access to information which has been released in response to a Freedom of Information (FOI) request, subject to relevant exceptions, as required under section 11C of the *Freedom of Information Act 1982* (the FOI Act).
- The TGA provides this information through its FOI disclosure log on the TGA website (www.tga.gov.au).

- Exceptions to this requirement are principally personal information, or information about the business, commercial, financial or professional affairs of a person, that it would be unreasonable to publish.
- As a result, there may be some differences between the information published on the disclosure log and the information provided to the FOI applicant in relation to their request.
- Section 11C of the FOI Act only requires the publication of information released to an FOI applicant, subject to the exceptions noted above. It does not require publication of requests or decisions on requests (e.g. it does not require the publication of decisions to refuse access to an FOI applicant).
- The TGA FOI disclosure log is regularly updated, in accordance with the requirement in subsection 11C(6) of the FOI Act to do so within 10 working days of having provided access to the FOI applicant. Within those 10 working days, there may be some brief delays between the making of a decision to grant access to an FOI applicant and the updating of the disclosure log.

Division:	MRD
Contact Officer:	Nick Henderson
Date:	6 February 2023

s22

Document 9

s22

[redacted]

From: KAY, Elspeth <Elspeth.Kay@health.gov.au>
Sent: Tuesday, 14 February 2023 9:52 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; s22 [redacted] @health.gov.au>; BEDFORD, Chris <Chris.Bedford@health.gov.au>; NOYEN, Benjamin <Benjamin.Noyen@health.gov.au>
Cc: s22 [redacted] @health.gov.au>; TGA Social Media s22 [redacted] @tga.gov.au>; PEGG, Grant <Grant.Pegg@health.gov.au>
Subject: RE: Twitter commentary re COVID [SEC=OFFICIAL]

Not aware of any other regulators who have antiphospholipid syndrome as CI for an mRNA vaccine.

Note that the case that Rennick's tweets describe appears to be the very sad case of myocarditis linked to Spikevax. Let me know if it would be useful to have a summary of the actions we took in response to that case.

From: SKERRITT, John <John.Skerritt@health.gov.au>
Sent: Tuesday, 14 February 2023 7:34 PM
To: HENDERSON, Nick <Nick.Henderson@health.gov.au>; s22 [redacted] @health.gov.au>; BEDFORD, Chris <Chris.Bedford@health.gov.au>; NOYEN, Benjamin <Benjamin.Noyen@health.gov.au>
Cc: s22 [redacted] @health.gov.au>; TGA Social Media s22 [redacted] @tga.gov.au>; KAY, Elspeth <Elspeth.Kay@health.gov.au>; PEGG, Grant <Grant.Pegg@health.gov.au>
Subject: RE: Twitter commentary re COVID [SEC=OFFICIAL]

NO it should be fine – no need to trouble Elspeth and her clinical teams

The most material point raised by Rennick is whether people who have antiphospholipid syndrome are at greater risk of having adverse events following vaccination with a mRNA COVID vaccination.

Im aware of at least 3 studies published in reputable journals that clearly show there is NO elevated risk of adverse events in people with antiphospholipid syndrome (which affects 1-5 % of the population, so hundreds of thousands of mRNA vaccinated individuals)

Im happy to take that question if he wants to ask it again and can share the journal articles with colleagues

Grant /Elspeth – I don't think any regulators globally have antiphospholipid syndrome as a contraindication ? Even the UK patient society (yes there is one) say mRNA vaccines are fine for their members

John
Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Australian Government Department of Health and Aged Care
PO Box 100 Woden ACT 2606 AUSTRALIA

(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)
T: 02 6289 4200 | E: john.skerritt@health.gov.au
F: 02 6203 1265
Executive Assistant s22 T: s22 | E: s22 @health.gov.au
Executive Officer s22 T: s22 | E: s22 @health.gov.au

From: HENDERSON, Nick <Nick.Henderson@health.gov.au>
Sent: Tuesday, 14 February 2023 7:29 PM
To: s22 @health.gov.au>; SKERRITT, John <John.Skerritt@health.gov.au>; BEDFORD, Chris <Chris.Bedford@health.gov.au>; NOYEN, Benjamin <Benjamin.Noyen@health.gov.au>
Cc: s22 @health.gov.au>; TGA Social Media s22 @tga.gov.au>
Subject: RE: Twitter commentary re COVID [SEC=OFFICIAL]

Thanks s2
John, I'll work with Elspeth on some specific dot points for SEs
Nick

From: s22 @health.gov.au>
Sent: Tuesday, 14 February 2023 6:12 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>; BEDFORD, Chris <Chris.Bedford@health.gov.au>; NOYEN, Benjamin <Benjamin.Noyen@health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>
Cc: s22 @health.gov.au>; TGA Social Media s22 @tga.gov.au>
Subject: Twitter commentary re COVID [SEC=OFFICIAL]

Hi all
Russell Broadbent MP – Youtube video 'Where's the TGA's transparency?' - https://www.youtube.com/watch?v=xD1ZV4xBl-o
This video is being shared by multiple users on Twitter today, including Craig Kelly:

Craig Kelly
@CKellyUAP

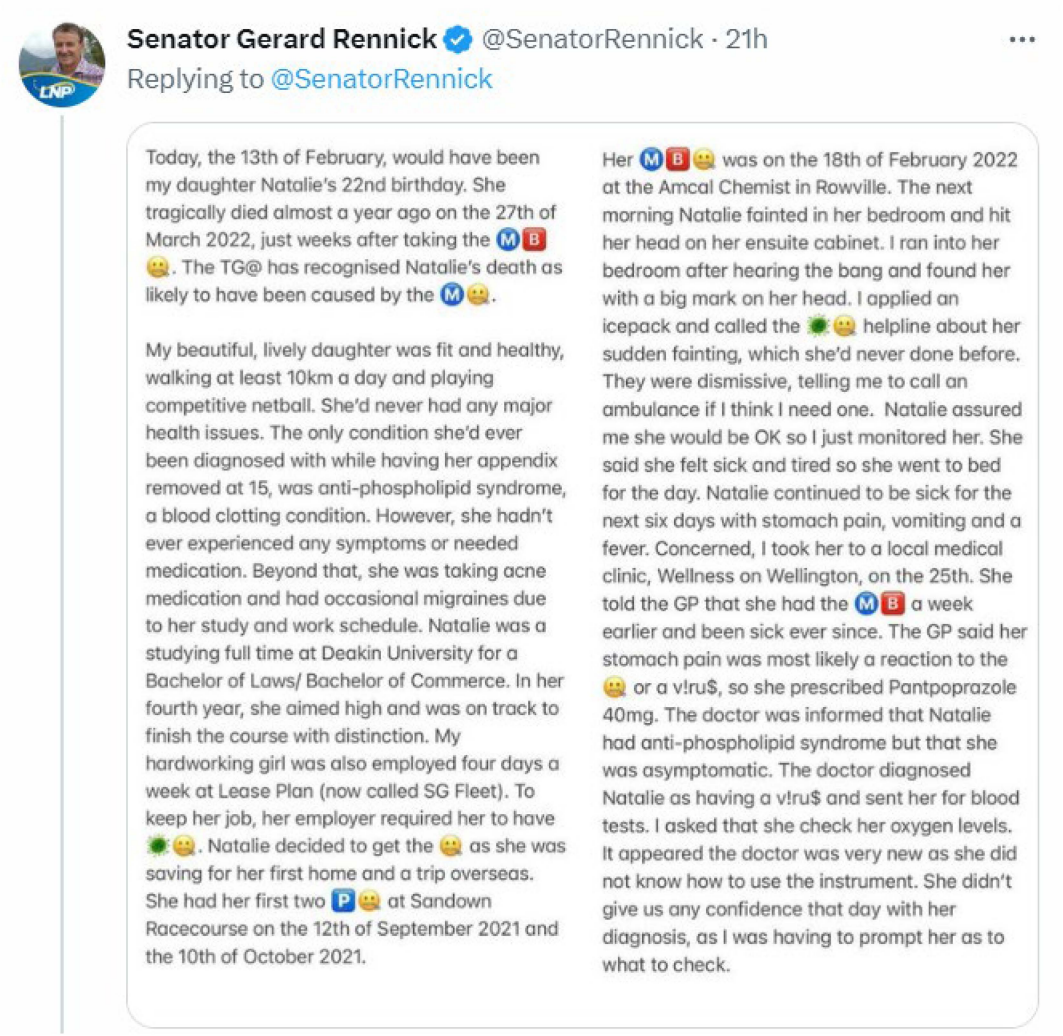
TGA accused of what amounts to criminal malfeasance in Federal Parliament today by covering up the deaths of Australians caused by the vaccines.

The TGA have acted as stooges for Pfizer, Moderna & AstraZeneca from the outset.

Senator Rennick has also been sharing Natalie's story via Twitter (about 20 hours ago):

Senator Gerard Rennick
@SenatorRennick

This is tragic story of Natalie, a 21 year old healthy girl who died from the vaccine. #auspol



Senator Gerard Rennick @SenatorRennick · 21h

Replying to @SenatorRennick

Today, the 13th of February, would have been my daughter Natalie's 22nd birthday. She tragically died almost a year ago on the 27th of March 2022, just weeks after taking the Ⓜ️🅱️😬. The TG@ has recognised Natalie's death as likely to have been caused by the Ⓜ️😬.

My beautiful, lively daughter was fit and healthy, walking at least 10km a day and playing competitive netball. She'd never had any major health issues. The only condition she'd ever been diagnosed with while having her appendix removed at 15, was anti-phospholipid syndrome, a blood clotting condition. However, she hadn't ever experienced any symptoms or needed medication. Beyond that, she was taking acne medication and had occasional migraines due to her study and work schedule. Natalie was a studying full time at Deakin University for a Bachelor of Laws/ Bachelor of Commerce. In her fourth year, she aimed high and was on track to finish the course with distinction. My hardworking girl was also employed four days a week at Lease Plan (now called SG Fleet). To keep her job, her employer required her to have 🦠😬. Natalie decided to get the 😬 as she was saving for her first home and a trip overseas. She had her first two 🅿️😬 at Sandown Racecourse on the 12th of September 2021 and the 10th of October 2021.

Her Ⓜ️🅱️😬 was on the 18th of February 2022 at the Amcal Chemist in Rowville. The next morning Natalie fainted in her bedroom and hit her head on her ensuite cabinet. I ran into her bedroom after hearing the bang and found her with a big mark on her head. I applied an icepack and called the 🦠😬 helpline about her sudden fainting, which she'd never done before. They were dismissive, telling me to call an ambulance if I think I need one. Natalie assured me she would be OK so I just monitored her. She said she felt sick and tired so she went to bed for the day. Natalie continued to be sick for the next six days with stomach pain, vomiting and a fever. Concerned, I took her to a local medical clinic, Wellness on Wellington, on the 25th. She told the GP that she had the Ⓜ️🅱️ a week earlier and been sick ever since. The GP said her stomach pain was most likely a reaction to the 😬 or a v!ru$, so she prescribed Pantpoprazole 40mg. The doctor was informed that Natalie had anti-phospholipid syndrome but that she was asymptomatic. The doctor diagnosed Natalie as having a v!ru$ and sent her for blood tests. I asked that she check her oxygen levels. It appeared the doctor was very new as she did not know how to use the instrument. She didn't give us any confidence that day with her diagnosis, as I was having to prompt her as to what to check.

Senator Gerard Rennick @SenatorRennick · 21h

Replying to @SenatorRennick

At 9.30pm I received a text from Natalie saying, "I'm still waiting for a doctor 2 hours after ultrasound this is just ridiculous, I've been here 15 hours!". At around 10pm she was finally discharged from Monash, with the doctor telling her she likely had a v!ru$. One doctor commented that her liver looked "messy" on the ultrasound but said that was common after the 😬. They did not investigate the liver inflammation, her low iron level, or her high temperature. Natalie was sent home with a report from both an attending doctor and a specialist saying that she "looked well". The nurse discharging her told her she really should follow hospital protocol and have a PCR test because she still had a high temperature. Natalie flatly refused as she wasn't going to wait another three hours and had already had several negative rapid tests done by the nurses. The hospital discharged her with a high temperature, extremely low iron blood levels and no treatment plan for either.

I understand a messy liver is a sign of heart issues, and the three bags of fluids they gave her put more pressure on her heart. When I picked Natalie up at 10.30pm at night I knew she wasn't right and wanted to take her straight to Mulgrave Private Hospital for another opinion. Natalie said, "I would rather die than go to another hospital after the way Monash has treated me."

Natalie continued to be very sick the next day, vomiting and having difficulty breathing, so on Saturday the 5th of March at 4.18pm I called 000 and begged the operator to send an ambulance urgently. I told the operator that I thought Natalie had blood clots on her lungs, but she refused to send an ambulance, telling me a paramedic would call me back within half an hour and then they would decide if an ambulance would be sent or not. I couldn't wait that long as I knew Natalie was in serious trouble, so I put her in my car and drove her to Mulgrave Private Hospital myself in around 12 minutes. She was passing in and out of consciousness in the car. I called the ambulance enroute to cancel and they were more worried about checking my personal details than my dying daughter's welfare.

Arriving at Mulgrave Private Hospital, Natalie was going in and out of consciousness, but they made us wait 15 minutes in triage until she tested negative for 🦠. When she was seen by the emergency doctor on duty, he immediately diagnosed Natalie as being in heart failure and called in an off-duty cardiologist. A scan confirmed the diagnosis. The emergency doctor took me to a private room of the hospital and explained to me that Natalie was extremely unwell and that they thought it was best she was immediately transferred to The Alfred Hospital.

Senator Gerard Rennick @SenatorRennick · 21h

Replying to @SenatorRennick

She gave us the form to get blood tests done and as I was paying at the counter, the doctor ran out and added a D dimer test to the pathology form. She said to call the surgery in a few days for the test results. She didn't check for myocarditis. I wasn't happy with the doctor's opinion and wanted to take Natalie to hospital, but Natalie refused because the doctor assured her it was just a v!ru$. In the early hours of the next morning, the 26th, I checked on Natalie and found her on the couch downstairs and not in bed. I asked her what was wrong and she complained of calf pain. I was seriously concerned she may have a DVT and drove her immediately to the Angliss Hospital in Ferntree Gully at about 1.30am. I told the nurse about her APS and the nurse had no idea what it was. I was then told that I had to leave the hospital due to 🦠 protocols, and despite being triple 😬, I couldn't stay with her as she was not a minor. They said I could sit in the car or come back later to pick her up. It was so distressing not knowing what was going on. I made the decision to go home rather than sit in the car. Natalie texted me that she waited two and half hours to be seen by any doctor and despite being in immense pain, many patients who arrived after her were seen before her. While there, she sent me numerous text messages, one of them saying "this is so unfair, no-one understands the pain I am in".

If I had been allowed to be with her, I would have advocated for her and demanded answers. The doctors did more blood tests, took an ECG and gave her two bags of fluid for her dehydration. They sent her home at about 6.30am, telling her she had a reaction to the 🦠🅱️😬. They also prescribed the same anti-reflux medications. Natalie did not get better and continued to vomit and be in pain. She took the prescribed medicine, but they did nothing. On Thursday, March the 3rd at 7am I decided to take her to Monash Hospital in Clayton. The administration staff were rude, didn't know about her medical condition and I was again told I had to wait in the car. Because she was vomiting, Natalie was placed in a section where people had to be isolated. Natalie said everyone else in that room had someone with them and begged me to come back and be with her. She texted me at 10.35am saying a doctor had finally seen her, taken bloods and then sent her back to the waiting room. The doctor told her she was severely dehydrated, and they were waiting for somewhere to become available to give her an IV drip. She texted me: "I am having the IV drip in the waiting room. This hospital is a joke." She had thrown up numerous times, was holding a bag of vomit, but was being ignored by the doctors and nurses.

Senator Gerard Rennick @SenatorRennick · 21h

Replying to @SenatorRennick

In the end, Natalie spent about 15 and a half hours at Monash Hospital. At one point a doctor told her she was severely anaemic, then wandered off, leaving her alone for hours. She was then told they were talking to the gastro doctors, and after that then she was going to be sent home. Natalie told me the doctors and nurses repeatedly told her she was irresponsible for not being on the contraceptive pill because she was on acne medication. She told them she wasn't sexually active and with the APS condition, she couldn't take the Pill as it causes blood clots. It really upset her that they were focussed on that rather than her symptoms. She said no-one would take the full vomit bag from her, and she held it until 2.15pm while sitting in the waiting room. She was humiliated and sick, but the staff didn't care. Just before they were due to release her, she was told she had a high temperature and now couldn't go home, and finally at 2.30pm she texted me that she was being taken to the short stay area and could I please come now. I immediately went to Monash to pick her up, but they were so rude and would not let me see her. I tried to talk to the staff but no-one would help and Natalie by this stage was really distressed. She told me she was in a segregated area and every other patient had a companion except her. Natalie said nurses were being trained on how to use the IV drip.

A doctor told her she needed an ultrasound, but she didn't get it for another five hours. She was left with an empty drip in her arm for hours. A drug-affected patient with [redacted] was also walking around the waiting room for eight hours where she was left sitting in a chair. There was no security managing this person and the nurses and doctors had to keep taking him back to his room. Natalie told me that the doctor scolded her for taking Nurofen and queried why she was taking it when she had a temperature, saying she should be taking Panadol instead. She told him that it was the only thing that was working for her pain. I have since discovered that this was a warning sign of heart issues, but the doctor did not investigate her heart.

I called the hospital for two hours from my car in the carpark, asking to be let in to support and to speak up for Natalie. After no satisfactory response, I went in an asked if I could discharge her as I wanted to take her to a private hospital instead. None of the administration staff would help me, and just gave me three telephone numbers to call. I went back to my car and rang repeatedly for two hours but the phone numbers just rang out. When I finally got through at about 8pm at night, I was told by the receptionist that a doctor would call me to update me on her condition. It never happened.

Senator Gerard Rennick @SenatorRennick · 21h

Replying to @SenatorRennick

Natalie was transferred to the Alfred in an ambulance about 2.15am Sunday morning. While putting her in the ambulance, the AV doctor told me to hop in and have a final talk to her. Little did I know that would be the last time Natalie and I would speak. She never woke again. The doctor said I couldn't go with them in the ambulance but to meet them at the Alfred. I drove straight there, but triage would not let me enter and be with my girl, so I had to go home. Alfred doctors called me throughout the night with updates. I recall they could not believe that Monash Hospital had sent her home so seriously ill and hadn't tested her heart, knowing she'd had three 🦠😬's. They told me that if Natalie's heart did not improve, she would have to put her on an ECMO machine, the highest form of life support, to mechanically operate her heart. They advised that the risks of the machine were brain damage and spinal cord damage. It was my daughter's only option to stay alive, so I gave them permission. Doctors kept me informed on Natalie's condition the first few days but then after I was not contacted. I was only allowed to see her for one hour a day and it was during that time I would find out about her condition. I was told a treating doctor - a professor - would oversee her care and that he was the best available with the ECMO machine. He spoke to me the second day and then he never spoke to me again.

All the other doctors and nurses told me she would recover and that it would be a long recovery and months in a rehabilitation hospital. I began researching the hospitals in preparation. For the next three weeks, Natalie had numerous procedures and scans but never regained consciousness. The Alfred made the decision to take her off the ECMO machine after about two weeks to see if her heart would improve. They told me that if it didn't, they would put her back on it. Her heart did not improve but they didn't put her back on it. Three days before she died, she was put on dialysis as her kidneys were not functioning. I only found out when I went for my one-hour visit. The nurse said that day they were doing the MRI but it never happened as they said she was not stable enough to perform it. The nurse did not seem as thorough and walked off twice while I was there and left her unattended. When I visited on the 26th of March she had been moved back to the room in the middle and not in the corner, and they showed me Natalie's foot and it had turned black. They said they were waiting for her to have a scan to see if she had lost blood flow. A vascular surgeon called me that evening to say that they needed to operate and that Natalie was not in a good way so it was a risky procedure.

Senator Gerard Rennick @SenatorRennick · 21h

Replying to @SenatorRennick

She was operated on at about 9pm and the surgeon called me at about 10.30pm to say that the operation was a success and he had removed the clot. The very next day they decided to do the MRI as they thought she had lost feeling in her leg and were worried about spinal cord damage. This MRI was not urgent. When I rang that morning, the nurse told me that she had an unstable night so they might not do the MRI today. I had booked a visit time early afternoon, and I was called to say can I please come in later as she was booked for the MRI. My sister and I arrived about 3pm and were told to come back in half an hour as Natalie was still having the MRI scan. We came back and the male nurse in charge apologised and said it shouldn't be too much longer and that everything was ok, they were just re-connecting her back up to all the machines. He said they were taking longer than he expected so he had just sent another nurse down to help. We then heard the Code Blue called to MRI. A doctor walked past us not in any urgent manner and asked a nurse where MRI was as she had been called there, and the nurse told her she was on the wrong floor. About an hour later we were taken into a room and told Natalie had passed away, as her body couldn't cope with being off the ECMO life support machine for so long.

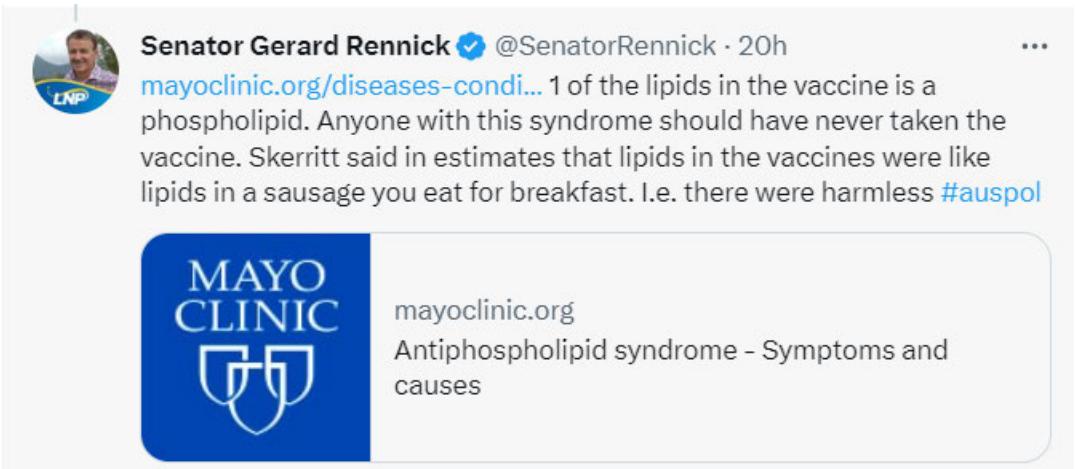
The person who was doing the MRI discovered that she had spinal cord damage so made the call to do a further MRI on her brain to see if she had brain damage. They said that she still had full brain function. The doctor and nurse who gave us the news were both crying and could not stop saying how sorry they were. I was in shock and numb. She died on my passed Mum's birthday on the 27th of March 2022. Her death certificate states Natalie died of myocardial infarction and that she had subacute myocarditis. Being just 21 years old when she died, Natalie's death was referred to the Victorian State Coroner. An autopsy was undertaken and provided to me in September 2022. I cannot publicly share the contents of the report as I would apparently be in contempt of court. I am still awaiting the Coroner's Report and have been advised it could be another year. The Coroner's Office called me in early September 2022 as a courtesy to tell me that the TG@ was releasing a report about Natalie and that it might gain media attention. Searching online, I found the 🦠😬 safety report published on the TG@ website on the 23rd of September, which stated:

Senator Gerard Rennick @SenatorRennick · 21h

Replying to @SenatorRennick

"The TG@ convened an external expert group to consider whether any additional advice to the general public and healthcare professionals is required following a very sad case of a young woman in her 20s who died as a result of myocarditis a few weeks after receiving a 🅱️ of the Ⓜ️😬. The TG@ extends its sincerest condolences to the family and loved ones of this young woman.The expert group included a panel of experts in cardiology and 😬, as well as a consumer representative and a community engagement expert. The panel agreed with the TG@'s assessment that the myocarditis the woman experience ed was likely to have been related to 😬 given the available information, including the absence of other apparent causes of myocarditis, and the timeframe for the onset of symptoms. However, the panel acknowledged there were several complicating factors that may have contributed to her death. The circumstances and potential causes that led to this woman's death will be officially investigated by a state coroner.... The panel confirmed that serious cases of myocarditis have occurred and recommended updates to the existing warnings in the Product Information and referred this case to the Australian Technical Advisory Group on Immunisation (AT@G1) who is publishing an update to clinical guidance."

This is the first I had heard that Natalie's death was being investigated by the TG@, and that they had determined she was likely to have died from the 🦠😬. I had to search and find the report online. I was never contacted by the TG@ to be part of their inquiries or sent any findings from this report. No one in the TG@ has contacted me to this day. Yet my girl's death has prompted the TG@ to update Ⓜ️'s product information to doctors to warn of myocarditis as a possible serious complication from the 😬. This is disgraceful treatment of a grieving mother who could have made a meaningful contribution to their investigations, given I was with Natalie throughout this horrific misadventure. No media outlets or journalists have contacted me to discuss Natalie's death from myocarditis after the 😬. I feel that so many people failed Natalie. She was a happy, young healthy active girl who had her whole life ahead of her. She was successful in university and a conscientious, hard worker who achieved so much in her life. She had dreams to travel the world and buy her own home one day. This was all taken from her, and her death could have been prevented if she was given the correct care that she deserved.



s22
Director Regulatory Education
Regulatory Engagement Branch
Regulatory Practice and Support Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: 27 Scherger Drive, Fairbairn
PO Box 100, Woden ACT 2606, Australia

Regulatory Engagement Service Gateway

Direct access to our services and resources.

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: SKERRITT, John
To: MEDIA, TGA
Cc: s22 s22 BEDFORD, Chris; s22
Subject: RE: ATTN John- MEDIA ENQUIRY -due 5pm Wednesday (8/2) - s22 [SEC=OFFICIAL]
Date: Tuesday, 7 February 2023 5:29:11 PM
Attachments: image002.png
image004.png

The response is as follows:

Senior departmental officers offered to provide briefings to the Senator during 2021 and early 2022. In keeping with long-established protocols, any decision on whether officials provide a briefing to a backbench Senator is to be made by the Minister's office – in this case former Minister Hunt's office.
Extensive and detailed information on the Therapeutic Goods Administration's (TGA) evaluation of these vaccines has been provided to the Senator during hearings of the Senate Community Affairs Committee during 2021 and 2022.

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Australian Government Department of Health and Aged Care
PO Box 100 Woden ACT 2606 AUSTRALIA

(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)
T: 02 6289 4200 | E: john.skerritt@health.gov.au
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Executive Assistant s22 T: s22 | E: s22
Executive Officer s22 T: s22 | E: s22

From: MEDIA, TGA s22 @health.gov.au>
Sent: Tuesday, 7 February 2023 4:20 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; BEDFORD, Chris <Chris.Bedford@health.gov.au>; s22 @Health.gov.au>
Subject: ATTN John- MEDIA ENQUIRY -due 5pm Wednesday (8/2) - s22 SEC=OFFICIAL]
Importance: High

Dear John,

We have received a media request from a journalist, s22 requesting access to information contained in a SQoN. A response has been requested by **5pm Wednesday (8/2).**

Query:

does the Health Department have records of offers made by John Skerritt during Estimates and/or Covid-19 committee hearing to provide briefings to Senator Rennick that you could send me / point me to?

The attached SQ22-00638 and MC22-017554 a CoS response sent on 4 October 2022 appear to be the most relevant documents.
Could you please advise how you would like to respond to this media request?

Thanks in advance.

Kind regards,

s22
HPRG Regulatory Engagement Services
Collaboration Services Section
Regulatory Practice & Support Division | Health Products Regulation Group
Regulatory Engagement Branch
Australian Government Department of Health and Aged Care
P: s22
After Hours: s22 | E: TGA.Media@health.gov.au
Location: Fairbairn, Level 2 South

Regulatory Engagement Service Gateway

Direct access to our services and resources.

From: News <news@health.gov.au>
Sent: Tuesday, 7 February 2023 12:07 PM
To: MEDIA, TGA s22 @health.gov.au>
Cc: News <news@health.gov.au>
Subject: MEDIA ENQUIRY - Senator Rennick Invites - not urgent, due Wednesday [SEC=OFFICIAL]

Hi team

Please see the below request from s22. Are you able to assist with a response some time tomorrow?

Thanks

s22
Media Unit
Australian Government, Department of Health and Aged Care
T: s22 E: news@health.gov.au

throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 [redacted]
Sent: Tuesday, 7 February 2023 11:23 AM
To: News <news@health.gov.au>
Subject: RE: s22 [redacted] [SEC=OFFICIAL]

Hi s22 [redacted],

Thanks so much for your help, I really appreciate it.

One more thing -- does the Health Department have records of offers made by John Skerritt during Estimates and/or Covid-19 committee hearing to provide briefings to Senator Rennick that you could send me / point me to?

Thanks,
s22 [redacted]

s22 [redacted]

s22

s22

From: SKERRITT, John
To: MURPHY, Brendan
Subject: FW: Negative feedback regarding retirement announcement incl from Senator Rennick [SEC=OFFICIAL]
Date: Wednesday, 8 February 2023 2:21:45 PM
Attachments: image005.png
Negative social media commentary regarding John Skerritt retirement.docx

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Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Australian Government Department of Health and Aged Care
PO Box 100 Woden ACT 2606 AUSTRALIA

(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)
T: 02 6289 4200 | E: john.skerritt@health.gov.au
F: 02 6203 1265

Executive Assistant s22 T: s22 E: s22 @health.gov.au
Executive Officer s22 T: s22 | E: s22 @health.gov.au

Negative social media commentary regarding John Skerritt's retirement

Platform	Post/comments
Instagram & Facebook & Twitter	

s22

s22

s22