Submission to the COVID-19 Response Inquiry

This submission addresses the term of reference regarding 'Governance including the role of the Commonwealth Government', specifically procedures and decisions of the Therapeutic Goods Administration (TGA) and the Office of the Australian Information Commissioner (OAIC). It will also provide information for recommendations to improve Australia's future preparedness.

I am a medical practitioner with 40 years' experience in public and private health care, subspecialising in reproductive health care. I am the Medical Director of [redacted]. As a primary health provider, I have had several peer-reviewed papers published in the British Medical Journal (Case Histories 2012 and the BMJ Journal of Evidence Based Medicine 2019), The Journal of Investigative Medicine (High Impact Case Reports), Brighton Collaboration Vaccine Safety Quarterly magazine (2/2014), and two peer-reviewed poster presentations at the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) Annual Scientific Meeting (2017) and RANZCOG Sydney Symposium July 2023.

The research I present hereto was published in the Journal of Clinical Toxicology in 2022[1] (see **Attachment 1**) and its summary was presented as poster at the most recent RANZCOG Sydney Symposium on July 25th 2023[2] (see **Attachment 2**).

I am happy to appear in person or provide any further information to assist the inquiry.

Key Issues:

1. **Failure of the TGA to require accessible organ histology reports in pre-clinical studies for COVID-19 vaccines. Pre-clinical histology reports are particularly relevant to reproductive organs as clinical trials did not include reproductive health parameters;**
2. **Failure of the TGA to extract ovary and testis histology reports when requested by a reproductive health clinician under FOI 2565;**
3. **Failure of the OAIC to provide a result to a requested review of the TGA rejection of FOI 2565 in over two years since the original request for review was made;**
4. **The TGA agreement to withhold studies (or parts thereof) containing the ovary and testis histology reports from the general public in accord with 'active steps' taken by pharmaceutical companies 'to ensure the information contained within the documents is not disclosed to the general public' (see TGA Internal Review Decision of 27 September 2021, a copy of which is provided as Attachment 3);**
5. **Failure of the TGA to query the effect of rising nanoparticle concentration in mammalian ovaries, which doubled from 24 to 48 hours post single 50mcg injection[3] (after which measurements ceased). In the context of ovarian accumulation of nanoparticles, the TGA failed to consider prior research identifying rat ovarian and uterine toxicity known caused by a nanoparticle constituent[4] in COVID-19 vaccines which mimics diethylstilboestrol effects in rat ovary and uterus.**

---

[1] Little D. Abnormal Menstruation Following COVID-19 Vaccines: A Toxicologic Consideration. *J Clin Toxicol*. 2022;12(4):517. https://www.longdom.org/open-access/abnormal-menstruation-following-covid19-vaccines-a-toxicologic-consideration-93970.html.

[2] Little D. COVID Vaccines, Abnormal Menses, PMB: Toxicologic Considerations. Poster presented at: RANZCOG Symposium; 25 July 2023; Sydney, Australia.

[3] Australian Government Department of Health. *TGA Nonclinical Evaluation Report: BNT162b2[mRNA] COVID-19 vaccine (COMIRNATY™)*. January 2021. Accessed via TGA FOI disclosure log: FOI 2389. https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf.

[4] Gajdova et al. Delayed Effects of Neonatal Exposure to Tween 80 on Female Reproductive Organs in Rats. *Food Chem Toxicol*. 1993;31(3):183-190. https://doi.org/10.1016/0278-6915(93)90092-D.

Introduction:

New onset menstrual abnormalities, post-menopausal bleeding and bleeding in women who do not normally menstruate have been notified and reported in medical literature.[5,6] The European Medicines Agency has advised the Product Information of mRNA COVID-19 vaccines be updated to include 'heavy menstrual; bleeding' as a potential side effect.[7] The cause of this signal remains unknown to RANZCOG and to the Royal College of Obstetricians and Gynaecologists (RCOG), since no clinical trials recorded or observed reproductive health markers or parameters.

Expansion of Key Issues:

1. Adverse reproductive health events necessitate review of pre-clinical COVID-19 reproductive organ histology - specifically of rat ovary and uterus microscopy - to further future research, to establish safety, and to facilitate public vaccine confidence in women of reproductive age. Reproductive organ histology (microscopy) reports in COVID-19 vaccine pre-clinical studies cannot be accessed by reproductive health clinicians. They are allegedly not presented in readily identifiable, accessible format to the TGA. As stated in the TGA Internal Review Decision of 27 September 2021, 'the histopathology in relation to reproductive tissues…is dispersed throughout each of the studies', requiring review of 3,667 pages (para 28).
2. On 29th July 2021 I made an FOI request for reproductive organ histology reports from COVID-19 vaccines' Developmental and Reproductive Toxicity Studies (FOI 2565). As a reproductive health clinician, this was a reasonable and relevant request.

   On 21st August 2021 this FOI request was reduced, as I was asked to do, to:

   > *"histopathology/microscopic evaluation of gonads (ovaries/testis) of vaccinated animals in relation to Pfizer and AstraZeneca COVID-19 vaccines".*

   On 26th August 2021 FOI 2565 request was rejected on grounds the ovary and testis organ microscopy reports were 'too voluminous'. I was provided with numerous references to other research papers which did not present the histology reports required.

   On 4th September 2021, I requested an Internal Review of the decision in relation to FOI 2565. On 16th September I was asked to reduce my FOI application to exclude raw data, annexures and appendices. This I declined to do as the histology reports were most likely therein. Indeed a later FOI request (FOI 3093) by another applicant on terms excluding raw data, annexures and appendices failed to yield histology reports.

   On 27th September 2021 FOI 2565 with its reduced scope was rejected at Internal Review. Reasons provided for this rejection included:

   - the rat ovary and testis microscopy reports after vaccination likely 'contain information that is commercially sensitive' (para 30).
   - both pharmaceutical companies 'have taken active steps to ensure the information contained within the documents is not disclosed to the general public' (para 31).
3. The rejected FOI 2565 was then submitted for review to the OAIC (OAIC Reference: MR21/01138).

---

[5] Blix K et al. Unexpected Vaginal Bleeding and COVID-19 Vaccination in Nonmenstruating Women. *Sci. Adv.* 2023;9(38). https://www.science.org/doi/10.1126/sciadv.adg1391.

[6] Medicines and Healthcare products Regulatory Agency. *Coronavirus Vaccine-Weekly Summary of Yellow Card Reporting.* Last updated 8 March 2023. https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting.

[7] European Medicines Agency. *Meeting Highlights from the Pharmacovigilance Risk Assessment Committee (PRAC).* 24-27 October 2022. https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-24-27-october-2022.

On 26th October 2021 receipt was acknowledged by the Intake and Early Resolution Team.

On 9th May 2022 the OAIC notified the TGA of my application for Information Commissioner review. My submission supporting this application was forwarded as requested and received 27th July 2022. I also replied to the TGA submission. Despite two subsequent enquiries, including a letter to the Minister for Home Affairs Clare O'Neil requesting a response I have had no result in over two years since my original request for OAIC review was made.

4. The TGA has acknowledged agreed arrangements whereby pharmaceutical companies may 'take active steps' to ensure pre-clinical study data (including data relevant to women's health requested in FOI 2565) 'not be disclosed to the general public' (para 31 of the 27th September 2021 Internal Review Decision). This is an obstruction to women's health. It hampers reproductive health research of unexpected safety signals and undermines public vaccine confidence. Such arrangements require further investigation and clarification.
5. Disregarding the documented high and rising concentration of nanoparticles in the mammalian ovary, doubling in the 24 hours preceding measurement discontinuation, raises questions about the competency of the TGA to recognize anomalies. The TGA did not subsequently require coherent gonad organ microscopy reports, permitting reproductive organ microscopy descriptions to be dispersed across 3,000 pages, rendering the time required to extract them excessive, expensive, and not feasible. The TGA further failed to appreciate the need for coherent reproductive organ histology review even after the appearance of unexpected safety signals in both pre- and postmenopausal women suggestive of oestrogenic effects. Vaccines' nanoparticle constituents (polyoxyethylene sorbitan monooleate in AstraZeneca vaccine and closely related polyethylene glycol in mRNA vaccines) injected into rats cause decreased ovarian weights, ovarian cystic cavities, prolonged oestrous cycle, persistent vaginal oestrous, and plano cellular metaplasia in uterine endothelium and endometrial glands mimicking effects of di-ethylstilboestrol.[8]

Conclusion:

The TGA has thus far failed to meet the expectations of the Freedom of Information Act of 1982. This compounds a failure of the TGA to comply with a reasonable request from a health care provider. It highlights other significant systemic failures of the TGA relating to scientific and clinical competency, arrangements with pharmaceutical companies, and the lack of safety data transparency of taxpayer funded vaccines.

Recommendations:

1. No arrangements should be agreed between the TGA and pharmaceutical companies to withhold organ microscopy reports of pre-clinical safety studies.
2. More reasonable efforts should be made to comply with FOI requests by reproductive health clinicians in the context of a) new and unexpected reproductive health safety signals; b) absence of reproductive health data in clinical trials.
3. The OAIC's failure to provide a result to a formal and reasonable request for FOI decision review should be examined.

Dr Deirdre Little MBBS DRANZCOG FACRRM
Medical Director [redacted]

[8] Gajdova et al. Delayed Effects of Neonatal Exposure to Tween 80 on Female Reproductive Organs in Rats. *Food Chem Toxicol*. 1993;31(3):183-190. https://doi.org/10.1016/0278-6915(93)90092-D.