Charmian Gaud, [redacted] 12 December 2023

Submission to the COVID-19 Response Inquiry

1. My background

Retiree from [redacted] I worked as University researcher in economic modelling (ANU), a University administrator (Syd Univ USU and UTS Registrar's Office), a recreation consultant incl community consultation and modelling. I lead a 𝕏 community group [redacted]

My health had been compromised much of my life by chronic cough & respiratory issues likely cause [redacted]. **COVID-19 scares me.** I have remained NOVID using throat and nose anitvirals. I mask, ensure clean air, am vaccinated 6 times. I also make sure I have antiviral protection at all times throughout the pandemic. Pre early 2000s, common colds (which are often coronaviruses) would invariably turn to [redacted] and even [redacted] needing double courses of antibiotics to recover.

Worldwide, in the 80s/90s several new antiviral therapies were developing to treat HIV/AID and other viruses. Acyclovir (Zorivex) offered a very effective treatment/preventative for herpes/cold sores.

In 1996 I read in the UK Telegraph about antiviral properties of natural pomegranate extract

FRUIT 'MAY HOLD KEY TO CONTROLLING AIDS VIRUS
Sat 2 Mar 1996 By [redacted] Social Affairs Correspondent,

[redacted]

Using internet research I discovered a patent held by the researchers and [redacted] 1995-2015 for antiviral benchwashes and fruit spray.

https://patents.google.com/patent/US5840308A/en

With abundant supply of pomegranates in our own garden, I started making a natural therapy of pomegranate skin extract for my own use. Guided by the early and frequent use of acyclovir, at the first tickle of cold or flu I would take ½ tsp into my mouth/throat. As if by magic within hours, cold symptoms stopped. About 5 mins absorbing my mixture into saliva, it coated the bronchial area before swallowing. My experience was 20 years of this remarkable antiviral home treatment.

Just 3 months after the pandemic was first declared in March 2020, I was amazed to read that lozenges using pomegranate skin with similar properties to my "magic" extract had treated covid within just 3 days. University of Milan was involved in the study

https://www.nutritioninsight.com/news/pomegranate-lozenge-reduces-covid-19-presence-in-asymptomatic-patients-says-study.html

Also referenced in US NIH research paper, was the suggestion that by-product of the fruit juice industry would make cheap antiviral protease inhibitors as treatment in the third world. The active ingredient in the skin was Punicalagin and it seemed easy to make at home into stored liquid or lozenges.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8114579/ In the conclusions:

The study here presented paves the way for longer and in depth-investigations on the activity of pomegranate peel polyphenols in preventing SARS-CoV-2 infection in vivo and it may also promote new ideas on how to reuse an agroindustry byproduct for valuable and healthy applications.

In mid 2022 I discussed the potential of antivirals with [redacted] Seeking Alpha contributor. From him I learned about the **very strange IRRATIONAL actions of TGA during the pandemic** in banning and fining a simple **AUSTRALIAN antiviral nasal spray Viraleze** made by Starpharma PL Abbottford which could be literally saving the world - everyone over 12 years, vaccinated or not.

https://seekingalpha.com/author/[redacted]

Why was VIRALEZE banned by TGA, this enquiry needs to find answers re barrier antiviral sprays & COVID.

COVID PREVENTION AND TREATMENT FOR ALL AUSTRALIANS is NOT JUST ABOUT VACCINES AUSTRALIANS SHOULD LIVE AS NORMAL LIVES AS POSSIBLE WITH GOOD SIMPLE THERAPIES THAT ARE AVAILABLE IN PHARMACIES AND AVAILABLE IMMEDIATELY IF YOU GO TO RISKY PLACES OR TEST POSITIVE

2. Terms of Reference items in my submission

2.1 Governance - COVID-19 Response lacked transparency - PM Scott Morrison was **the ONLY "member" of National Cabinet.** Premiers, Commonwealth Health Dept Officer incl CMO, State Chief Health Officers were all just advisory, even the Health and Aged Care Minister was not a member. Until mid 2022 after Albenese Government

election, Australians did not know that the Governor General had made Scott Morrison **Secret Health Minister** as early as March 2020, with full alternate powers to make health decisions/set regulations. No opacity or collective responsibility. This inquiry should be a **ROYAL COMMISSION** to compel witnesses from the public service, contracted organisations, politicians and pharmaceutical organisations etc to expose what decisions were made, by whom and who benefited. What secret controls did Scott Morrison and others use. Potentially like the ROBODEBT Royal Commission we need to expose any nefarious behaviour detrimental to any cohort of Australians. Providing no treatment or prevention to any group of Australians included.

2.2 Covid-19 response failed ETHICAL standards by GOVT TGA DOH in regulatory decisions
Some journalists have questioned the influence of BIG PHARMA on Australian Health regulators - see [redacted] - Health correspondent ABC; BMJ article June 2022.
https://www.bmj.com/content/377/bmj.o1538
Page2: Of the six regulators, Australia had the highest proportion of budget from industry fees (96%) and in 2020- 2021 approved more than nine of every 10 drug company applications. Australia's Therapeutic Goods Administration (TGA) firmly denies that its almost exclusive reliance on pharmaceutical industry funding is a conflict of interest (COI).
Page 4 TGA should not be relying on the analysis of that data produced by the drug companies.
[redacted]The New Daily, quoted TGA boss [redacted] from Sept 2021 and the challenge to TGA being independent of govt when they wait for a signal from government before approving therapeutics
https://www.thenewdaily.com.au/news/2022/01/06/michael-pascoe-morrison-novax-serve-rats-disaster
*"..We're saying to companies, submit your data, show us, but we can't formally make an approval decision until we get a **signal** from the government," Mr Skerritt said at the time…"*
[redacted], Saturday Paper, questioned the redactions in the Dec 2022 Prof [redacted] report to ALP Health Minister Mark Butler and DOH influence in hiding relevant information from public scrutiny.
https://www.thesaturdaypaper.com.au/news/politics/2023/01/07/exclusive-halton-report-warns-repeating-morrison-errors
https://www.thesaturdaypaper.com.au/news/health/2023/02/11/exclusive-268-million-doses-covid-19-vaccine-wasted
"The Saturday Paper applied for the full report under freedom of information (FOI) law and published details last month of what was obtained. Sections of the 153-page document were heavily redacted and some pages were missing, omitted without acknowledgment."
Strangely, [redacted] referred to future need for antiviral development with no mention of Viraleze and Heparin [redacted] **report** Review of COVID-19 Vaccine and Treatment Purchasing and Procurement
https://mcusercontent.com/8a3d58d1cfb663c4dcefbc00d/files/24613b1d-c960-6a3d-1a71-42012493be39/Halton_Report_Exec_Summary_and_Recs.pdf
"Regulation of vaccines and treatments: Where appropriate, Australia should continue to look for opportunities to ensure consistency with global regulators. Consideration should be given to permanent implementation of changes made during the pandemic which ease regulatory burden and do not impact public safety. Funding available to the TGA should enable it to continue its important work regarding pharmacovigilance and consumer safety…"
"Treatments: Ongoing monitoring of new treatments and engagement with suppliers will be needed to ensure adequate supply of promising emerging treatments for Australia.'
In the full report (redacted) [redacted] mentions only three approved omicron AV treatments drugs Lagevrio and Paxlovid & injectable Veklury. Treatments were a critical issue in late 2022 p95 mentioned Paxlovid efficacy of 51% in vaxxed participants down from 89% unvaxed in Dec 2021
See Pfizer media release June 2022. Lagevrio subsequently in 2023 is now NOT recommended EU (Feb 23) US & WHO (Nov 2023)
https://www.pfizer.com/news/press-release/press-release-detail/pfizer-reports-additional-data-paxlovidtm-supporting

AUSTRALIA needs to have an expert Centre for Disease Control like the USA and Europe ECDPC

MANY FAILURES IN TRANSPARENT GOVERNANCE IN THE PANDEMIC MEANS A ROYAL COMMISSION WITH POWERS TO COMPEL RESPONSES FROM POLITICIANS, PUBLIC SERVANTS AND ORGANISATIONS IS NEEDED

3. Covid-19 Response with Vaccinations and Treatments suitable for all ages and population cohorts
3.1 Aged Care Vaccine delivery slow to achieve targets from start 22 Feb 2021. Dividing residents AZ vaccination delivery from staff lost protection; stopping visitors was cruel. Both could have been avoided by using antiviral nasal sprays. TGA should have approved Viraleze (Astodrimer sodium) in Nov 2020 when approved by European regulator ECDPC/EMA. AV spray bottles next to hand sanitisers and masks in Aged Care reception would have been a low cost method to stop Covid-19 cross contamination of visitor/staff/ residents. Plus awareness of AV protection would have spread throughout the community and become important in hospitals, schools, sports and public transport. As early as March 2021 Viraleze was manufactured in Belgium. AV sprays were NEVER to replace vaccines but enhanced protections as Covid-19 vaccines have never been 100% effective and have never lasted more than 6mths.
3.2 Was NOVEL mRNA vaccine really a better than Astra Zeneca. By March 2021, AZ was reported to cause 8cases per million from blood clots in mostly young women which could be associated with thin muscle and inexperienced staff not required to aspirate needles. By comparison by 2022, mRNA vaccines were associated with serious mio/pericarditis mainly in men under 50, rate 27cases per million. Starting in Sept 2020 mRNA Pfizer took

preorders internationally. Health Minister Hunt was widely criticised for missing preorders. That "miss" became critical in March 2021 when pariah status was given to AZ re blood clots. A significant announcement by Morrison and CMO Murphy after National Cabinet on 8 April 2021 spoke of **a high-level overnight meeting with Pfizer** securing early additional mRNA. https://www.theguardian.com/australia-news/2021/apr/09/scott-morrison-pledges-20m-more-pfizer-vaccine-doses-for-australias-trouble-plagued-rollout Pfizer CEO Bourla met business leaders and ex PM Rudd to ensure early July mRNA delivery https://www.abc.net.au/news/2021-07-11/kevin-rudd-australia-covid-pfizer-vaccine-supply-senior-execs/100284902 This mRNA delivery coincided with the Viraleze ban on 2 July 21. A ROYAL COMMISSION could call for a forensic investigation into any commercial advantage which Pfizer gained with the potential removal of a competing antiviral preventative/treatment Viraleze which would likely gazump Pfizer's nascent novel PF-07321332 Paxlovid drug. Viraleze was banned in its country of origin overshadowing the recent approved by European regulators. Pfizer went on to make $US22B profit just on Paxlovid. Phase 1 trials of Paxlovid started March 2021, Viraleze was banned and fined on 2 July 2021 just before escalated combined phase 2/3 Paxlovid trials. The ban also curtailed Australians online ordering access under the legal personal importation scheme. Not only was worldwide reputational damage done to Viraleze but web searches continue to question why this product which could have helped so many was banned.

3.3 More info on VIRALEZE and why it should have been a VERY important Covid-19 response. Developed in Feb 2020 in response to call for covid therapeutic preventions and treatments, Starpharma's Vivagel™ (Branded Fleurstat in Aust) had TGA approval from 2018 as a Medical Device – a unique barrier antiviral gel for Bacterial Vaginosis with active ingredient Astodrimer sodium it outperformed antibiotics. Tests had shown a very safe non poisonous and non antibiotic for mucosa use. Starpharma SPL (Abbotsford Vic) first notified SPL7013 Viraleze effectiveness re Covid-19 in April 2020, using WHO pandemic preferred humanized mouse genome at Scripp Research Institute US resulting in 99.9% inactivation of Covid and many other viruses SARS MERS RSV Flu etc, SPL received a Commonwealth Development Grant of $1m in Sept 2020 (ASX docs sourced https://www.asx.com.au/markets/trade-our-cash-market/announcements.spl

In Nov 2020 European regulators (experts in Nano Particles & reference for TGA) approved Viraleze as Medical Device. With Europe UK covid emergency, manufacturing started in Belgium. Viraleze first sold in UK late March 2021 with rapid sales growth (the same week that Paxlovid Ph1 trials start - so timeline at least 8 months behind). On-line sales in Europe and India began the next month. To date 35 regulators worldwide approved (not US FDA which has also not approved Vivagel) and it is sold in over 80 countries. With the Brexit separation of Health Regulation from Europe - product was withdrawn from market June 2021 to April 2022 in UK and repackaged. In May 2021 there was a news broadcast about the Australian Olympic team relying on Viraleze to protect them at the games in Tokyo https://www.facebook.com/7NEWSGoldCoast/videos/3904860009602164/

Then just as SPL expected fast track TGA approval, TGA instead issued an infringement notice with no warning – an unexpected announcement https://www.tga.gov.au/news/media-releases/starpharma-holdings-limited-fined-93240-alleged-unlawful-advertising-viraleze-relation-covid-19

Subsequent to 2 Jul 2021, TGA has ordered Starpharma to block the website viraleze.co to Australian IP addresses. TGA also said any future application must be as a Medicine even though Europe & 35 regulators approved as Medical Device MD. In Feb 2022 on appeal an adjudicator told TGA that MD was appropriate. In April 2022 Starpharma applied again for MD approval. Contrast with 2mths approvals of Pfizer Cominnaty Feb 2021 after company safety trial with unreported adverse events incl monkey death, Viraleze had to wait 18 months before the public consultation opened in Sept 2023 https://consultations.tga.gov.au/tga/scheduling-pre-meeting-november-2023/user_uploads/pre-meeting-public-https://consultations.tga.gov.au/tga/scheduling-pre-meeting-november-2023/user_uploads/pre-meeting-public-notice-acms-43--accs--37---joint--35-november-2023.pdf

It is now on hold whilst the Advisory Committee on Medical Scheduling (ACMS) makes its interim decision on Astodrimer sodium as barrier nasal spray to be published in February 2024 - that is 4 years into the pandemic where an effective antiviral nasal spray could have been available to all Australians aged 12yrs and over with absolutely minimal contraindications on use. So this to me is the biggest scandal of the pandemic.

Viraleze Research reports: Scripp Research Institute https://www.scripps.edu/gallay/sars-cov-2.html
and later safety trial Astodrimer sodium Astodrimer sodium human v placebo safety trials reported
https://www.researchgate.net/publication/361382162_Astodrimer_sodium_antiviral_nasal_spray_for_reducing_respiratory_infections_is_safe_and_well_tolerated_in_a_randomized_controlled_trial
Due to report Dec 2023: Placebo controlled trial revViraleze patient's viral load over a seven-day treatment period.
https://cdn-api.markitdigital.com/apiman-gateway/ASX/asx-research/1.0/file/2924-02715741-3A626784

With Wave 8 approaching and even smaller numbers of Australians having had a vaccine in the last 6 months, it is imperative that access to Antiviral Nasal Sprays for all occurs asap and Viraleze is best of class.

THE EXPERIENCE WITH TGA and VIRALEZE NON-APPROVAL IN AUSTRALIA IS APPAULING
I have a lot of further information I would be pleased to impart to the COVID-19 Response enquiry particularly how TGA's biased action on Viraleze compare with online purchases from Australia of ENOVID have led to many being scammed…. but have reached my 3 page limit.