From: S22
To: SKERRITT, John

Subject: Re: This email is private and is addressed directly to Adj Professor John Skerritt, kindly forward

CCEMS:06230001516 [SEC=OFFICIAL]

Date: Monday, 18 January 2021 6:54:37 PM

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Dear Prof Skerritt,

Thank you for your response. I appreciate you having taken the time to write this.

With thanks,



From: SKERRITT, John < John. Skerritt@health.gov.au>

Sent: Monday, 18 January 2021 7:27 AM

To: **\$22**

Cc: SKERRITT, John < John. Skerritt@health.gov.au>

Subject: RE: This email is private and is addressed directly to Adj Professor John Skerritt, kindly

forward CCEMS:06230001516 [SEC=OFFICIAL]



One of the main approaches that regulators use globally as part of the establishment of causality of potential serious adverse events from vaccines is to estimate the background rates of the "event" in the unvaccinated population.

For example, we are certain that thousands of people who are vaccinated with a COVID vaccine in any month globally will be diagnosed with advanced lung cancer within two weeks of their vaccination. This is because sadly thousands of people in the overall population receive such a diagnosis every month – the job of pharmacovigilance investigators is to thoroughly determine whether there is an increased rate of serious events over and above the expected rate, such as the cancer diagnosis, after a particular vaccination. This still doesn't necessarily mean cause and effect but it is an integral part of the investigation.

The Minister's statement and TGA's are factually correct – many of the people vaccinated in Norway are very frail and have months or less to live. In Norway we were told that 400 people died each week in aged care facilities in that small country alone, prior to the COVID pandemic.

The Norwegian Institute of Public Health vaccination guide has just been updated to say:

For most elderly who live with frailty the reduced risk of becoming seriously ill from COVID-19 will greatly outweigh the possibility to experience adverse reactions after taking the vaccine. However, for those who have serious frailty, relatively mild adverse reactions to the vaccine can

have serious consequences. For those who have a <u>very short lifespan left</u>, the gains of taking the vaccine can be marginal or irrelevant. For severely frail patients (for example equivalent to Clinical Frailty Scale 8 or higher) and terminally ill patients, it is therefore recommended to do a careful assessment of the benefit versus risk of the vaccination.

The role of patient consent is an individual one made by the patient (or their designate if they have delegated power of attorney), and not that of the Minister or a government official. The list of possible adverse events is to be provided in the Product Information (for vaccinators) and Consumer Information (for patients) – both are publicly available documents. These documents are only finalised on approval of a vaccine.

TGA has had a number of enormous responsibilities since its creation in the late 1980s; stewardship of medicines and vaccines safety is just one of these.

John Skerritt

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Department of Health

(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)

PO Box 100 Woden ACT 2606 Australia Phone: (02) 6289 4200 Fax: (02) 6203 1265

Email: john.skerritt@health.gov.au

------ Original Message

From: **\$22**

Received: Mon Jan 18 2021 17:27:50 GMT+1100 (Australian Eastern Daylight Time)

To: info@tga.gov.au; info-Queue;

Subject: This email is private and is addressed directly to Adj Professor John Skerritt, kindly forward

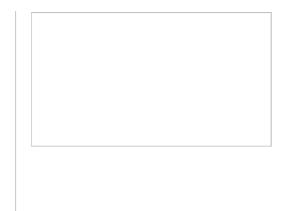
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Dear Professor Skerritt,

I heard Greg Hunt's interview last night (17 Jan, since edited), where he said that some of those who died in Norway may have had only a couple of weeks to live, anyway. I notice that now, the TGA (whoever the spokesperson is) has said that some of those who died possibly only had several months to live, anyway.

[https://www.skynews.com.au/details/ 6223514113001]

TGA releases statement about Pfizer vaccine deaths in Norway | Sky News Australia



The Therapeutic Goods
Administration has released a
statement to reassure Australians of
the vaccine approval process after
reports of around 23 deaths among
elderly recipients of the Pfizer ...

www.skynews.com.au

My question to you is very simple. When people are asked to give their consent, they will be told of the possible adverse effects. Will death be listed amongst those possible adverse effects? I would also like to ask if - given Greg Hunt is now minister for aged care - given his response last night, should he be in a position to give consent for any of the people (aged care inmates) who come under his jurisdiction?

I appreciate that you have an enormous responsibility, and that it is you, not the Health Minister or the Health Secretary, who will be blamed for every adverse effect. By having a statement released that says, in effect, these people were going to die *anyway*, it already gives the TGA a cold-hearted 'face'.

Yours sincerely,



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