CLEMENSHASKIN
LEGAL

Suite 261, 585 Little Collins St
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Australia

8 January 2021

Dr Brendan Murphy
Secretary
Department of Health
Therapeutic Goods Administration

By email: Elizabeth.Santolin@health.gov.au

Dear Dr Murphy,

COVID-19 Vaccines
Consumer Protection

1. I act for People for Safe Vaccines Ltd, a not-for-profit promoting vaccine safety and efficacy. My client's membership consists of a growing number of healthcare professionals, scientists, people experienced with vaccine injuries and the general public concerned as to the safety and efficacy of the COVID-19 vaccines. My client instructs as follows.

2. The Commonwealth is in the process of granting provisional approval to certain COVID-19 vaccines. Under the relevant legislative provisions, sponsors will be allowed up to 6 years after supply of the vaccines to all Australians to demonstrate the safety and efficacy of the goods. Usually, this 'fast track' process is reserved for strictly experimental medicines targeting a very narrow group who are close to death, suffering serious illness and without therapeutic alternatives.

3. In light of the Commonwealth's emphatic policy to have all adult Australians vaccinated commencing February 2021 and the unprecedented measures that have accompanied this coronavirus to date, the importance of detailed, accurate and timely information cannot be understated.

4. As well as the general requirements under the Australian Consumer Law ("ACL"), there are extensive requirements under the *Therapeutic Goods Act 1989* addressing the provision of product, patient and consumer information and advertising. However, the TGA permits sponsors of provisionally registered medicines to apply certain blanket *pro forma* statements, such as:

> *This medicine has provisional approval in Australia for (insert indication). The decision to approve this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.*

5. This approach would obviate the need for a sponsor to disclose a raft of information of critical importance to all Australian consumers in relation to the COVID-19 vaccines, including details of the following.

- The experimental nature of the vaccines lacking validated data, preclinical trial data, long term data, performance data, biological reactivity data and toxicological data.

- The vaccines' potential to cause severe adverse reactions including death, paralysis, anaphylaxis, palsy, miscarriage and/or infertility, and others presently unknown.

- The exclusion of various groups from sponsors' trial and study participation, including people with serious pre-existing conditions such as cancer, respiratory disease, heart disease, prior history of allergic reactions, angioedema, anaphylaxis and immunodeficiencies.

- The extensive indemnities given by the Commonwealth to various sponsors, and lack of avenues for redress in the event of injury.

6. By contrast, the epidemiological data in relation to COVID-19 shows that:

    - the risk of infection and transmission is extremely low.

    - most if not all deaths occur due to pre-existing serious conditions and frailties, often exacerbated by dangerous medical interventions.

    - the risk of reasonably fit and healthy people suffering more severely than with the seasonal flu is negligible.

    - the preferred diagnostic method, nucleic acid testing, is far from conclusive in producing results (especially in symptomless subjects and in a low prevalence setting) and cannot in any event distinguish between 'live' and non-infectious virus.

7. Further, coronavirus vaccines have an incredibly poor safety and efficacy track record and are rapidly rendered obsolete by new viral strains. Compare this to various off-label COVID-19 beneficial treatments including chloroquine, zinc, ivermectin and vitamins associated with many successful recoveries, which have been extensively reported and endorsed by credible front-line medical professionals.

8. Clearly, the foregoing reveals a real basis to seriously doubt whether these experimental COVID-19 vaccines can be held out as safe or effective or likely to be reasonably fit for purpose or of acceptable quality, particularly as their ability to prevent viral infection and transmission is largely unknown.

9. Australians need to be made aware of all these matters in order to be in a position to make an informed choice as to whether vaccination is right for them and their families. Also, influencers such as employers, businesses and institutions ought to be prohibited from demanding or pressuring people into inoculation and strictly warned that it would be unlawful and unconscionable for them to apply punitive measures to those who decline such inoculations.

10. Silence can amount to misleading or deceptive conduct where one person fails to disclose facts known to them that are relevant to a decision, where important details a person should know are not conveyed to them, and where a change in circumstance means information already provided was incorrect.

11. As the Commonwealth is now investing and dealing in these vaccines and has entered into commercial purchasing arrangements indemnifying sponsors and subscribed to the international COVAX facility, its conduct in relation to these activities will likely also be subject to the ACL. It is therefore all the more important that the Commonwealth take decisive and impartial action in relation to ensuring the Australian public is properly informed upfront as to all relevant matters.

12. My client therefore requests that the Commonwealth and its principal agencies on these matters to commit to the following.

    (a) Ensure COVID-19 vaccine sponsors engage in ongoing timely public disclosure of detailed and accurate product and consumer information.

    (b) Conduct widespread campaigns to inform and educate the public and medical professionals as to all relevant matters, including the risks of these experimental vaccines, the alternatives, the risk profile of the virus and the shortcomings of the testing methods.

    (c) Ensure that individuals are given detailed information warning of the experimental and potentially hazardous and ineffective nature of the vaccines prior to inoculation.

    (d) Ensure individuals acknowledge having read and understood the information and are given an opportunity to seek independent medical advice when giving signed consent prior to inoculation.

    (e) Prohibit discrimination, undue influence or pressure, coercion or force being imposed upon any individual who may decide against inoculation.

13. My client is prepared to take legal action to protect its members and the Australian public, and reserves all its rights and remedies in this regard.

14. We look forward to receiving your reply by **22 January 2021** confirming the Commonwealth's commitment to implement the above requests prior to marketing and supplying these COVID-19 experimental vaccines to the nation.

Yours sincerely
CLEMENS HASKIN LEGAL
Per:

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