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2 February 2021

The Hon. Greg Hunt
Minster of Health
Department of Health
Canberra ACT 2600

By email: jenny.francis@health.gov.au

Dear Minister,

Pfizer Vaccine for COVID-19
Consumer Protection

1. I act for People for Safe Vaccines Ltd and refer to previous correspondence to Dr Murphy dated 8 January 2021 and the Department's brief reply by email from Ms Francis dated 14 January 2021. In light of recent developments, I am instructed to write as follows.

2. First, my client welcomes the recent statements at the Health.gov.au website assuring Australians that vaccination will be voluntary and they will not be denied certain benefits if they decline. My client remains strongly in favour of informed consent and opposed to any forms of pressure, undue influence or discrimination, including (without limitation) inducements for people to take the vaccine and financial incentives that could bias the recommendations of health care professionals.

3. Next, the Commonwealth has made it abundantly clear to the Australian public that safety and efficacy are the essential preconditions to vaccine approval in the context of the national COVID-19 vaccine rollout strategy. These conditions, as we understand from the limited information released, were also applicable to the vaccine purchasing agreements and presumably also to the indemnities given by the Commonwealth to certain vaccine companies.

4. Public statements that vaccines are safe and effective convey the ordinary meanings of those terms.[1] Vaccines are held to a higher standard than other medications because they are generally given to healthy people to prevent illness and death.[2] Typically, vaccines may require 10 or more years to develop, even within a specific target population and for well understood pathogens. No vaccine is completely safe or effective.

[1] *Australian Competition and Consumer Commission v Homeopathy Plus! Australia Pty Limited* [2014] FCA 1412 at [51]-[52]: Safety is "the quality of being unlikely to cause hurt or injury; the quality of not being dangerous or presenting a risk." Efficacy is "the ability to bring about the intended result." (link)
[2] Ibid [53]

5. On 25 January 2021, the Therapeutic Goods Administration ('TGA') granted provisional approval to Pfizer Australia Pty Ltd ('Pfizer') to supply its mRNA vaccine named 'COMIRNATY BNT162b2', indicated for the prevention of COVID-19 in individuals 16 years of age and older. The provisional approval pathway allows for up to 6 years' post-market validation.[3] Any such approval is therefore necessarily granted on limited safety and efficacy data. In this case the data consists of Pfizer's published trial and study documentation and results,[4] and the TGA's published documentation which accompanies the Pfizer approval, including the Product Information, Consumer Medical Information ("CMI") and Australian Public Information Report ("AusPAR").[5]

6. The AusPAR outlines various limitations of the sponsor's safety and efficacy data,[6] which prevents current assessment of:
    - longer term effects (more than 2 months);
    - duration of protection;
    - asymptomatic infection;
    - viral transmission (and hence vaccine-induced herd immunity);
    - concomitant use with other vaccines;
    - real world use in a large and diverse population, including pregnant women and breastfeeding mothers, immunocompromised individuals, paediatric subjects (under 16 years old) and Aboriginal and Torres Strait Islanders; and
    - a correlate of protection, which has not been established.[7]

7. Other limitations of the Pfizer trial and studies include lack of data on:
    - the potential for vaccine-induced auto-immune disorders including antibody dependent enhancement and pathogenic priming, which may also increase susceptibility to viral infection;[8]
    - successful preclinical trials the potential of the lipid nanoparticles or the vaccine formulation for complement activation or stimulation of cytokine release;[9]
    - toxicity in relation to particular excipients such as polyethylene glycol;
    - the potential for adverse fertility impacts including sterility;
    - reduction in morbidity (eg measured by hospital and intensive care visits);
    - reactogenicity, as measured in less than 20% of trial participants, and only for 7 days on a solicited basis and 14 weeks on an unsolicited basis (despite the plan to monitor for 6 months);
    - adverse events and severe adverse advents, which were monitored for just 28 days after the second dose;
    - significance – only results within a sub-group of 170 out of 43,448 trial participants were used to support the claim of 95% efficacy;

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[3] *Therapeutic Goods Regulations 1990*, reg.10L(d) (link)
[4] https://www.pfizer.com/science/coronavirus
[5] https://www.tga.gov.au/covid-19-vaccine-pfizer-australia-comirnaty-bnt162b2-mrna
[6] AusPAR p.34
[7] Plotkin D "*Correlates of Protection Induced by Vaccination*" CVI 12/5/10 (link) defines "correlate of protection" as "An immune response that is responsible for and statistically interrelated with protection."
[8] See eg. Lyons-Weiler "*Pathogenic priming likely contributes to serious and critical illness and mortality in COVID-19 via autoimmunity*" PubMed 9/4/20 (link)
[9] AusPAR, ibid p.14

- the potential relevance of the 'suspected Covid' sub-group of 3,410 participants, who had symptoms but were not PCR-confirmed or re-tested.[10]
- the reliability of the PCR test results, especially cycle thresholds, calibration and repeat testing; and
- the reliability of test results due to the very low prevalence of confirmed cases within the trial population (less than 0.5 percent).

8. Moreover, other matters not addressed in the Pfizer or TGA documentation include:
    - the comparative risks to morbidity and mortality of vaccinating or not;
    - an analysis of need, the prevalence of natural immunity and the achievement of herd immunity without vaccination;
    - lack of any successful precedent for coronavirus vaccines in general;
    - the availability, safety and efficacy of treatment alternatives (including reduction of reinoculation, combination antiviral therapy, immunomodulation, antiplatelet/antithrombotic therapy and administration of oxygen, monitoring, and telemedicine techniques,[11] ivermectin, zinc and vitamins[12]);
    - risks inherent in novel use of gene therapy techniques as vaccination methods;
    - potential flow-on genetic effects associated with mRNA vaccines;
    - lack of a case definition for COVID-19 in Australia;
    - the general limitations of PCR, including its inability to distinguish between 'live' and non-infectious virus, lack of standardisation and susceptibility to false-positive results at low prevalence and high cycles,[13] in asymptomatic individuals[14] and due to cross-contamination throughout the collection, storage, transport, preparation, extraction and production workflow steps;
    - deficiencies in the methods of isolation and characterisation of the virus; and
    - deficiencies in the proof of aetiology of COVID-19, including lack of evidence of reproducibility of symptoms in healthy subjects.

9. Further, the AusPAR identifies numerous adverse health impacts which were significantly higher in the vaccinated group than the placebo group, including general disorders and administration site conditions, musculoskeletal and connective tissue disorders, nervous system disorders, lymphadenopathy (a disease of the lymph nodes) and facial paralysis.[15]

10. Whether or not you accept the above *in toto*, it is abundantly clear from the TGA's own admissions that the Pfizer documentation both discloses and omits salient matters that would ordinarily and reasonably be required to demonstrate vaccine safety and efficacy.

11. Indeed, it is difficult to discern any scientific basis for claims of prophylactic safety and/or efficacy for any recipient (especially in the longer term), and more particularly for people diagnosed with asymptomatic infection, members of the excluded groups and those who may be susceptible to risks beyond the scope of the Pfizer study parameters.

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[10] Doshi "*Pfizer and Moderna's "95% effective" vaccines—we need more details and the raw data*", BMJ Opinion, 4/1/21 (link)
[11] McCullough et al, "*Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection*", AJM, 6/8/20 (link)
[12] FLCCC Alliance, "*Prophylaxis and Treatment Protocols for COVID-19*" (link)
[13] See eg WHO "*Information Notice for IVD Users 2020/05,*" 20/1/21 (link)
[14] PHLN, "*Statement on asymptomatic testing for SARS-CoV-2,*" 6/8/20 (link)
[15] AusPAR, ibid pp.27-28

These factors are of considerable scope and impact. More than one third of diagnosed COVID-19 cases are without any symptoms[16] and most experience only mild symptoms, over 5% of the population have immune deficiencies (many of which are undiagnosed and increase with age), and many people take other medications and vaccines. Under these circumstances it is also unclear why the vaccine has been exempted from Poisons Standard warning and potency labelling requirements.

12. Further, the dangers of this experimental vaccine are correlated in the pharmaco-monitoring from the U.S., which has recorded numerous reports of adverse events since the emergency use authorisation in December 2020. The CDC reported significant health impacts rising to 3,150 or 2.7% for just the first 5 days of experimental use.[17] As at 29 January 2021, the U.S.-based VAERS system had logged 7,765 adverse events in connection with the Pfizer vaccine, including some 80 deaths occurring within hours or days of vaccination, and which due to underreporting may be only a fraction of the total.[18] Diligent long-term monitoring of adverse events needs to occur before it can be asserted the vaccine is generally safe. Pfizer's decision to abandon its plan to monitor the placebo group for 2 years post-vaccination is unhelpful in this regard.[19]

13. As to the issues of efficacy and need, Pfizer's touted 95% efficacy test results showing 162 to 8 out of a total 37,086 recipients of 2 doses reflect a prevalence of less than 0.5%, which renders the results unreliable under positive predictive value analysis. Further, the vaccine performs poorly against the benchmark of the body's natural immune response, as reflected by a prognosis of mild flu-like symptoms and recovery without any special treatment or hospitalisation,[20] and survival rates worldwide in the unvaccinated population of better than 99%.[21] In Australia, where the average age of COVID-related death is above average life expectancy, with most suffering serious pre-existing conditions, the prevalence is so low (less than 0.25 percent) as to render any test results scientifically worthless.

14. Despite the foregoing, the Commonwealth evidently considers the Pfizer vaccine to be generally safe and effective. The CMI only contains warnings for people who are allergic to the vaccine or its ingredients, and children under 16 years. It merely advises consumers to 'check with your doctor' in certain limited circumstances, such as during pregnancy or if an adverse reaction occurs, or for people over 85 years of age.

15. The Australian Consumer Law ('ACL') affords consumers protection against, among other things:[22]
    (a) marketing information that is misleading or likely to mislead;
    (b) goods that are not of acceptable quality, reasonably fit for purpose and safe; and
    (c) unconscionable conduct generally and in the supply of goods and services.

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[16] McNamara, "*More Than One Third of COVID-19 Infections Are Asymptomatic: Review*", Medscape 25/1/21 (link)
[17] ACIP COVID-19 Vaccines Work Group, Clark, "*Anaphylaxis Following m-RNA COVID-19 Vaccine Receipt*", 19/12/20, CDC, p.6 (link)
[18] Vaxopedia, "Underreporting of Side Effects to VAERS", 26/8/17 (link)
[19] Polack et al, "*Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine*", NEJM 31/12/20, p.2612 (link)
[20] RACGP, "*Supporting patients in their home*", 1/2/21 (link)
[21] Swiss Policy Research, "*Facts about COVID-19*" 1/21 (link)
[22] ACL, ss.18, 20, 21 and 54

16. Clearly, the current CMI warnings are inadequate, considered against the extensive limitations, the lack of data, the dangers and the high safety and efficacy standards required of vaccines at law. Accordingly, the TGA documents should be amended and the information in Attachment A be conveyed to healthcare providers and consumers as recommendations in large, prominent, bold and preferably capitalised lettering, in the CMI, national advertising campaign, and any packaging and point of care materials.

17. Further, information should be publicly disclosed regarding:
    (a) Pfizer's track record as an international 'habitual offender' in illegal and corrupt marketing practices, bribing physicians and suppressing adverse trial results;[23]
    (b) any financial incentives offered to healthcare providers in connection with the vaccine; and
    (c) any conflict or potential conflict of interest of any ministerial or public service officer connected with the COVID-19 vaccine strategy.

18. The Commonwealth has assumed the role of wholesale supplier, distributor and marketer of the COVID-19 vaccines in Australia. It has taken the extraordinary step of indemnifying disreputable manufacturers against incalculable liabilities in respect of complex experimental and under-tested products. As you, Minister, are aware of the manifest shortcomings of the Pfizer vaccine in relation to safety and efficacy, it is incumbent upon you as a matter of public trust in good conscience to take all necessary steps to protect the nation from risks of vaccine-related injury and death.

19. I would be grateful if you could also provide answers to the following questions.
    (a) Are financial incentives being planned or offered to health care professionals or institutions to recommend vaccination to their patients?
    (b) Why were the exemptions from the Poisons Standard given to the Pfizer vaccine?
    (c) Has Pfizer been granted the benefit of an indemnity and if so, on what terms?
    (d) What is the Commonwealth's total estimated financial exposure to claims assessed under its COVID-19 vaccine indemnities?

20. In light of the imminent rollout of the vaccine, I look forward to receiving your reply by **17 February 2021** confirming that the above information will be included in all relevant information, to ensure the risk/ benefit profile of the Pfizer vaccine is accurately and adequately disclosed.

21. My client reserves all its rights and remedies pending satisfactory resolution of these matters.

Yours sincerely
CLEMENS HASKIN LEGAL
Per:

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[23] Evans, "*Tough on Crime? Pfizer and the CIHR*", Healthcare Policy, 5/2010 (link)

ATTACHMENT A

Important Information for Health Providers and Consumers

Pfizer COVID-19 vaccine COMIRNATY BNT162b2

SAFETY

- **WARNING: THIS VACCINE MAY CAUSE SERIOUS ILLNESS AND DEATH.**
- **This vaccine is new and experimental and has not been fully validated for safety or efficacy.**
- **This vaccine has not been safety-tested for medium term and long term side-effects.**
- **This vaccine has not been tested for genetic impacts.**
- **If you are pregnant or breastfeeding, immune compromised, otherwise ill, frail, taking other medications, or an Aboriginal or Torres Strait Islander, you should not take this vaccine.**

EFFICACY

- **This vaccine may not prevent infection or give lasting protection from infection.**
- **This vaccine may not prevent viral transmission.**
- **This vaccine will not reduce symptoms.**
- **Before taking this vaccine, you should carefully weigh the risks and benefits against the risks associated with infection, including mortality and morbidity data.**
- **You should carefully consider whether this vaccine is right for you in all the circumstances.**