PJ O'Brien & Associates
PO Box 916
The Junction
NSW 2291

27 September 2023

Attorney-General
Robert Garran Offices
3-5 National Circuit
BARTON ACT 2600

Attention: Hon Mark Dreyfus KC MP, Attorney-General
and Hon Matt Thistlethwaite MP, Assistant Minister for the Republic.

Dear Messrs

BRIEF OF INFORMATION & EVIDENCE

AS FILED WITH THE AUSTRALIAN FEDERAL POLICE

Alleged Offence: Dealing with genetically modified organisms (GMOs) without a license
Defendants: Pfizer Australia Pty Ltd and Moderna Australia Pty Ltd
Pfizer and Moderna's Covid-19 mRNA products are or contain GMOs

Preface

Under Section 13 of the *Crimes Act* 1914 Dr Julian Fidge has the right to institute proceedings for the commitment for trial of Pfizer Australia Pty Ltd and Moderna Australia Pty Ltd, in respect of the indictable offences set forth under Section 32 and Section 33 of the *Gene Technology Act* 2000.

Instituting criminal proceedings is a matter of urgency in light of the continued dealing and supply of the Covid-19 products by Pfizer and Moderna in Australia, which for containing *genetically modified organisms*, GMOs, including synthetic DNA contamination as another form of GMO, continue to threaten and/or actually cause irreparable harm to recipients, including death, and including irreversible alterations to the natural chromosomal DNA of recipients, which changes are inherited by offspring. These threats, harms, and irreversible alterations to chromosomal DNA have likely already been experienced by a significant number of Australians. These Covid-19 products are still available to Australians who can, with the institution of the proceedings described here, avoid these harms or the greater likelihood of these harms that exposure/s to these products would result in.

1. Commissioner Kershaw, our office has been instructed to provide your office by way of this correspondence the opportunity to consider this brief of information and evidence, so that your office may determine whether it is more appropriate given the seriousness of the matters and allegations detailed below, that the Australian Federal Police institute the proceedings described in the preface.

2. Commissioner Kershaw, your office is in a position to prevent further threatened or actual harm to recipients, including death, and including irreversible alterations to the natural chromosomal DNA of recipients, which changes are inherited by offspring.

3. In the event your office confirms it is unwilling to institute the proceedings described in the preface, our office has been instructed to institute those proceedings.

4. We appreciate the subject is confronting and involves crimes never before perpetrated in Australia to such an extent, involving so many Australians. Equally, though the science on the adverse effects consequent upon infiltration by GMOs is extensive, particularly as it relates to effects when certain forms of GMO enter the nucleus of cells, never before in human history have we experienced a mass contamination of a population with GMOs known to seriously dysregulate or silence and alter the integrity of natural human DNA. We Sir are in uncharted waters, a fact all readers of this information must reconcile themselves with.

5. Separately, and on behalf of Dr Fidge, our firm has already instituted civil proceedings in the Federal Court of Australia (VID510/2023) on 6 July 2023, pursuant to Section 147 of the *Gene Technology Act* 2000 (**the GT Act**), seeking the remedy of injunction from any further dealing by the Respondents with their Covid-19 products in Australia, due to the failure by each Respondent to first obtain GMO licenses under the *Gene Technology Act* 2000 for each of their Covid-19 products, which failures and the Respondents' subsequent and ongoing dealings with the products in Australia without the required GMO licenses, constitute serious and ongoing criminal offences as described in preface. As those are civil proceedings the onus of proof is the balance of probabilities. Further details available here.

Summary

6. A concise summary of how these products constitute GMOs follows.

Defining GMOs

7. The Covid-19 vaccines (both the monovalent and bivalent products) produced by Pfizer and Moderna satisfy the Australian legal definitions for being properly deemed *Genetically Modified Organisms*, GMOs, pursuant to section 10 of the *Gene Technology Act* 2000.

8. The relevant definitions are applied in the context of the products containing 'LNP-modRNA complexes' and 'LNP-modDNA complexes'. These are accepted scientific terms. The prefix 'mod' stands for *modified* for correctly denoting the RNA and DNA within the products is synthetic and manmade. These terms are used by Pfizer and Moderna. They are *complexes* where in the case of the modRNA, the modRNA would have no effect or value or purported benefit without first being bound and encapsulated in LNPs for transport and delivery of the modRNA throughout the human body. For any purported benefit to be derived the two components must be combined into *complexes* (ie LNP-modRNA), using scientific manufacturing processes, before any therapeutic value can possibly be derived by the use of the components.

Note – modDNA contamination: The LNP-modDNA complexes were recently discovered to be present in the Covid-19 products of both Pfizer and Moderna and represent ***serious and excessive contamination*** of those products. Those findings have been verified by other independent laboratories.

9. Relevantly, the LNP-modRNA and LNP-modDNA complexes each fulfill the definition of ***Organism***, which means:

> *"organism" means any biological entity that is:*
>
> *(a) viable; or*
>
> *(b) capable of reproduction; or*
>
> *(c) capable of transferring genetic material.*

10. Breaking down the definition.

11. First, the LNP-modRNA and LNP-modDNA complexes fulfill being '***any*** biological entity'. The chief ingredient in the Pfizer and Moderna products are the nucleoside-modified RNAs (modRNA) which is ***genetic material***.

12. "Any biological entity" is not defined in the GT Act, so the ordinary meaning of the words apply. This was confirmed in an email from the Office of the Gene Technology Regulator (**OGTR**) on 6 February 2023.

13. In support of this is both Pfizer and Moderna's applications to the Therapeutic Goods Administration (**TGA**) for provisional approval of their Covid-19 products as a "New **biological entity**" submission for each of their products.[1]

14. Secondly, the LNP-modRNA and LNP-modDNA complexes do and are *'capable of transferring genetic material*', insofar that the LNP encapsulating the modRNA/modDNA bio-distributes throughout the human body, and directly assists to transfer (transfect) the modRNA/modDNA across cell membranes and into the cytoplasm of cells of all organ types and classes, including the brain, heart, kidneys, liver, testes, ovaries, with as yet unknown effects/risks of transfection/exposure for unborn children.

15. This encapsulation, transport, and transfection using LNPs involves the physical *'transferring of genetic material*' (the modRNA and modDNA) throughout the body of recipients.

16. Some parts of the modDNA contamination is also ***capable of reproduction***, in that it is *replication competent* in some cells, meaning it can self-replicate independently within human cells. See the report of Dr Angela Jeanes below.17. Having satisfied the above, it then follows, a:

> *"genetically modified organism" means:*
>
> *(a) an organism that has been modified by gene technology;*

[1] Pfizer Monovalent: https://www.tga.gov.au/resources/auspmd/comirnaty
Pfizer Bivalent: https://www.tga.gov.au/resources/auspmd/comirnaty-originalomicron-ba1-covid-19-vaccine
Moderna Monovalent: https://www.tga.gov.au/resources/auspmd/spikevax
Moderna Bivalent: https://www.tga.gov.au/resources/auspar/auspar-spikevax-bivalent-originalomicron-ba4-5

18. Where:

> *"gene technology" means **any technique** for the modification of genes or other genetic material.*

19. The degree of genetic modifications involved in the creation of the modRNA is beyond question and well settled.

20. **Annexure 1** to this brief of information contains the Expert Witness report by Dr Angela Jeanes (Molecular and Cellular Biology) filed in our civil proceedings against Pfizer and Moderna. Dr Jeanes directly addresses the GMO definitions above in the context of the LNP-modRNA and LNP-modDNA complexes in respect of the Pfizer and Moderna products, and concludes the complexes do satisfy Australian legal definitions for being properly deemed GMOs: see answers to Question 3 through Question 14 starting from PDF page 48 of this Brief (or page 25 of Dr Jeanes' report).

21. In light of the ease with which Dr Jeanes was able to find the LNP-modRNA/DNA complexes fulfill Australian legal definitions for being deemed GMOs, we assert and allege both Pfizer and Moderna have long been aware these legal definitions apply to their Covid-19 products, but both companies chose to ignore their legal responsibilities under the GT Act when seeking to introduce their Covid-19 products to the Australian market.

22. Turning then to Section 32 of the GT Act, which contains the following offence:

Person not to deal with a GMO without a licence

(1) *A person commits an offence if:*

(a) *the person deals with a GMO, knowing that it is a GMO; and*

(b) *the dealing with the GMO by the person is not authorised by a GMO licence, and the person knows or is reckless as to that fact; and*

(c) *the dealing with the GMO is not specified in an emergency dealing determination, and the person knows or is reckless as to that fact; and*

(d) *the dealing is not a notifiable low risk dealing, and the person knows or is reckless as to that fact; and*

(e) *the dealing is not an exempt dealing, and the person knows or is reckless as to that fact; and*

(f) *the dealing is not included on the GMO Register, and the person knows or is reckless as to that fact.*

Note: Chapter 2 of the Criminal Code sets out the general principles of criminal responsibility.

23. Upon inquiry with the OGTR your office will confirm (1)(c) through (f) are satisfied, namely:

a. There is no *emergency dealing determination* specifying the Covid-19 products: (1)(c).

b. The Covid-19 products are not *notifiable low risk dealings*: (1)(d).

c. The Covid-19 products are not *exempt dealings*: (1)(e).

d. The Covid-19 products of Pfizer and Moderna are not included in the *GMO Register*: (1)(f).

24. We further assert and allege documents in the possession of Pfizer and/or Moderna will show the companies turned their minds to the issue of their products being

GMOs, and intentionally chose to avoid seeking GMO licences. Alternatively, in the absence of any such documentary proof, Chapter 2 of the Criminal Code is sufficient for demonstrating both companies were negligent and/or reckless and cannot plead *mistake* as to the fact of their products fulfilling the Australian legal definitions requiring them to first seek GMO licences - which only ***if*** approved and granted - would then have entitled them to seek provisional approval from the TGA. The actual grant of provisional approval by the TGA never cured the serious and ongoing criminal offences of Sections 32, 33, and 38.

25. AstraZeneca on the other hand did not avoid its legal obligations and properly sought a GMO License from the OGTR prior to seeking provisional approval from the TGA: see DIR 180.

26. AstraZeneca took this course because its Covid-19 product uses a genetically modified adenovirus known scientifically as a *viral vector*, which after injection ***is designed to enter the nucleus of cells***, where the adenovirus causes the nucleus to transcribe (make a copy of) its genetic code for creating Spike specific modRNA, which modRNA then exits the nucleus into the cytoplasm to interact with ribosomes for the production of Spike proteins said to prompt an immune response to SARS-CoV-2/Covid-19.

27. Because the AstraZeneca product unequivocally involves ***entry into the nucleus of human cells***, AstraZeneca had to first seek a GMO license from the OGTR.

28. ***Entry into the nucleus of cells*** by any ***genetically modified*** substance is ***the defining mode of action*** the GT Act is meant to protect Australians from being exposed to, let alone injected into their bodies without their knowledge.

29. Although expert witnesses could be used in court to contort and contend for *other than* the plain English meaning of the definitions as they apply to a particular product, ***the mode of action ultimately defines a substance*** such that, where a substance created from ***gene technology*** can be shown to enter the cell nucleus, or known probabilities exist indicating that the substance is capable of entering the cell nucleus, that probability or fact brings the substance into the definitions for being deemed a ***genetically modified organism***. This is because the carriage through the cell membrane (transfection) alone is the physical action and ***transferring of genetic material*** (the first ***mode of action*** satisfying the definitions). Once cell entry has

been gained, that is enough where humans are concerned for a substance to undergo proper examination by competent authorities (a risk assessment by the OGTR, for instance); that subsequent information confirms further physical carriage of the genetic cargo into the nucleus is the ***final mode of action*** the *Gene Technology Act* was created to protect the Australian public from, particularly when such a final mode of action was never declared by the manufacturers, or investigated by authorities nor especially, made known to recipients.

> Object of Act.
>
> The object of this Act is *to protect the health and safety of people ... by identifying risks posed by or as a result of gene technology*:

Entry into the Cell Nucleus

30. Statements that the Pfizer and Moderna Covid-19 products 'never enter the nucleus' are nothing more than baseless assertions.

31. Pfizer and Moderna as professed experts in the field of modified mRNA products both knew and know the claim their products 'never enter the nucleus' to be baseless, and themselves have ***never provided any scientific data to support the claim***. Indeed there is ***no scientific evidence supporting the claim***.

32. On the contrary, there is instead over 40 years of science evidencing natural and exogenous (foreign) mRNA entering the nucleus of cells, and reverse-transcribing into genomic DNA (natural chromosomal DNA). This natural process has always formed part of human biology.

33. With the rollout of Covid-19 products globally this established science of mRNA reverse-transcription with genomic DNA was intentionally kept from the public everywhere: see the peer reviewed paper at **Annexure 2**, *The Canaries in the Human DNA Mine* (Gillespie 2023) from PDF page 98 of this Brief.

34. The Covid-19 products of Pfizer and Moderna have been demonstrated to ***enter the nucleus of cells***. The OGTR and the TGA were informed by this office and by another law firm (Maat's Method) of this fact, yet both agencies have refused to act.

35. That the TGA has not acted on this information is remarkable when TGA documents released under FOI confirm the TGA was in fact ***informed by Pfizer*** that synthetic Spike protein produced by their Covid-19 product does enter the nucleus of the cell. Despite this, the TGA has maintained public statements contradicting the information supplied by Pfizer: see FOI 2389-6 TGA *Nonclinical Evaluation Report*, containing the Pfizer submitted merged Hoechst slides on page 35.

36. The information supplied by Pfizer to the TGA evidencing the Spike protein created by its product entering the cell nucleus was supplied to the TGA in 2020. Pfizer therefore possessed ***knowledge*** of this fact in 2020 at the time it was making application to the TGA.

37. Additionally, by correspondence dated 8 March 2022 passed directly from law firm Maat's Method to instructing solicitors representing the Secretary of Health during the case AVN v. Secretary of Health (NSD52/2022), the Secretary was presented with an earlier expert report by Dr Angela Jeanes addressing a peer reviewed paper evidencing the SARS-CoV-2 Spike protein entering the nucleus of human cells and adversely interfering with DNA processes, (the same Spike protein produced by Pfizer and Moderna), together with a peer reviewed paper evidencing Pfizer's modRNA undergoing reverse-transcription with human cell line (see the Alden et al paper below), and discussion of the merged Hoechst slides contained in TGA FOI 2389-06 evidencing Pfizer's induced Spike protein entering the nucleus of cells. In light of the evidence showing infiltration of the nucleus and the very real risks and observed interference with natural DNA, the Secretary was requested to cancel or suspend the Pfizer and Moderna products. The Secretary did not respond. Importantly, the OGTR is housed within the offices of the Department of Health.

38. Excerpt from the 8 March 2022 report by Dr Angela Jeanes:

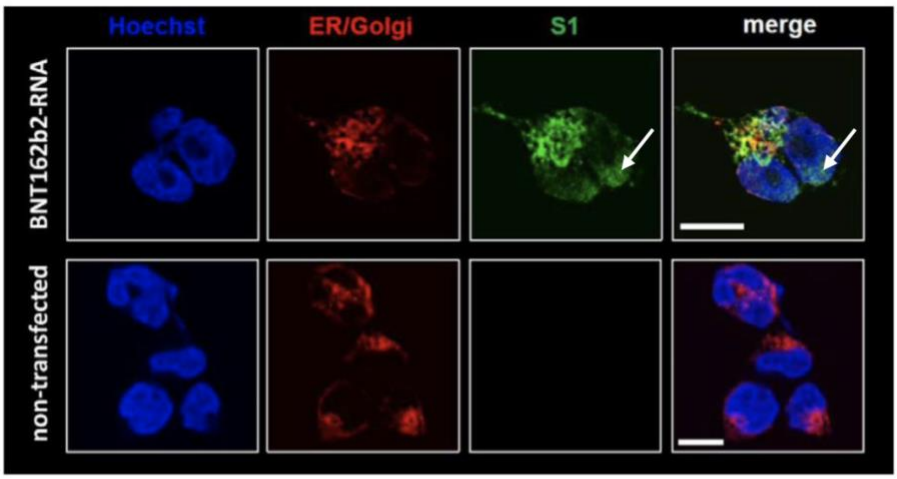
39. 

Figure 3. Taken from page 35 of the TGA Nonclinical Evaluation Report. The top four panels show staining in HEK293 cells that were treated with the BNT162b2 mRNA: Hoechst shows the location of the nucleus within the HEK293 cells (shown in blue), the ER/Golgi compartments (shown in red) are where the mRNA is used to produce the Spike protein and process it on the way to the cell membrane. The green staining shows the location of the Spike protein (S1). Note the addition of the white arrow pointing to Spike protein localised to the nucleus. This is best demonstrated in the final (merge) panel where the "green" overlaps with the "blue".

In response to the correspondence sent by law firm Maat's Method alerting the OGTR to the fact the modRNA and synthetic Spike protein induced/created by the modRNA subsequently enters the nucleus of human cells, the OGTR's response was simply:

> *For your information OGTR has never regulated those vaccines, or been required to. Accordingly the GTTAC has never considered or advised OGTR with respect to them.*

40. The above statement fails to address the ***mode of action*** evidence provided by Maat's Method to the OGTR, which was further detailed and reiterated by our office to the OGTR in 4 July 2023 correspondence which the OGTR has failed to reply to.

41. The above statement from the OGTR is untenable and ignores the four decades of science concerning ***reverse-transcription***, which science has been re-examined in the laboratory in respect of the modRNA products of Pfizer and Moderna, and has unsurprisingly been shown to be equally applicable to the modRNA products of Pfizer and Moderna, which findings this office (and the law firm Maat's Method) has provided to the OGTR (and TGA) showing specifically the LNP-modRNA complexes are involved in:

a. ***Nuclear localisation*** - entry into the nucleus of both SARS-CoV-2 spike mRNA and the viral Spike protein created by that mRNA, representing evidence the synthetic modRNA (and synthetic Spike it creates) contained in the products of Pfizer and Moderna could mimic the same *mode of action*, which was ***confirmed by Pfizer*** in FOI 2389-6: Sattar et al 2022.

b. Once within the nucleus, the synthetic modRNA in the Pfizer product undergoes ***reverse-transcription*** with the possibility of incorporation into natural chromosomal DNA: Alden et al 2022.

c. The reverse-transcription is not only potentially resulting in ***genomic integration*** of the synthetic modRNA (the modRNA is being integrated into natural chromosomal DNA), as evidenced by the Alden paper, but there is additional evidence of ***heritable altered immune traits*** induced by the modRNA in injected subjects, ***being inherited by offspring*** (3rd and 4th generation offspring are also displaying the same altered immune traits seen in the original recipients): Qin et al 2022.

42. The above papers by Sattar *et al*, Alden *et al*, and Qin *et al* together with the ***nuclear localisation*** information supplied by Pfizer to the TGA, render utterly baseless the assertion these products 'never enter the nucleus'. To publicly maintain this assertion amounts to intentionally misleading the public.

43. From the above statement from the OGTR which we can assume to be the position of the Gene Technology Regulator (**GTR**), Dr Raj Bhula, we can infer the GTR never sought advice from the Gene Technology Technical Advisory Committee (GTTAC), on whether or not the Pfizer and Moderna products satisfied the Australian legal definitions for being properly deemed GMOs. Instead we are only left with Dr Bhula's assessment of whether these products fulfilled the legal definitions, which assessment Dr Bhula provided to the Community Affairs Legislation Committee hearing on 16 February 2023 (see page 93), where she stated (see video from 1:28 min/sec):

> *'The mRNA Covid-19 vaccines did not involve any step of genetic modification.'*

44. This statement is patently wrong and evidences the incorrect basis upon which the GTR deemed any detailed assessment by the body charged to advise her, the GTTAC, unnecessary.

45. As a consequence the 14 member GTTAC has been denied the opportunity to inform the GTR that her statement above (re *genetic modifications*) is wrong and entirely at odds with the scientific literature, and statements made by Pfizer ('Our COVID-19 vaccine (BNT162b2) is a ***nucleoside-modified*** mRNA formulated in lipid nanoparticles') and Moderna ('our platform employs ***chemically-modified*** uridine nucleotides') filed with the US Securities and Exchange Commission (SEC).

46. Further, and the TGA documents granting provisional approval to the Pfizer and Moderna products specifically recognise the products contain modified nucleosides.

Pfizer AusPAR at page 9:

> *'The Pfizer-BioNTech COVID-19 vaccine, BNT162b2 mRNA (tradename Comirnaty), comprises a **nucleoside-modified** messenger RNA (modRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2. The RNA is encapsulated in lipid nanoparticles (LNPs), which enables entry into host cells'*

Moderna AusPAR at page 16:

> *'The Spikevax COVID-19 mRNA-1273 vaccine contains a **nucleoside-modified** mRNA encoding the viral S protein of SARS-CoV-2 formulated in lipid particles. It forms an **mRNA-lipid complex** (lipid nanoparticle, LNP)'*

47. Nucleosides are the structural subunits of genes. Pfizer and Moderna took the genetic blueprint of the SARS-CoV-2 virus, isolated the mRNA portion of the virus that produces Spike protein, then using gene technology, modified the nucleosides of the natural mRNA for creating *en mass* synthetic modified RNA/modRNA, which modRNA has been genetically modified as compared to the natural viral mRNA.

48. For a comprehensive understanding of the ***gene technology modifications*** both Pfizer and Moderna undertook for the creation and production of their Covid-19 products, please see the Expert Witness report by Dr Angela Jeanes (Annexure 1): in

particular, see paragraphs 1-3 of the *Opening Statement* at PDF page 28 of this Brief (or page 5 of Dr Jeanes' report), and the responses to Questions 1 and 2 by Dr Jeanes at PDF page 35 of this Brief (or from page 12 of Dr Jeanes' report).

49. By the GTR taking this entirely incorrect position which ***speaks against*** the gene technology part for the legal definition of what constitutes a GMO detailed above, the GTR shut down any proper consideration by the 14 member GTTAC which would have advised Dr Bhula of her fundamentally mistaken position in fact and law.

50. Moreover, Dr Bhula by her own admission never sought the advices of the GTTAC on this critical issue of *gene technology*. By so remaining uninformed and able to maintain this patently incorrect view of the science, facts, and law, the GTR has been able to erroneously assert the Pfizer and Moderna products never required regulation by the OGTR.

51. By the OGTR continuing to maintain this patently false position we are bearing witness to a complete failure by that department and the OGTR to regulate and protect the Australian community from the Pfizer and Moderna Covid-19 products, which are in fact, GMOs. This failure we assert has had and will continue to have, fatal consequences, and vast and unimaginable adverse health outcomes and effects for generations of Australians now and to come.

52. However, and despite the inexplicable view held by the GTR, both Pfizer and Moderna have consistently stated in public filings their products do involve genetic modifications, thereby admitting their products satisfy the gene technology part of the legal definition for being deemed GMOs in Australia. The TGA AusPAR documents further confirm the point.

53. As a consequence of this ***knowledge***, and irrespective of the view of the GTR, Pfizer and Moderna always remained bound to apply for GMO licences under section 40 of the GT Act.

54. Though an application under section 40 appears discretionary with 'A person ***may*** apply to the Regulator for a licence', the serious criminal offences of dealing with a GMO without a licence set forth under sections 32 and 33 make application for a section 40 licence positively obligatory, for those seeking to deal with GMOs in Australia.

55. Lastly, and we can also see in Pfizer's own data submitted to the TGA, that Pfizer possessed ***knowledge*** in 2020 of their product entering the nucleus of cells, being the very mode of action that made it incumbent upon AstraZeneca to seek a GMO licence from the OGTR.

Synthetic DNA contamination

56. Compounding the above is the recent unexpected/unintended/surprising discovery by genomics expert Kevin McKernan of dangerously excessive DNA cell-substrate contamination. This discovery has now been independently verified by other internationally recognised laboratories using different vials, evidencing gross, pre-existing, and continuing global supply contamination by Pfizer and Moderna in their Covid-19 products.

57. The synthetic DNA (modDNA) contamination is anywhere between 18-70 times over the European Medical Agency (**EMA**) limit (EMA documentation on 330ng/1 mg DNA/RNA limit. Page 74), where the TGA sets the upper limit to no more than 10ng (nanograms) per injection of any therapeutic substance. In some instances up to 35% of the volume contained in a single Covid-19 dose constitutes this synthetic DNA contamination. By way of example, one Pfizer Covid-19 dose contains 30 ug (micrograms). A dose containing up to 35% synthetic DNA contamination represents 10.5 ug synthetic DNA, which converted to nanograms amounts to 10,500 ng of synthetic DNA received per dose - 1,050 times above the limit set by Australia's TGA.

58. However, this contamination is much worse than contemplated by outdated regulations as the modDNA is also encapsulated (wrapped) in LNPs, which LNPs ensure bio-distribution of the modDNA throughout the human body and ensures transfection (entry) of the modDNA into cells of all major organ types including the brain, heart, ovaries, testes, liver, spleen, eyes, with as yet unknown effects/risks of transfection/exposure for unborn children.

59. Naked DNA whether synthetic or exogenous by itself is quickly 'mopped up' and eliminated when detected in the bloodstream and has no intrinsic ability to transfect or enter human cells (cross through the cell membrane). However, synthetic DNA encapsulated in LNPs avoids detection in the bloodstream, where the LNP is specifically designed to transport the DNA across the cell membrane for entry (transfection) into all types of human cells.

60. For the purposes of the *Gene Technology Act* this excessive contamination also fulfills the legal definitions for being correctly deemed ***Genetically Modified Organisms***, and perhaps the worst type of GMO, as genomic integration by the modDNA with natural chromosomal DNA ***does not require reverse-transcription***, and some of this modDNA (by Pfizer) has the opportunity of becoming ***replication competent*** (self-replicating) in certain persons known to be infected with SV40 related viruses (in some populations up to 20% of persons).

61. Perversely, and as a strict matter of law, both Pfizer and Moderna were/are required to possess GMO Licenses to *deal* with this LNP-modDNA contamination in Australia; though any organisation responsible for such licensure (again the OGTR here) would never allow any product into their country that contains this form of GMO contamination. This form of GMO contamination alters the course of humanity, and what it means to be human.

62. The Expert Report of Dr Angela Jeanes (Annexure 1) specifically addresses the known threats, dangers (innumerable adverse health outcomes) and likely genomic integration - ***transgenic alterations to the human genome*** – associated with this modified DNA contamination: specifically see Opening Statement paragraphs 4-7 of PDF page 29 of this Brief (or page 6 of Dr Jeanes' report), and the reply by Dr Jeanes to Question 15 from PDF page 56 (or from page 33 of Dr Jeanes' report).

63. To be clear, issues of contamination have always been the responsibility of the TGA to independently test for, or at the very least to confirm independent testing in relation to, for contamination by a recognised drugs regulator overseas prior to the same batches of a product shipping to Australia. This independent testing by the TGA is in addition to the obligations imposed upon manufacturers to also test for contamination. What has usually been termed ***DNA cell-substrate*** contamination typically arises from a failure in one or more steps of manufacturing process, where the natural or synthetic DNA used to produce the final product has not been properly filtered out of the final product. The known adverse and potentially fatal consequences from DNA contamination has a long history in the scientific literature and is common knowledge amongst global drug regulators. In this instance of synthetic DNA contamination in the Pfizer and Moderna products, specific analysis of known, potential, and likely adverse outcomes is conveniently summarised in Schedule 2 of the *Letters of Demand* presented to each of Pfizer, Moderna, the TGA, and OGTR on 4 July 2023. Neither the TGA nor the OGTR have responded to those

Letters of Demand despite the serious findings they detail and the dangers to the Australian population they entail.

64. Historically, the TGA has notably shown the utmost concern towards ***DNA cell-substrate*** contamination, with drug approvals whose manufacturing involves the use of DNA being an area of discrete and independent testing by the TGA to confirm the absence of DNA cell-substrate contamination, or contamination at or below the regulatory limits. However, with the arrival of the Covid-19 products of Pfizer and Moderna, the TGA suddenly and inexplicably ceased to perform independent testing for any synthetic DNA contamination, despite unequivocal knowledge in the TGA of synthetic DNA being used in critical steps of the production process for creating the modRNA.

65. Testing for DNA contamination takes 1 hour or less, and costs less than $10 for a fully resourced laboratory.

66. Despite the apparent failings of the TGA in this regard, the more pressing and consequential information is the fact of this synthetic DNA contamination also being a GMO, and as previously stated, a more lethal form of GMO due to the intrinsic ease with which it associates/interacts with human DNA, and its functional ability to readily dysregulate or silence normal chromosomal functioning, which necessarily results in a range of adverse outcomes (genetic disorders) and disease, including cancers and tumours, depending on the nature of the dysregulation or silencing. Those outcomes are dealt with extensively in the Expert Report of Dr Angela Jeanes.

67. For present purposes, and in light of the silence from the TGA and OGTR, the presence of this synthetic DNA contamination is actionable against the manufacturers both at civil and criminal law, by both your office and suitably aggrieved applicants.

68. We trust and pray the Australian Federal Police will see it as fit and proper and necessary to proceed against Pfizer and Moderna using the criminal law powers and resources afforded your office, for the protection of the Australian public and future generations hopefully still to come.

The Decision to Prosecute

69. Turning now to the Prosecution Policy of the Commonwealth:

Is there evidence sufficient to justify the institution of a prosecution?

Yes.

What are the prospects of conviction like?

Strong.

Are there grounds for believing the evidence might be excluded?

No.

Does the public interest require a prosecution to be pursued?

Yes.

These are serious criminal offences now involving the contamination with GMOs of a majority of the Australian population, without their consent, or informed consent being provided by recipients.

The offences are aggravated in so far that the defendants can be shown to have knowledge their products contained GMOs. As per Section 38 of the GT Act, the contamination referenced above is likely to cause significant damage to the health and safety of people, and the failure to seek a license was (at the very least) reckless.

The prevalence of the alleged offences quite probably affects a majority of the Australian population, for which there is a need for deterrence.

The consequences of any resulting conviction would not be unduly harsh and oppressive, as the defendants are public companies.

The alleged offences are of considerable and historic public concern and importance.

The attitude of Australian victims of the alleged offences to a prosecution should be assumed in favour of prosecution, in so far that Australian recipients were not informed, nor did they provide, nor could they provide, informed consent to receiving the subject GMOs they were never made aware of.

The actual or potential harm, occasioned to each individual recipient is acknowledged in the scientific literature, and still to be properly quantified. Indeed, never before have so many been contaminated to this extent,

requiring therefore national observation and medical and scientific investigations for accurately reporting on the actual, expected, and possible detriments to recipients.

The likely length of a trial will be of short to medium duration, and be of relatively low expense due to the small number of witnesses, and limited scope of disclosure involved. Indeed once the synthetic DNA contamination is again confirmed to the satisfaction of the Commonwealth through further testing, the offenders will be motivated to submit to the mercy of the Commonwealth.

Given the near complete population wide impacts brought about by the conduct of the defendants, and the perception of vicarious involvement or negligence or misfeasance on the part of Commonwealth agencies specifically legislated to guard against such conduct, there arises the necessity to maintain public confidence in the rule of law and the administration of justice through the institutions of democratic governance including the Parliament and especially the Courts for bringing the offenders to justice.

In light of the millions of Australians affected by the conduct of the defendants, and the as yet unquantified effects on their health, lives, genomic integrity, and abilities to produce offspring without complications or ramifications, there is a need to give effect to regulatory or punitive imperatives provided for under the *Gene Technology Act 2000*, as the stated will of the Parliament and the people of Australia.

The *Gene Technology Act 2000* does not provide an enforcement mechanism which is an alternative to prosecution.

70. The above prosecution criteria and answers are not exhaustive.

71. In this matter the ramifications flowing from the offences alleged also reach into being clear and fundamental violations of the human rights of all Australian recipients of these Covid-19 products, as articulated in the following treaties and conventions of the Commonwealth of Australia, on behalf of all Australians, is not only a party to, but bound and obligated to uphold and advance for the protection and welfare of Australians.

72. We say these protections have been seriously and grossly violated; and the welfare, health, and prospects of millions of Australians has been utterly disregarded if not destroyed, in the pursuit of profits by the alleged offenders, which violations speak to the aggravated nature of the conduct involved (see Section 38), requiring the utmost attention and intention by the Australian Federal Police to prosecute these offenders.

73. The violations and disregard of enshrined human rights include:

From the *International Covenant on Civil and Political Rights (**ICCPR**)* (emphasis added):

> *Part III, Article 7*
>
> Article 7 states as follows:
>
> > No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. **In particular, no one shall be subjected without his free consent to medical or scientific experimentation.**

74. The term ***scientific experimentation*** is emphasised here as each of the Pfizer and Moderna Covid-19 products are still the subject of ongoing Phase 3 clinical trials, being clinical trials normally undertaken and completed prior to any therapeutic being considered for approval by the TGA. In the instance of these products the TGA utilised the 'provisional approval' pathway that allowed the products to be made available before all safety data could be known. To this end the statement by former Health Minister Greg Hunt is correct when he said (see video here): "The world is engaged in the largest clinical trial, the largest global vaccination trial ever". Clinical trials for drugs are by definition scientific experiments.

75. From the *Universal Declaration on Bioethics and Human Rights* (**UDBHR**):

Article 4

Benefit and harm

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, **research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.**

Article 6

Consent

1. **Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information**. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

2. **Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned.** The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.

3. **In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or**

the consent of a community leader or other authority substitute for an individual's informed consent.

76. It must be noted here that the following three articles have particular relevance:

Article 16

Protecting future generations

The impact of life sciences on future generations, including on their genetic constitution, should be given due regard. **Article 18**

Decision-making and addressing bioethical issues

1. Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular declarations of all conflicts of interest and appropriate sharing of knowledge. Every endeavour should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues.

2. Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.

3. Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted.

Article 20

Risk assessment and management

Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

77. It should be emphasised that these are rights, in most cases ***non-derogable***, covenanted into by the Australian Government for the express purpose of protecting the citizens of Australia; for protecting their human right not to be experimented upon without their knowledge, particularly with contaminates with lethal consequences; for

protecting their human right to optimal health; for protecting their human right to retain their natural genetic integrity, and that of their offspring. This is a case where demonstrable criminal activity (via the offences in the GT Act pleaded above) has resulted in an unprecedented and irreversible breach of those rights. The Australian public is entitled to a prompt prosecution of those crimes, which in turn will demonstrate to that public that those rights do in fact mean something.

78. As an aside, it is worth noting that, on a domestic level, the Australian courts have a long and noble tradition of protecting and advocating for the doctrine of informed consent. The following cases are exemplary:

From *Wallace v Kam [2013] HCA 19*:

> The common law duty of a medical practitioner to a patient is a single comprehensive duty to exercise reasonable care and skill in the provision of professional advice and treatment […] The component of the duty of a medical practitioner that ordinarily requires the medical practitioner to inform the patient of material risks of physical injury inherent in a proposed treatment is founded on the underlying common law right of the patient to choose whether or not to undergo a proposed treatment.

From *Hunter and New England Area Health Service v A by his Tutor [2009] NSWSC 761*:

> Whenever there is a conflict between a capable adults' exercise of the right of self-determination and state's interest in preserving life – the right of the individual must prevail.

Hunter and New England citing with approval the Canadian case *Malette v Shulman (1990) 67 DLR (4th) 321*:

> [a] competent adult is generally entitled to reject a specific treatment or all treatment, or to select an alternative form of treatment, even if the decision may entail risks as serious as death and may appear mistaken in the eyes of the medical profession or of the community…it is the patient who has the final say on whether to undergo the treatment.

A Final Observation

We say so graven have and continue to be the actions of Pfizer and Moderna, particularly in respect of the synthetic DNA contamination, primarily involving one or more flawed steps in the manufacturing process, ***which flaws were always easily detectable*** as soon as those processes were brought on line in 2020, that in the event knowledge of the synthetic DNA contamination can be shown in Pfizer and Moderna in 2020, or ***should have been known*** to each company by simply following established *Good Manufacturing Practices*, then such knowledge or imputed knowledge should serve as a sufficient basis for the Commonwealth to rescind all indemnities subsequently afforded to the companies in respect of the Covid-19 products, when the contamination issue was always able to be ***easily*** detected and ***easily*** eliminated by each of Pfizer and Moderna, in circumstances where leaving the contamination in their products would lead to foreseeable injuries, deaths, and adverse consequences for the offspring of recipients of their products.

This office stands ready to discuss the science and many details contained in this extensive brief of information.

Kind regards

Katie Ashby-Koppens
Lawyer
PJ O'Brien & Associates
katie@pjob.com
04 7256 7477

Together with:

Peter Fam, Principal Lawyer, Maat's Method

Julian Gillespie LLB, BJuris