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

3 December 2023

Via Email

[redacted]@cdpp.gov.au

Attention: Ms Raelene Sharp KC,
Director of Public Prosecutions

Dear Ms Sharp KC

BRIEF OF INFORMATION & EVIDENCE

Alleged Offence: Dealing with genetically modified organisms (GMOs) without a license – serious criminal offence

Defendants: Pfizer Australia Pty Ltd and Moderna Australia Pty Ltd

Pfizer and Moderna's Covid-19 mRNA products are or contain GMOs

No AFP investigation required

MATTERS TO BE REFERRED TO THE DIRECTOR

With respect to CDPP policy document

Matters to be referred to the Director

This brief satisfies Item 2: **Politically Sensitive Matters**
Requiring the Director to be informed

and

Satisfies Item 3: **Significant Cases**

Namely parts

(ii) the matter breaks new ground by being the first case brought under unusual legislative provisions;

(iv) the matter will have an impact on relations with other agencies;

(v) the matter involves high profile defendants and many probable victims;
the matter is politically sensitive
because of the identity of the defendants and the subject matter; the matter has already begun to attract close attention from local and foreign press, the Government and/or Parliament, including overseas members of foreign parliaments;

The matter falls within the following categories and must be marked as a “significant matter” in CRIMS:

• matters where there is significant media interest in the matter

• matters that are significant because of political interest or potential interest in the matter

Prosecution Policy of the Commonwealth considerations at [33].

Contents

We act for Dr Julian Fidge.

Concise Statement

I) On 26 October 2023 the Gene Technology Regulator for Australia confirmed before a Senate Estimates hearing the Covid-19 products of Pfizer and Moderna are GMOs.

II) The fact an investigation was briefly undertaken then terminated by the Australian Federal Police into the above allegations is no longer relevant.

III) In light of the admission by the Gene Technology Regulator no further investigation is required by the Commonwealth Director of Public Prosecutions for initiating proceedings under section 32 and section 33 of the Gene Technology Act 2000.

IV) The admission by the Gene Technology Regulator requires both Pfizer and Moderna to answer serious criminal charges as to whether they knowingly dealt with GMOs in Australia pursuant to section 32 and section 33 of the Gene Technology Act 2000.

Timeline of Information

V) On 16 August 2023, our office contacted Mr Matt Sinnett of your office to discuss the best manner for presenting an earlier version of this brief to the DPP.

VI) Mr Sinnett advised to first make complaint to the Australian Federal Police (AFP) so the AFP could commence a formal investigation.

VII) Following Mr Sinnett's advice we submitted the earlier version of the brief to the AFP on 29 August 2023.

VIII) On 27 September 2023, Senator Gerard Rennick presented the Attorney-General the earlier version of the brief, requesting Mr Dreyfus ensure the brief come to the attention of the AFP Commissioner Mr Reece Kershaw.

IX) On 12 October 2023, Detective Acting Sgt Folkes of the AFP emailed our office to inform us the AFP was rejecting the matter, and no further investigation would be undertaken, without speaking to the many probative evidential matters the earlier version of the brief contained.

X) On 13 November 2023 Senator Gerard Rennick presented to the Attorney-General an update to the earlier version of the brief, which update and letter from Senator Rennick highlighted three developments:

A. Further international evidence confirming the Covid-19 vaccines of Pfizer and Moderna contain grossly excessive synthetic DNA contamination; and

B. The inexplicable termination of the investigation by the AFP of the earlier version of the brief; and

C. The admission by Australia's Gene Technology Regulator on 26 October 2023 to a Senate Estimates committee that the Covid-19 vaccines of Pfizer and Moderna are or contain Genetically Modified Organisms, or GMOs.

XI) To date Senator Rennick has received no acknowledgment, reply, nor response to his 27 September or 13 November 2023 correspondence with the Attorney-General.

Preface

XII) 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.

XIII) 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 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 repeated exposure/s to these products would result in.

Instructions

1. Director Of _pn I A, 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, to institute the proceedings described in the Concise Statement and Preface.

2. Director Of _pn I A, 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 are in uncharted waters, a fact all readers of this information must reconcile themselves with.

5. Separately, and on behalf of Dr Fidge, this office 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

1. A concise summary follows.

Defining GMOs

2. 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.

3. On 26 October 2023 the Gene Technology Regulator, Dr Raj Bhula, gave evidence to the Senate Community Affairs Legislation Committee (page 127), where Dr Bhula stated:

> 'If, indeed, the mRNA was being manufactured here—and it's correct that gene technology was used in the modification of the mRNA—then, under the Gene Technology Act, an approval would have been required for that manufacturing step.'

4. In respect of - **'an approval would have been required'** - under the Gene Technology Act 2000 there is only one type of approval Dr Bhula is speaking about, namely, the approval of a GMO license.

5. The Gene Technology Act and the Office of the Gene Technology Regulator (OGTR) regulate and approve only one thing: GMOs. As a consequence, the answer provided by Dr Bhula on 26 October 2023 is an implicit admission that Dr Bhula and the OGTR have always understood and deemed the Covid-19 products of Pfizer and Moderna to be GMOs.

6. In the 26 October 2023 hearing Dr Bhula asserted that as the Pfizer and Moderna Covid-19 products are manufactured overseas the OGTR had no jurisdiction to regulate the products as GMOs in Australia: see video of testimony.

7. This assertion by Dr Bhula directly contradicts April 2022 Senate hearing testimony from Dr Bhula confirming the OGTR is responsible for granting authorisations for the import, storage, transport and disposal of GMOs manufactured overseas: see video of testimony. By 'authorisation' Dr Bhula is again speaking of the possible grant of

GMO licenses in respect of these activities, which activities are described as ‘dealings’ under the Gene Technology Act 2000, where any one or more dealing requires submission of an application for a GMO licence under section 40, followed by an extensive risk assessment and risk management plan performed by the OGTR (section 50), requiring public consultation (section 52) for determining whether a GMO license can be granted, and if so, regulating the dealings in question. The dealings under the Act are set forth under section 10:

> *"**deal with**", in relation to a GMO, means the following:*
>
> *(a) conduct experiments with the GMO;*
>
> *(b) make, develop, produce or manufacture the GMO;*
>
> *(c) breed the GMO;*
>
> *(d) propagate the GMO;*
>
> *(e) use the GMO in the course of manufacture of a thing that is not the GMO;*
>
> *(f) grow, raise or culture the GMO;*
>
> *(g) import the GMO;*
>
> *(h) transport the GMO;*
>
> *(i) dispose of the GMO;*
>
> *and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (i).*

8. As a consequence of the clear statutory duties set forth under the Gene Technology Act 2000 the testimony from Dr Bhula in respect of the authority of the OGTR to regulate the Pfizer and Moderna Covid-19 products was false. Regardless of the motivations for this testimony at odds with previous testimony, and the long established practices of the OGTR, (by way of example, see grant of GMO licence DIR 193 which was in respect of transport, storage, and disposal only), there always remained the legal obligation under section 40 of the Act for Pfizer and Moderna to

submit GMO applications, made compulsory by the serious criminal offences under section 32 and 33 for dealing with GMOs in Australia without a GMO licence.

9. **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 under the Gene Technology Act 2000 and also concludes the Covid-19 products of Pfizer and Moderna do satisfy Australian legal definitions for being properly deemed GMOs.

10. In particular, Dr Jeanes addresses the following issues:

    a) **The LNP-modRNA complexes in the products fulfill the Gene Technology Act definitions for being deemed GMOs**: see Questions 3 – 6 and answers at paragraphs 23 – 27, at pages 25 – 27 of Dr Jeanes' report.

    b) **The LNP-modDNA complexes (contaminate) in the products fulfill the Gene Technology Act definitions for being deemed GMOs**: see Questions 8 – 13 and answers at paragraphs 30 – 39, at pages 28 – 32 of Dr Jeanes' report.

    c) **How modRNA integrates into the human genome**: see paragraphs 18 – 20 at pages 28 – 32 of Dr Jeanes' report.

    d) **The threats and harms created by modRNA and modDNA to humans**: see question 15 and answers at paragraphs 43 – 85, at pages 33 – 54 of Dr Jeanes' report.

11. In light of the 26 October 2023 admission by Dr Bhula and the ease with which Dr Jeanes was able to confirm the Covid-19 products of Pfizer and Moderna 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. Further, and Pfizer has in our civil proceedings disclosed they attended a meeting with the OGTR in or about October of 2020 to discuss their Covid-19 products with the OGTR.

12. Section 32 of the Gene Technology Act 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.

13. Upon inquiry with the OGTR your office will confirm sub-subsections (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).

14. 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. Indeed the disclosed meeting between the OGTR and Pfizer mentioned in paragraph 11 will assist in this regard. Alternatively, 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.

15. Additionally, both Pfizer and Moderna have publicly stated their Covid-19 products involve steps in genetic modification in filings with the US Securities and Exchange Commission (SEC):

> Pfizer: 'Our COVID-19 vaccine (BNT162b2) is a ***nucleoside-modified*** mRNA formulated in lipid nanoparticles'; and
> Moderna: 'our platform employs ***chemically-modified*** uridine nucleotides'.

16. Though an application for a GMO licence under section 40 of the Gene Technology Act 2000 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.

Synthetic DNA contamination

17. Compounding the above is the 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:

a) Dr Sin Lee of Connecticut, USA

b) Phillip Buckhaults, PhD, South Carolina, USA

c) Professor Brigette Konig, Germany

d) Dr David Speicher, of Ontario, Canada

18. **Dr. Sin Lee**, MD, F.R.C.P.(C), FCAP of Milford Molecular Diagnostics designed his own BNT162b2 amplicons targeting longer molecules for PCR and Sanger sequencing. This is an important evaluation and confirms the primers Mr McKernan designed for qPCR detection of the DNA contaminate are appropriate.

19. **Phillip Buckhaults PhD**, Professor and Director of the Cancer Genetics Lab at University of South Carolina. Dr Buckhaults' work led to him giving evidence on 11 September 2023 to the South Carolina Senate to describe his serious concerns about the DNA contamination. Professor Buckhaults stated during his testimony:

> *'During the process they chopped them [the DNA plasmids] up to try to make them go away but they actually increased the hazard of genome modification'*

20. This testimony by Dr Buckhaults suggests that Pfizer and Moderna both know and knew that the synthetic DNA which is a laboratory tool used in the manufacturing process of these Products, should never be in the Products, and undertook preliminary steps for its removal. Cursory research will evidence it has long been understood throughout the pharmaceutical manufacturing industry, that synthetic DNA used in production must be completely filtered out due to the known risks and harm to human health including cancer and death.

21. In response to Dr Buckhaults' testimony, the Associate Dean of Medicine and Director of the Cancer Centre at Brown University, Dr Wafik El-Deiry tweeted, stating, Professor Buckhaults:

> *'...explains how pieces of naked DNA allowed in protein vaccines at a certain threshold was not so problematic in a different era but that with encapsulation in liposomes they can now easily get into cells. If they get into cells they can integrate in the genome which is permanent, heritable and has a theoretical risk of causing cancer depending on where in the genome they integrate'*

22. **Professor Brigitte Konig,** of Germany, has confirmed the same DNA contamination and was then interviewed on 28 September 2023 (in German, which can be translated using Google translate). The results are between 83 and 284 times over the limit of 10ng per dose.

23. This testing was ordered by Dr Kirchner and he presented the findings to the Bundestag on 18 September 2023. A German version of the report prepared by Professor Konig can be viewed within the correspondence sent by Dr Kirchner to the German Health Minister, Professor Lauterbach, dated 16 September 2023. A translated version of the report by Professor Konig has been made available with Google translate, with the correction that the second table should state 'yes' under plasmids and not 'And'.

24. **Dr David Speicher,** of Ontario, Canada, recently tested 27 vials of the Pfizer and Moderna Products and identified using fluorometry, all vaccines exceed the guidelines for residual DNA set by FDA and WHO of 10 ng/dose by 188 – 509-fold. Australia follows the same guidelines.

25. Further, and this office has been reliably informed by concerned scientists in Japan that vials of the Pfizer product tested there also evidence this excessive DNA contamination, inclusive of the SV40 *promoter* and *enhancer* genetic sequences for gaining entry into the nucleus of human cells. These Japanese vials have been securely shipped to Kevin McKernan to undergo Fluorometry analysis to confirm the extent of the contamination above regulatory limits, with results expected soon.

26. This office is presently organising for Australian vials to be tested in Australian labs for confirming the same synthetic DNA contamination and residual endotoxins. Pfizer and Moderna Covid-19 products originate from just a few manufacturing sites that ship to America, Germany, Canada, Japan, and Australia.

27. 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: see Opening Statement, and paragraphs 4 - 7 at page 6 of Dr Jeanes' report, and reply to Question 15 at page 33 of Dr Jeanes' report.

28. On 9 October 2023, an Urgent Expert Hearing on Reports of DNA Contamination in mRNA Vaccines by the World Council for Health was convened to discuss the issues associated with the DNA contamination that was identified.

29. 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 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 articulated.

30. Historically the TGA has shown the utmost concern towards ***DNA cell-substrate*** contamination, with drug approvals involving the use of synthetic DNA in manufacturing 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 Covid-19 modRNA drugs.

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

32. 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 interacts and/or integrates with human DNA, and its functional ability to readily dysregulate or silence normal chromosomal functioning, resulting 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.

33. Turning now to the Prosecution Policy of the Commonwealth.

The Decision to Prosecute

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 Gene Technology Act, the contamination referenced above is likely to cause (or has

caused) 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.

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

35. In addition to the prosecution criteria 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. Those violations are detailed in **Annexure 2**.

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 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 recipients and 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 3579 1200

Together with:

Peter Fam, Principal Lawyer, Maat's Method

Julian Gillespie LLB, BJuris

Form 59
Rule 29.02(1)

Affidavit

No. of 20

Federal Court of Australia

District Registry: Victoria

Division: Commercial and Corporations NDA

Sub-area: Regulator and Consumer Protection

Dr Julian Fidge

Applicant

Pfizer Australia Pty Limited

First Respondent

Moderna Australia Pty Limited

First Respondent

Affidavit of: **Dr Angela Jeanes**

Address: [redacted]

Occupation: Scientist

Date: 6 July 2023

Contents

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Document number	Details	Paragraph	Page
4	Annexure "AJ-3" Letter from PJ O'Briens & Associates dated 3 May 2023	5	63

I **Dr Angela Jeanes**, scientist affirm:

1. I am a scientist specialising in the molecular, cellular and environmental aspects of health and disease, specifically relating to embryonic development. I received my PhD in the area of Molecular and Cellular Biology, relating to cancer biology. My expertise is in this area.

2. A copy of my report is annexed hereto marked **"AJ-1"**.

3. I confirm as a part of this report that I have read, understand and agree to comply with the Expert Evidence Practice Note.

4. A copy of my curriculum vitae is annexed hereto marked **"AJ-2"**.

5. A copy of the letter from PJ O'Brien & Associates outlining the questions posed to me is annexed hereto marked **"AJ-3"**.

Affirmed by the deponent)
[redacted])
[redacted])
on 6 July 2023)
Before me:)

Dr Angela Jeanes

Signature of witness

CL Ashby-Koppens
185 Corlette Street, The Junction, NSW 2291
An Australian legal practitioner within the meaning
of the Legal Profession Uniform Law (NSW)

Pursuant to s14G(2)(d) of the *Electronic Transactions Act 2000*, this affidavit was affirmed remotely by way of audio-visual link.

No. of 20

Federal Court of Australia

District Registry: Victoria

Division: Commercial and Corporations NDA

Sub-area: Regulator and Consumer Protection

Dr Julian Fidge

Applicant

Pfizer Australia Pty Limited

First Respondent

Moderna Australia Pty Limited

First Respondent

This is the annexure marked **"AJ-1"** referred to in the affidavit of Dr Angela Jeanes affirmed before me on 6 July 2023 at [redacted]

Signature of witness:

CL Ashby-Koppens
185 Corlette Street, The Junction, NSW 2291
An Australian legal practitioner within the meaning
of the Legal Profession Uniform Law (NSW)

“AJ-1”

Expert Report by Dr Angela Jeanes BSc(Hons), PhD

Expert Report by Dr Angela Jeanes BSc(Hons), PhD

1. My name is Angela Jeanes. I am a scientist specialising in the molecular, cellular and environmental aspects of health and disease, specifically relating to embryonic development. I received my PhD in the area of Molecular and Cellular Biology, relating to cancer biology. My expertise is in this area.

Opening Statement (Provided)

1. Covid-19 vaccine manufacturers Pfizer and Moderna have taken the SARS-CoV-2 virus and analysed its genomic code (made of RNA, which is Ribonucleic Acid (RNA). A primary role of RNA is to convert the information stored in human DNA into proteins).

2. Once understanding the elemental construction for that genomic code, they identified that portion of the genomic code required for the production of the Spike protein part of the SARS-CoV-2 virus, and then separately they used techniques to produce from scratch, a *modified version* of that isolated genome sequence that encodes for the Spike protein, to produce the modRNA (nucleoside-modified messenger RNA) that is subsequently encapsulated in Lipid Nanoparticles (LNP) found in vials of Pfizer and Moderna Covid-19 vaccines. The virus that causes Covid-19 (called SARS-CoV-2) has spikes of protein on each viral particle. These "spike proteins" allow the virus to attach to cells and cause disease. The modRNA can be understood as the 'LNP-modRNA complex' contained in each vial of the Pfizer and Moderna Covid-19 vaccines.

3. The modifications from the natural genome sequence involved first isolating that part of the SARS-CoV-2 genome which codes for the Spike protein. Upon mapping and understanding that section of the genome, the manufacturers then reproduced in the laboratory the same section of the genome that translates to the Spike protein of the virus, but instead made the following modifications from the natural version, being:

   (i) Pseudouridylation – being, the replacement of existing uracil nucleotides within the genomic sequence with N1-Methylpseudouridine for the purpose of stabilising the modRNA against degradation;

   (ii) Codon Optimisation – being, the exchange of the nucleotides from the original natural mRNA sequence for alternate coding nucleotides which in theory does

not change the protein sequence, where in this instance, by the inclusion of G-C nucleotides led to an increase in the amount of the protein product translated, or produced, namely, the Spike protein;

(iii) 3'UTR modification using a novel 3'UTR specifically targeted to induce exaggerated induction of protein – being, the terminal end of the coding sequence of the modRNA is designed in such a way that its modification results in a far higher production of protein from the same modRNA sequence, than could ever be expected in the natural environment. In this instance the modification to the 3'UTR acts as a biological version of an adjuvant or stimulant.

4. Within a preprint paper dated 11 April 2023 titled ***Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose***[1], the study authors disclose the following findings:

> Several methods were deployed to assess the nucleic acid composition of four expired vials of the Moderna and Pfizer bivalent mRNA vaccines.
>
> Multiple assays support DNA contamination that exceeds the European Medicines Agency (EMA) 330ng/mg requirement and the FDAs 10ng/dose requirements.
>
> These data conclude that all Pfizer vectors contain a homoplastic 2 copy 72bp SV40 Enhancer associated with more robust expression and nuclear localization.
>
> Agilent Tape StationTM electrophoresis reveal 7.5 - 11.3 ng/µl of dsDNA compared to the 23.7 -55.9ng/µl of mRNA detected in each 300µl sample. QubitTM 3 fluorometry estimated 1-2.8ng/µl of DNA and 21.8ng - 52.8ng/µl of RNA. There is higher fragmentation seen in the DNA electrophoresis. The total RNA levels are less than the anticipated 30ug (100ng/µl) and 100ug (200ng/µl) doses suggesting a loss of yield in DNA and RNA isolation, manufacturing variance or RNA decay with expired lots.
>
> This work was further validated by testing 8 unopened Pfizer monovalent vaccines with both qPCR and RT-qPCR.
>
> Multiple methods highlight high levels of DNA contamination in the both the monovalent and bivalent vaccines.
>
> .. it is orders of magnitude higher than the EMAs limit of 330ng DNA/ 1mg RNA.

[1] McKernan, K., Helbert, Y., Kane, L. T., & McLaughlin, S. (2023, April 10). Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose. https://doi.org/10.31219/osf.io/b9t7m

dsDNA contamination of sequence encoding the spike protein wouldn't require LINE-1 for Reverse Transcription and the presence of an SV40 nuclear localization signal in Pfizer's vaccine vector would further increase the odds of integration.

This also brings into focus if these EMA limits took into consideration the nature of the DNA contaminants. Replication competent DNA should arguably have a more stringent limit. DNA with mammalian promoters or antibiotic resistance genes may also be of more concern than just random background E.coli genomic DNA from a plasmid preparation (Sheng-Fowler et al. 2009). Background E.coli DNA was measured with qPCR and had CT over 35.

While the sequencing delivered full coverage of the plasmid backbones, it is customary to assemble plasmids from DNase I fragmented libraries. These methods have not discerned the ratio of linear versus circular DNA in the vials. While plasmid DNA is more competent and stable, linear DNA may have higher genome integration risks.

5. Concerning the testing of 8 unopened Pfizer monovalent vaccines the lead author for the above preprint, Kevin McKernan, published his findings on 30 March 2023 in an article titled ***DNA contamination in 8 vials of Pfizer monovalent mRNA vaccines***[2], with results evidencing:

> 8/8 monovalent vaccines sourced from a single case from a single lot of Pfizer monovalent vaccines all fail the EMA specification of 3030:1 RNA:DNA (330ng/mg DNA/RNA). They are over the limit by an order of magnitude (18-70 fold). The DNA contamination is very consistent and the vial to vial ratio of RNA:DNA is very consistent within the same lot of monovalent vaccines.

6. The following indented section heavily summarises the recent paper by Palmer (MD) and Gilthorpe (PhD), ***COVID-19 mRNA vaccines contain excessive quantities of bacterial DNA: evidence and implications***, analysing the data returned by Kevin McKernan and presented in three articles[3] prior to publication of the preprint in paragraph 4 above:

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[2] McKernan, 30 March 2023: DNA contamination in 8 vials of Pfizer monovalent mRNA vaccines; see also McKernan,25 March 2023: DNA contamination in Pfizer monovalent vaccines.

[3] K. McKernan, 16 February 2023: *Deep sequencing of the Moderna and Pfizer bivalent vaccines identifies contamination of expression vectors designed for plasmid amplification in bacteria*;
K. McKernan, 9 March 2023: *Pfizer and Moderna bivalent vaccines contain 20-35expression vector and are transformation competent in E.coli*;

K. McKernan, 30 March 2023: *DNA contamination in 8 vials of Pfizer monovalent mRNA vaccines*.

Nucleic acids were extracted from the Pfizer and Moderna vaccine samples.

The nucleic acids were mixed with a suspension of E. coli cells that had been rendered competent for DNA uptake.

The E. coli were spread onto Petri dishes filled with solidified growth medium containing kanamycin.

Kanamycin will kill any E. coli cells that do not contain a resistance gene to it.

Observed growth of bacterial colonies on those Petri dishes confirmed acquired resistance to kanamycin by taking up and propagating plasmid DNA.

This was observed with both the Pfizer and the Moderna vaccine samples.

Only circular plasmid DNA molecules, but not linearized DNA, can be efficiently introduced into E. coli, evidencing therefore plasmid DNA had escaped the linearization step during manufacturing by Pfizer and Moderna.

The number of bacterial colonies observed in this experiment was not high, indicating an unknown quantity of the DNA had been linearized.

The exact proportions of circular and linear DNA in the mixtures remains to be determined.

Additionally, quantitation by multiplex PCR of both DNA and mRNA contained in the Pfizer and Moderna vaccines was undertaken to determine the abundance of DNA contamination, targeting the Spike protein gene (in the mRNA and plasmid DNA) and the kanamycin resistance gene (in the plasmid DNA only).

The DNA contamination is likely causing extended duration of spike protein expression.

Multiple studies[4] on vaccinated individuals evidence that both the spike protein itself and the modRNA encoding it can be detected in the bloodstream and in various organs, for weeks and even months after the injection.

For the bacterial plasmid DNA to support prolonged expression of the spike protein, two conditions must be fulfilled:

1. the plasmid DNA must persist inside our body cells, and
2. the spike protein gene on that plasmid must be transcribed into

[4] S. Bansal et al.: Cutting Edge: Circulating Exosomes with COVID Spike Protein Are Induced by BNT162b2 (Pfizer-BioNTech) Vaccination prior to Development of Anti- bodies: A Novel Mechanism for Immune Activation by mRNA Vaccines. J. Immunol. 207 (2021), 2405– 2410; J. A. S. Castruita et al.: SARS-CoV-2 spike RNA vaccine sequences circulate in blood up to 28 days after COVID-19 vaccination. APMIS 131 (2023), 128–132; T. E. Fertig et al.: Vaccine mRNA Can Be Detected in Blood at 15 Days Post-Vaccination. Biomedicines 10 (2022), 1538; E. Magen et al.: Clinical and Molecular Characterization of a Rare Case of BNT162b2 mRNA COVID-19 Vaccine- Associated Myositis. Vaccines 10 (2022); K. Röltgen et al.: Immune imprinting, breadth of variant recognition and germinal center response in human SARS-CoV-2 infection and vaccination. Cell (2022).

mRNA by our own cellular RNA polymerase II.

Recombinant plasmids expressing coagulation factor IX have been found to persist in the liver cells of experimental animals at stable levels for up to 1.5 years[5].

Recombinant viral DNA has been shown to persist in linear form within animals for equally long periods of time[6], which suggests that the same can occur with the linearised plasmid DNA of both Pfizer and Moderna.

The spike protein gene contained in Pfizer's and Moderna's expression plasmids is under the control of a T7 bacteriophage promoter. It has been experimentally confirmed[7] that the T7 promoter also binds the cellular RNA polymerase II and causes protein expression in mammalian cells.

As such the possibility that the observed long-lasting expression of spike protein is caused by the plasmid DNA contained in the mRNA vaccines must be taken seriously, and creates an altogether unacceptable safety risk.

Pfizer's bivalent vaccine plasmid DNA contamination also contains the Simian Virus 40 (SV40) DNA sequence for promoting antibiotic resistance. The protein encoded by this resistance gene will be expressed in any cell containing this DNA. Like the spike protein, this protein is a foreign antigen and may therefore trigger an immune attack on the cells expressing it.

The SV40 promoter also includes an internal origin of replication that can potentially cause copies of the plasmid to be made inside human cells. This replication would require either the SV40 virus itself, which already infects a minority of humans, or by the human BK or JC polyomaviruses[8]. Any additional copies of the plasmid DNA generated would amplify the risk of genomic integration with human DNA and increase the risk of malignant tumours associated[9] with the SV40 virus.

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[5] C. H. Miao et al.: Long-term and therapeutic-level hepatic gene expression of human factor IX after naked plasmid transfer in vivo. Mol. Ther. 3 (2001), 947–57; X. Ye et al.: Complete and sustained phenotypic correction of hemophilia B in mice following hepatic gene transfer of a high- expressing human factor IX plasmid. J. Thromb. Haemost. 1 (2003), 103–11.

[6] L. Jager and A. Ehrhardt: Persistence of high-capacity adenoviral vectors as replication-defective monomeric genomes in vitro and in murine liver. Hum. Gene Ther. 20 (2009), 883–96.

[7] Y. Q. Li et al.: The function of T7 promoter as cis-acting elements for polymerase II in eukaryotic cell. Yi Chuan Xue Bao 27 (2000), 455–61.

[8] J. A. DeCaprio and R. L. Garcea: A cornucopia of human polyomaviruses. Nat. Rev. Microbiol. 11 (2013), 264–76; I. Hussain et al.: Human BK and JC polyomaviruses: Molecular insights and prevalence in Asia. Virus Res. 278 (2020), 197860.

[9] J. C. Rotondo et al.: Association Between Simian Virus 40 and Human Tumors. Front. Oncol. 9 (2019), 670.

This detection of copious amounts of plasmid DNA in both manufacturers' vaccines obviates the need to make that case genomic insertion of the plasmid DNA is occurring, as no specific sequence features are necessary for such integration to occur.

The stable chromosomal integration of a bacterial plasmid into the chromosomal DNA of mammalian cells was demonstrated as early as 1982[10]. The plasmid in question shares multiple features with those used in the production of Moderna's and Pfizer's mRNA bivalent vaccines.

The introduction of foreign or modified genes into mammalian cells using this and similar techniques has since become commonplace in experimental research and in biotechnology. The methodology is referred to as transfection, and organisms modified in this manner as transgenic. Stable integration can occur with both linear and circular plasmid DNA[11].

In this context, further consideration of the study previously published by Aldén et al[12], who detected DNA copies of the spike protein gene in a human liver cells exposed to the Pfizer monovalent mRNA vaccine, must, in light of McKernan's discovery that Pfizer vaccine vials contain substantial amounts of DNA, consider it equally possible that the observations by Aldén et al indicated the cellular uptake of this DNA contamination.

When genomic integration of exogenous recombinant DNA occurs at the wrong place within the genome, it frequently induces malignant diseases, especially leukemia[13].

The human genome contains multiple genes which may give rise to cancer if their expression level - the rate at which mRNA and protein molecules are synthesized from them - is altered by integrated foreign DNA which causes their expression levels to become too low or too high. A foreign DNA molecule may insert directly into such a gene and knock it out altogether, potentially halting the tumour suppressor function of a gene. These effects have been seen not only with viral DNA but also with bacterial plasmid DNA[14].

[10] P. J. Southern and P. Berg: Transformation of mammalian cells to antibiotic resistance with a bacterial gene under control of the SV40 early region promoter. J. Mol. Appl. Genet. 1 (1982), 327–41.

[11] G. Stuchbury and G. Münch: Optimizing the generation of stable neuronal cell lines via pre- transfection restriction enzyme digestion of plasmid DNA. Cytotechnology 62 (2010), 189–94.

[12] M. Aldén et al.: Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line. Curr. Issues Mol. Biol. 44 (2022), 1115–1126.

[13] F. J. T. Staal et al.: Sola dosis facit venenum. Leukemia in gene therapy trials: a question of vectors, inserts and dosage? Leukemia 22 (2008), 1849–1852.

[14] W. Doerfler et al.: Inheritable epigenetic response towards foreign DNA entry by mammalian host cells: a

Oocytes – immature ovum - can be transfected (with foreign DNA) in the body at certain stages of maturation[15], and so can sperm-producing cells within the testes[16]. In the latter case, the offspring of such treatment were shown to be transgenic. It can therefore not be ruled out that persons injected with mRNA vaccines that also contain DNA will subsequently give rise to transgenic children. DNA insertion into germline cells might also interfere with early intrauterine development and thereby induce miscarriages or malformations.

In the study by Wang et al[17], significant plasmid DNA transfection into cells was observed after intramuscular injection followed by electroporation [electric field applied to promote transfection/entry of plasmid DNA into cells] – up to a 34 fold increase.

While electroporation did increase the cellular uptake of the injected DNA, it was likely much less effective in this regard than the lipid nanoparticles contained in the mRNA vaccines would be[18], due to the extensive bio-distribution LNPs achieve throughout the human body, enabling magnitudes more DNA plasmids to be presented to magnitudes more cell varieties, which DNA plasmids are then aided by the transfection properties of the LNPs, for cellular entry throughout the human body.

7. In a follow-up article by lead author Kevin McKernan to the preprint in paragraph 4, titled ***LNP packaging of dsDNA***[19], McKernan further tested the same Covid-19 vaccines and was able to demonstrate:

> Over half of the DNA contamination in the vaccines is DNaseI resistant. This implies the DNA is protected by the LNPs and the DNA is packaged in the LNPs.

This data also suggests some of the DNA is not packaged.

guardian of genomic stability. Epigenetics 13 (2018), 1141– 1153.

[15] A. Laurema et al.: Transfection of oocytes and other types of ovarian cells in rabbits after direct injection into uterine arteries of adenoviruses and plasmid/liposomes. Gene Ther. 10 (2003), 580–4.

[16] S. Dhup and S. S. Majumdar: Transgenesis via permanent integration of genes in repopulating spermatogonial cells in vivo. Nat. Methods 5 (2008), 601–3.

[17] Z. Wang et al.: Detection of integration of plasmid DNA into host genomic DNA following intramuscular injection and electroporation. Gene Ther. 11 (2004), 711–21.

[18] Tanaka et al: Improvement of mRNA Delivery Efficiency to a T Cell Line by Modulating PEG-Lipid Content and Phospholipid Components of Lipid Nanoparticles. Pharmaceutics. 2021 Dec; 13(12): 2097.

[19] McKernan, 27 APRIL 2023: LNP packaging of dsDNA.

Question 1

Having considered paragraphs 1 through 3 of the Opening Statement above, do you agree with the statement? If not, please explain.

2. **Yes I agree with the statements above.** In addition to the points raised in Statement 3(i-iii), I also add the following:

3. **3(i-i):** mRNA molecules typically contain the nucleotide letters A, U, C and G. The substitution of the uracil (U) nucleotide for the N1-Methylpseudouridine (M1□) in the modified RNA (modRNA) molecule, conveys additional functions. Firstly, the M1□ allows the modRNA to evade the innate immune system, which is the first line of defence against foreign pathogens and agents. This modRNA design feature more directly stimulates the adaptive immune system, which is where antibodies are produced. This is advantageous for longer-lived, antibody-based immunity. However, treatment with the modRNA can negatively affect *Interferon* activity, which is an important component of the immune system for fighting viral infections (see Liu et al, 2021).[20] It is unclear how long this effect may last, and it could negatively impact an individual's ability to fight future viral infections.

   a) In less-scientific terms, the above means:

      The modified RNA in the vaccine (vaccine RNA) is specifically designed to avoid being broken down by the body's immune system. The consequences of bypassing the immune system in this way are unknown but the persistence of any foreign product in the body that cannot be broken down might be very detrimental to the body's own immune system.

4. **3(i-ii):** The substitution with pseudouridine (□) can modify the way the modRNA is read in the cell, such that it does not properly recognise the "STOP" part of the

[20] Liu, J., Wang, J., Xu, J. *et al.* Comprehensive investigations revealed consistent pathophysiological alterations after vaccination with COVID-19 vaccines. *Cell Discov* **7**, 99 (2021). https://doi.org/10.1038/s41421-021-00329-3.

sequence (ie the stop codon) (see Adachi & Yu, 2020).[21] This is referred to as *stop codon readthrough*. The implication then is that the M1□ would result in a longer protein that is different to what was encoded by the original mRNA sequence. The effects on the human body of this are unknown.

a) In less-scientific terms, the above means:

It is unclear if the correct protein is produced from this modified RNA sequence. Proteins are made up of a set of amino acid "building blocks" linked together in a chain, initially. Each amino acid has different properties. Even one change in a protein's amino acid sequence can cause severe disease in humans. The exact sequence of amino acids produced from these modRNA "instructions" have not been verified and any possible adverse functions of the resulting proteins have not been investigated. Therefore causing a human body to create foreign proteins without being certain which proteins are being produced is reckless and it carries extreme risk.

5. **3(i-iii):** In addition, M1□ alters the fidelity of amino acid selection during protein synthesis (See Monroe et al, 2022).[22] This implies that the modRNA sequence containing the M1□ could incorporate a different amino acid into the spike protein, compared with the original viral mRNA sequence. Different amino acids have the potential to change the structure and function of the resulting protein; therefore, it is predicted the spike encoded by the modRNA would be different in structure and function to the spike protein encoded by SARS-CoV-2 viral mRNA.

a) In less scientific terms, the above means:

Same as above namely, different proteins than that predicted to be produced by the vaccine modRNA may be produced. These have unknown effects on

[21] Adachi H, Yu YT. Pseudouridine-mediated stop codon readthrough in *S. cerevisiae* is sequence context-independent. RNA. 2020 Sep;26(9):1247-1256. doi: 10.1261/rna.076042.120. Epub 2020 May 20. PMID: 32434780; PMCID: PMC7430670.

[22] Jeremy G. Monroe, Lili Mitchell, Indrajit Deb, Bijoyita Roy, Aaron T. Frank, Kristin Koutmou. N1-Methylpseudouridine and pseudouridine modifications modulate mRNA decoding during translation bioRxiv 2022.06.13.495988; doi: https://doi.org/10.1101/2022.06.13.495988.

the human body and those effects have not been investigated. Even one change in a protein's amino acid (the building block of proteins that are usually made up of hundreds of amino acids) can cause severe disease in humans. Therefore asking the body to create foreign proteins without being certain which proteins are being produced carries extreme risk.

6. **3(i-iv):** Crucially, M1□ increases protein yield, compared with □ or U nucleotides (See Svitkin et al, 2017; See Andries et al, 2015).[23],[24] Thus, the total amount of spike protein produced after treatment with modRNA is likely many, many times higher than the amount of spike protein present after infection with SARS-CoV-2. In addition, the modRNA is located at many different locations all around the body, whereas the virus primarily infects the upper airways. To my knowledge, the manufacturers have not measured the amount of Spike protein produced, following treatment with modRNA.

a) In less-scientific terms, the above means:

The spike protein on the SARS-CoV-2 virus will primarily be located in the upper airways of an infected individual. The viral spike protein will only increase when the virus multiplies. This process is counteracted by an individual's immune system. In contrast, the modRNA, when injected into a human body is located in many different organs around the body, including the heart, brain, ovaries and bloodstream, among others. The modRNA is designed to have a significantly increased yield of spike protein, compared to the amount produced by the viral mRNA sequence. Finally, whereas the amount of virus, and therefore viral mRNA, will be counteracted by the individual's immune system, the modRNA is evading these usual immune mechanisms to remain in the human tissues for a lot longer and producing a

[23] Svitkin YV, Cheng YM, Chakraborty T, Presnyak V, John M, Sonenberg N. N1-methyl-pseudouridine in mRNA enhances translation through eIF2α-dependent and independent mechanisms by increasing ribosome density. Nucleic Acids Res. 2017 Jun 2;45(10):6023-6036. doi: 10.1093/nar/gkx135. PMID: 28334758; PMCID: PMC5449617.

[24] Oliwia Andries, Séan Mc Cafferty, Stefaan C. De Smedt, Ron Weiss, Niek N. Sanders, Tasuku Kitada, N1-methylpseudouridine-incorporated mRNA outperforms pseudouridine-incorporated mRNA by providing enhanced protein expression and reduced immunogenicity in mammalian cell lines and mice, Journal of Controlled Release, Volume 217, 2015, Pages 337-344, ISSN 0168-3659, https://doi.org/10.1016/j.jconrel.2015.08.051.

lot more spike. It has not been reported by the manufacturers or the Therapeutic Goods Administration as to what quantity of spike protein has been produced by the modRNA technologies and for how long they persist in the human body.

7. **3(ii-i):** Indeed, the codon optimisation is utilised to increase the protein yield from the modRNA. This process, however, also increased the G and C content of the modRNA. Most notably, the viral mRNA encoding the spike had a GC content of 36%, whereas this was increased to 53% and 61% in the Pfizer and Moderna modRNA sequences, respectively (See McKernan et al, 2021).[25] A previous study demonstrated that increased GC content could increase expression several fold to over a hundred-fold greater in sequences with significantly higher GC content (See Kudla et al, 2006).

a) In less scientific terms, the above means:

Same as above namely, the spike protein produced from the modRNA is much more abundant than the amount of mRNA from a virus encoding spike. By using multiple strategies to each increase the yield of the spike protein, cumulatively, this will lead to untold levels of spike protein. It has not been reported by the manufacturers or the Therapeutic Goods Administration as to what quantity of spike protein has been produced by the modRNA technologies and for how long they persist in the human body.

8. **3(ii-ii):** The significant increase in GC content in the Pfizer (53%) and Moderna (61%) modRNA products, led to a significant change in the structure of the modRNA molecules, compared with the viral mRNA structure, which had a 36% GC content (See McKernan et al, 2021).[26] It is not clear what effect this change in structure may have on the pathophysiology of the cells and tissues containing the modRNA. One

[25] McKernan, K., Kyriakopoulos, A. M., & McCullough, P. A. (2021, November 25). Differences in Vaccine and SARS-CoV-2 Replication Derived mRNA: Implications for Cell Biology and Future Disease. https://doi.org/10.31219/osf.io/bcsa6.

[26] McKernan, K., Kyriakopoulos, A. M., & McCullough, P. A. (2021, November 25). Differences in Vaccine and SARS-CoV-2 Replication Derived mRNA: Implications for Cell Biology and Future Disease. https://doi.org/10.31219/osf.io/bcsa6.

possibility is the formation of G-quadruplexes, which leads to an alternate structure of the modRNA molecule (See Seneff et al, 2022; See McKernan et al, 2021).[27,28] The presence of increased G-quadruplexes will affect the stability and processing of the modRNA, as well as with which proteins the RNA will interact (See Herdy, et al, 2018).[29] It is thought that the formation of G-quadruplexes in the RNA that encodes human Prion protein, is what creates the pathogenic Prion disease (See Olsthoorn, 2014).[30] Significantly, several groups have highlighted the similarity between regions of spike sequence, with typical prion-forming sequences (See Lukiw et al, 2022; See Tetz et al, 2022; See Bernadini et al, 2022).[31,32,33] Therefore, the combination of possible prion sequences in spike modRNA and the presence of G-quadruplex formation, could be a pathogenic combination of factors. This information has brought to light the possibility of a prion-like disease developing as a side-effect of these modRNA therapeutics. This possibility warrants an urgent investigation to rule out any such pathology.

[27] Stephanie Seneff, Greg Nigh, Anthony M. Kyriakopoulos, Peter A. McCullough, Innate immune suppression by SARS-CoV-2 mRNA vaccinations: The role of G-quadruplexes, exosomes, and MicroRNAs, Food and Chemical Toxicology, Volume 164, 2022, 113008, ISSN 0278-6915, https://doi.org/10.1016/j.fct.2022.113008.

[28] McKernan, K., Kyriakopoulos, A. M., & McCullough, P. A. (2021, November 25). Differences in Vaccine and SARS-CoV-2 Replication Derived mRNA: Implications for Cell Biology and Future Disease. https://doi.org/10.31219/osf.io/bcsa6.

[29] Barbara Herdy, Clemens Mayer, Dhaval Varshney, Giovanni Marsico, Pierre Murat, Chris Taylor, Clive D'Santos, David Tannahill, Shankar Balasubramanian, Analysis of NRAS RNA G-quadruplex binding proteins reveals DDX3X as a novel interactor of cellular G-quadruplex containing transcripts, *Nucleic Acids Research*, Volume 46, Issue 21, 30 November 2018, Pages 11592–11604, https://doi.org/10.1093/nar/gky861.

[30] Olsthoorn RC. G-quadruplexes within prion mRNA: the missing link in prion disease? Nucleic Acids Res. 2014 Aug;42(14):9327-33. doi: 10.1093/nar/gku559. Epub 2014 Jul 16. PMID: 25030900; PMCID: PMC4132711.

[31] Lukiw WJ, Jaber VR, Pogue AI, Zhao Y. SARS-CoV-2 Invasion and Pathological Links to Prion Disease. *Biomolecules*. 2022; 12(9):1253. https://doi.org/10.3390/biom12091253.

[32] Tetz G, Tetz V. Prion-like Domains in Spike Protein of SARS-CoV-2 Differ across Its Variants and Enable Changes in Affinity to ACE2. Microorganisms. 2022 Jan 25;10(2):280. doi: 10.3390/microorganisms10020280. PMID: 35208734; PMCID: PMC8878784.

[33] Andrea Bernardini, Gian Luigi Gigli, Francesco Janes, Gaia Pellitteri, Chiara Ciardi, Martina Fabris & Mariarosaria Valente (2022) Creutzfeldt-Jakob disease after COVID-19: infection-induced prion protein misfolding? A case report, Prion, 16:1, 78-83, DOI: 10.1080/19336896.2022.2095185.

a) In less-scientific terms, the above means:

The structure of the modRNA is predicted to be very different to the structure of the mRNA version found in the virus. As such, the overall shape change of the modRNA makes it more likely to interact with very different proteins in the human body that will affect how long the modRNA will remain in the cell. This particular shape change, referred to as G-quadruplex formation, is also what happens in prion disease formation. Namely, it is thought that the interaction of human Prion protein with the mRNA that encodes the Prion protein, while also containing a G-quadruplex structure, can produce the diseased Prion protein. The pathogenic version of the Prion protein begins to aggregate, which leads to tissue damage and cell death, manifesting as a neurodegenerative disease. Several groups have discovered similarities between the sequence for the spike protein and prion-forming sequences. It is very concerning that the sequence for spike protein is exhibiting features that may lead to a prion-like neurodegenerative disease.

9. **3(ii-iii):** The spike RNA sequence has been predicted to contain miRNAs (See Fujii et al, 2021).[34] This possibility raises many possible concerns on the safety of these sequences, based around how they may regulate the host genetic material. Within FOI-3604, it is clear that the impact from miRNAs, along with the other modifications, were never assessed by the manufacturers.

a) In less-scientific terms, the above means:

miRNAs are small molecules that control many cell functions and include cancer control mechanisms in the human body. Disruption of these can lead to disruption of normal cell mechanisms of which the most concerning is the generation of new cancers or failure to control existing cancers in humans.

10. **3(iii-i):** Indeed, the 3'-UTR was carefully optimised, according to a study by BioNTech CEO Ugur Sahin and their team (von Niessen'19). It was discovered that

[34] Fujii YR. Quantum microRNA Assessment of COVID-19 RNA Vaccine: Hidden Potency of BNT162b2 SASR-CoV-2 Spike RNA as MicroRNA Vaccine. Adv Case Stud. 3(1). AICS.000552. 2021. DOI: 10.31031/AICS.2021.03.000552.

incorporation of 3'UTR sequences from two different human genes, named *amino-terminal enhancer of split* (*AES*) and *mitochondrially encoded 12S rRNA* (*mtRNR1*), most optimally increased the expression of the modRNA they tested. The Pfizer BNT162b2 product utilised this sequence for the 3'UTR. The Moderna mRNA-1273 product utilised sequence from the human □-globin gene (*HBA1*) for the 3'UTR (see Granados-Riveron, 2021).[35] Given the *stop codon readthrough* phenomenon, mentioned above in 3(i-ii), it is not clear whether any part of these human sequences (either the AES-mtRNR1 sequence for Pfizer, or the □-globin sequence for Moderna) may be present in the resulting protein produced from the modRNA. In this instance, the risk of autoimmunity may arise, whereby antibodies are produced to target the AES, mtRNR1 and HBA1 portions of protein sequence.

a) In less scientific terms, the above means:

Both Pfizer and Moderna designed their modRNAs with human gene sequences at the end of the modified RNA, as yet another strategy to increase the amount of spike protein produced. If the protein produced from these modRNAs triggers an immune response against the human portion added at the end, the immune system may begin attacking those same proteins in other parts of the body, leading to an "autoimmune" reaction. The development or exacerbation of autoimmune disease would be a terrible outcome for the individual.

11. **3(iii-ii):** As the modRNA cannot be delivered on its own in the body, the modRNA has been packaged up in lipid nanoparticles, which act as special carriers of the modRNA. This is referred to as a "LNP-modRNA complex". It is known that the LNPs also have adjuvant activity, thereby enhancing the immune response (See

[35] Javier T. Granados-Riveron, Guillermo Aquino-Jarquin, Engineering of the current nucleoside-modified mRNA-LNP vaccines against SARS-CoV-2, Biomedicine & Pharmacotherapy, Volume 142, 2021, 111953, ISSN 0753-3322, https://doi.org/10.1016/j.biopha.2021.111953.

Alameh et al, 2021).[36] Significantly, one component of the LNP is polyethylene glycol (PEG), which can lead to anaphylaxis in susceptible individuals.

a) In less-scientific terms, the above means:

The lipid nanoparticles (LNPs) carrying the vaccine modified RNA can themselves activate the immune system. At least one of the components of the LNP, polyethylene glycol (PEG), is known to have the potential for inducing life-threatening anaphylaxis (a sudden and severe allergic reaction that involves the whole body).

Question 2

Having considered the modifications mentioned in paragraph 3(i), (ii), and (iii) of the opening statement above, have these modifications any known risks, and/or have they produced any known risks you are aware of?

12. Yes. Further, I say that in general, the modifications made to the modRNA sequence have implications for the abundance, stability, structure and function of both the modRNA molecule, as well as the resulting protein encoded by the modRNA. This may have far-reaching implications for many aspects of biology, including the immune system and cancer pathways. It is also possible that these changes have biological consequences yet to be determined.

13. More specifically, a study showed that the modRNA sequence was predicted to encode a range of micro RNA (miRNA) sequences (See Fujii et al, 2021).[37] miRNAs are short sequences of RNA that do not encode for proteins but instead bind to target mRNAs. This typically leads to their degradation and reduces the amount of

[36] Mohamad-Gabriel Alameh, István Tombácz, Emily Bettini, Katlyn Lederer, Sonia Ndeupen, Chutamath Sittplangkoon, Joel R. Wilmore, Brian T. Gaudette, Ousamah Y. Soliman, Matthew Pine, Philip Hicks, Tomaz B. Manzoni, James J. Knox, John L. Johnson, Dorottya Laczkó, Hiromi Muramatsu, Benjamin Davis, Wenzhao Meng, Aaron M. Rosenfeld, Shirin Strohmeier, Paulo J.C. Lin, Barbara L. Mui, Ying K. Tam, Katalin Karikó, Alain Jacquet, Florian Krammer, Paul Bates, Michael P. Cancro, Drew Weissman, Eline T. Luning Prak, David Allman, Botond Z. Igyártó, Michela Locci, Norbert Pardi, Lipid nanoparticles enhance the efficacy of mRNA and protein subunit vaccines by inducing robust T follicular helper cell and humoral responses, Immunity, Volume 54, Issue 12, 2021, Pages 2877-2892.e7, ISSN 1074-7613, https://doi.org/10.1016/j.immuni.2021.11.001.

[37] Fujii YR. Quantum microRNA Assessment of COVID-19 RNA Vaccine: Hidden Potency of BNT162b2 SASR-CoV-2 Spike RNA as MicroRNA Vaccine. Adv Case Stud. 3(1). AICS.000552. 2021. DOI: 10.31031/AICS.2021.03.000552.

translated protein. The study by Fujii utilised an *in silico* tool to predict which genes would be targeted and disrupted by these miRNAs (See Fujii et al, 2021).[38]. Many genes on this list encode proteins with functions in the immune system, as well as in pathways leading to cancer formation and progression. Therefore, one concern is disrupting these pathways could have significant negative impacts on the function of the host immune system, as well as increasing the risk of cancer.

14. According to a Freedom of Information Request FOI 3604, the Therapeutic Goods Administration (TGA) have not investigated any of the possible risks mentioned above. These risks include possible: miRNA sequences and their functional consequences; presence of oncomirs (oncogenic, cancer-causing, miRNAs); stop codon readthrough; composition and sequence of final protein product; risk from the use of the 3'-UTR sequence.

a) In less-scientific terms, the above means:

Short RNA sequences, called micro RNAs (miRNAs), can be produced in the human body from the modRNA. These short miRNAs can lead to other functions in the cells, including the disruption of the immune system and they have the potential to activate or worsen cancers in people.

15. In **3(i):** N1-methylpseudouridine (M1□) can sensitise the effects of miRNA. In a study by Parr et al. they established that the presence of M1□ led to higher expression of the target gene, and miRNA pairing was enhanced (See Parr et al, 2020).[39] A study by Lockhart et al. also established that incorporation of M1□ affected the regulation of *in vitro transcribed* (IVT) mRNAs (See Lockhart et al, 2019).[40]

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[38] Fujii YR. Quantum microRNA Assessment of COVID-19 RNA Vaccine: Hidden Potency of BNT162b2 SASR-CoV-2 Spike RNA as MicroRNA Vaccine. Adv Case Stud. 3(1). AICS.000552. 2021. DOI: 10.31031/AICS.2021.03.000552.

[39] Callum J C Parr, Shunsuke Wada, Kenjiro Kotake, Shigetoshi Kameda, Satoshi Matsuura, Souhei Sakashita, Soyoung Park, Hiroshi Sugiyama, Yi Kuang, Hirohide Saito, N^1-Methylpseudouridine substitution enhances the performance of synthetic mRNA switches in cells, *Nucleic Acids Research*, Volume 48, Issue 6, 06 April 2020, Page e35, https://doi.org/10.1093/nar/gkaa070.

[40] Lockhart J, Canfield J, Mong EF, VanWye J, Totary-Jain H. Nucleotide Modification Alters MicroRNA-Dependent Silencing of MicroRNA Switches. Mol Ther Nucleic Acids. 2019 Mar 1;14:339-350. doi: 10.1016/j.omtn.2018.12.007. Epub 2018 Dec 18. PMID: 30665183; PMCID: PMC6350232.

a) In less-scientific terms, the above means:

The presence of the artificial M1□ nucleotide also exacerbates the effects of the miRNAs. This can have unintended effects in humans on various cell functions including cancer control mechanisms.

16. **3(ii):** codon optimisation utilised in the modRNA products increases the GC content of the modRNA (McKernan'21). The significant rise in C and G bases results in an enhanced ability for G-quadruplex formation, which alters the secondary structure of the modRNA molecule (See Seneff et al, 2022; See McKernan et al, 2021).[41,42] It is known that G-quadruplexes in other molecules can contribute to pathologies such as prion-like diseases (See Pradhan et al, 2020).[43] Several groups have reported the similarities between the sequence encoding the spike and sequence that have the potential to produce prion proteins (See Lukiw et al, 2022; See Tetz et al, 2022; See Bernadini et al, 2022).[44,45,46] Therefore, there is risk that the modRNA has been changed in such a way as to alter its interaction with spike protein, raising concern for the potential formation of a prion-like disease.

[41] Stephanie Seneff, Greg Nigh, Anthony M. Kyriakopoulos, Peter A. McCullough, Innate immune suppression by SARS-CoV-2 mRNA vaccinations: The role of G-quadruplexes, exosomes, and MicroRNAs, Food and Chemical Toxicology, Volume 164, 2022, 113008, ISSN 0278-6915, https://doi.org/10.1016/j.fct.2022.113008.

[42] McKernan, K., Kyriakopoulos, A. M., & McCullough, P. A. (2021, November 25). Differences in Vaccine and SARS-CoV-2 Replication Derived mRNA: Implications for Cell Biology and Future Disease. https://doi.org/10.31219/osf.io/bcsa6.

[43] Prashant Pradhan, Ankit Srivastava, Jasdeep Singh, Banhi Biswas, Akanksha Saini, Ibrar Siddique, Pooja Kumari, Mohd. Asim Khan, Akhilesh Mishra, Pramod Kumar Yadav, Shivani Kumar, Neel Sarovar Bhavesh, Prasanna Venkatraman, Perumal Vivekanandan, Bishwajit Kundu, Prion protein transcription is auto-regulated through dynamic interactions with G-quadruplex motifs in its own promoter, Biochimica et Biophysica Acta (BBA) - Gene Regulatory Mechanisms, Volume 1863, Issue 3, 2020, 194479, ISSN 1874-9399, https://doi.org/10.1016/j.bbagrm.2019.194479.

[44] Lukiw WJ, Jaber VR, Pogue AI, Zhao Y. SARS-CoV-2 Invasion and Pathological Links to Prion Disease. *Biomolecules*. 2022; 12(9):1253. https://doi.org/10.3390/biom12091253.

[45] Tetz G, Tetz V. Prion-like Domains in Spike Protein of SARS-CoV-2 Differ across Its Variants and Enable Changes in Affinity to ACE2. Microorganisms. 2022 Jan 25;10(2):280. doi: 10.3390/microorganisms10020280. PMID: 35208734; PMCID: PMC8878784.

[46] Andrea Bernardini, Gian Luigi Gigli, Francesco Janes, Gaia Pellitteri, Chiara Ciardi, Martina Fabris & Mariarosaria Valente (2022) Creutzfeldt-Jakob disease after COVID-19: infection-induced prion protein misfolding? A case report, Prion, 16:1, 78-83, DOI: 10.1080/19336896.2022.2095185.

a) In less-scientific terms, the above means:

The changes in the modRNA sequence leads to significant changes in the overall shape of the modRNA molecule, which alters its function and behaviour in the tissues of the human body. There is significant concern that the altered behaviour of the protein encoded by the modRNA will begin to form aggregates, or clumps, leading to the development of a prion-like neurodegenerative disease.

17. In **3(iii):** The 3'-UTR encodes sequence from two different human genes, a tumour suppressor (auto-terminal enhancer of split (AES) protein) and sequence for producing ribosomal RNA (See Nance and Meier, 2021).[47] This creates a chimeric RNA sequence with elements of both human and viral-derived sequences. This is particularly relevant in the case of *stop codon readthrough*, where the translation into protein will not stop at the end of the spike sequence but may continue translating through into human sequence. This has the potential for creating an antigen based on the human protein and stimulating an immune response against itself. It is unknown if this is the case, however, a number of autoimmune disorders have been reported as occurring shortly after receipt of a modRNA injection (See Chen et al, 2021; See Schultz et al, 2021, See Kaulen et al, 2022).[48,49,50]

[47] Kellie D. Nance and Jordan L. Meier Modifications in an Emergency: The Role of N1 Methylpseudouridine in COVID-19 Vaccines *ACS Central Science* **2021** *7* (5), 748-756 DOI: 10.1021/acscentsci.1c00197.

[48] Chen, Y, Xu, Z, Wang, P, Li, X-M, Shuai, Z-W, Ye, D-Q, et al. New-onset autoimmune phenomena post-COVID-19 vaccination. *Immunology*. 2022; 165: 386– 401. https://doi.org/10.1111/imm.13443.

[49] Schultz NH, Sørvoll IH, Michelsen AE, Munthe LA, Lund-Johansen F, Ahlen MT, Wiedmann M, Aamodt AH, Skattør TH, Tjønnfjord GE, Holme PA. Thrombosis and Thrombocytopenia after ChAdOx1 nCoV-19 Vaccination. N Engl J Med. 2021 Jun 3;384(22):2124-2130. doi: 10.1056/NEJMoa2104882. Epub 2021 Apr 9. PMID: 33835768; PMCID: PMC8112568.

[50] Kaulen LD, Doubrovinskaia S, Mooshage C, Jordan B, Purrucker J, Haubner C, Seliger C, Lorenz HM, Nagel S, Wildemann B, Bendszus M, Wick W, Schönenberger S. Neurological autoimmune diseases following vaccinations against SARS-CoV-2: a case series. Eur J Neurol. 2022 Feb;29(2):555-563. doi: 10.1111/ene.15147. Epub 2021 Oct 31. PMID: 34668274; PMCID: PMC8652629.

a) In less-scientific terms, the above means:

> The modRNA comprises sequence from a few different places: the main part of the sequence encodes the spike from SARS-CoV-2 virus; but it also contains some sequence taken from humans stitched onto the end of the sequence. It would be hoped that the "stop" inserted at the end of the spike sequence, would lead to just spike protein, which then mounts the immune response to produce antibodies against the spike. However, the concern is that on injection into the human body, part of the human sequence is also turned into protein, which could then mount an immune response against the human portion. If antibodies are produced against the human portion, this may lead to an "autoimmune" response, which is detrimental for the individual.

Additional Molecular Biology Considerations:

18. A very recent study demonstrated that the adaptive immune system, the system that produces antibodies, was vastly altered in mice treated with an mRNA-LNP complex (See Qin et al, 2022).[51] While they did not use spike modRNA in these experiments, it highlighted the caution that must be used in the general use of this technology. In fact, in one of their experiments, they showed that the LNP on its own could also disrupt the adaptive immune system. Of particular concern, was the demonstration that the immune changes could be passed down to the next generations of mice (See Qin et al, 2022).[52] A study by Alden et al. (2022)[53] demonstrated that Pfizer BNT162b2 modRNA can be reverse-transcribed (converted from RNA to DNA) in a cell line. The authors demonstrated that the BNT162b2 modRNA sequence could be taken up by the cell and converted into DNA sequence. This is of extraordinary significance as this study demonstrates the potential for these modRNA sequences to be inherited if it

[51] Qin Z, Bouteau A, Herbst C, Igyártó BZ (2022) Pre-exposure to mRNA-LNP inhibits adaptive immune responses and alters innate immune fitness in an inheritable fashion. PLoS Pathog 18(9): e1010830. https://doi.org/10.1371/journal.ppat.1010830.

[52] Qin Z, Bouteau A, Herbst C, Igyártó BZ (2022) Pre-exposure to mRNA-LNP inhibits adaptive immune responses and alters innate immune fitness in an inheritable fashion. PLoS Pathog 18(9): e1010830. https://doi.org/10.1371/journal.ppat.1010830.

[53] Aldén, M.; Olofsson Falla, F.; Yang, D.; Barghouth, M.; Luan, C.; Rasmussen, M.; De Marinis, Y. Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line. *Curr. Issues Mol. Biol.* 2022, *44*, 1115-1126. https://doi.org/10.3390/cimb44030073.

was to be stably incorporated into the genome of the host cell. Indeed, it has been argued that the mechanisms used by cells to integrate RNA into host DNA, have been well-known for over 40 years (See Domazet-Loso, 2022).[54] Crucially, this mechanism of RNA integration was demonstrated in the context of SARS-CoV-2 viral RNA into infected humans (See Lehrer and Rheinstein, 2020; See Zhang et al, 2021).[55,56]

19. The ramifications of the modRNA entry into cells is not fully appreciated. Kyriakopoulos et al. discuss the many ways in which the modRNA may interact with host genetic material, and the broad range of consequences this may be having including neural and oncogenic pathologies (See Kyriakopoulos et al, 2022).[57]

20. Traditional vaccines do not contain genetic material that can locate into the nucleus of cells; from a functional perspective, these modRNA products are more reminiscent of gene therapies. This calls into question both the categorisation and safety of these modRNAs.

21. In addition, a study by Jiang et al. (2021) discovered that spike protein had the capacity to not only enter the cell nucleus, but also to disrupt several important, fundamental, cellular processes (See Jiang and Mei, 2021).[58] Specifically, disruption to DNA damage repair is a key driver of cancer formation and progression. Disruption to two key DNA repair factors 53BP1 and BRCA1 is extremely concerning, given their well-known roles in cancers of the breast and ovaries.

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[54] Domazet-Lošo T. mRNA Vaccines: Why Is the Biology of Retroposition Ignored? *Genes*. 2022; 13(5):719. https://doi.org/10.3390/genes13050719.

[55] Lehrer S, Rheinstein PH. SARS-CoV-2 *orf1b* Gene Sequence in the *NTNG1* Gene on Human Chromosome 1. In Vivo. 2020 Jun;34(3 Suppl):1629-1632. doi: 10.21873/invivo.11953. PMID: 32503821; PMCID: PMC8378031.

[56] Liguo Zhang, Alexsia Richards, M. Inmaculada Barrasa, Stephen H. Hughes, Richard A. Young, and Rudolf Jaenisch, Reverse-transcribed SARS-CoV-2 RNA can integrate into the genome of cultured human cells and can be expressed in patient-derived tissues May 6, 2021 118 (21) e2105968118 https://doi.org/10.1073/pnas.2105968118.

[57] Kyriakopoulos AM, McCullough PA, Nigh G and Seneff S. "Potential Mechanisms for Human Genome Integration of Genetic Code from SARS-CoV-2 mRNA Vaccination: Implications for Disease." J Neurol Disord 10 (2022):519.

[58] Jiang H, Mei Y-F. SARS–CoV–2 Spike Impairs DNA Damage Repair and Inhibits V(D)J Recombination In Vitro. *Viruses*. 2021; 13(10):2056. https://doi.org/10.3390/v13102056.

22. With these molecular changes taking place in the cell after exposure to spike modRNA, the prediction would then be a significant increase in cancers, particularly in the ovaries and breasts.

Question 3

For the term 'organism', please consider only the following definition to be applicable for defining the term 'organism':

'any biological entity'

Do the LNP-modRNA complexes contained in each of the Pfizer and Moderna Covid-19 vaccines satisfy this definition?

23. **Yes.** The LNP contains many of the lipid molecules you find on the cell surface. This allows the LNP to be readily taken up into any cell. The modRNA contained in the LNP is based on the viral RNA sequence encoding the spike. The modRNA can be read and translated in the host cell as any natural RNA would. Genetic material is a critical feature of all life.

Question 4

Please consider the following phrase:

'capable of transferring genetic material'

Are the LNP-modRNA complexes contained in each of the Pfizer and Moderna Covid-19 vaccines *capable of transferring genetic material*?

24. Yes.

Question 5

If yes to Question 4, how does the LNP-modRNA complex transfer genetic material?

25. The LNP acts as a transfectant, which enables the delivery of the modRNA across the membrane of human cells into the cytoplasm of cells. The design of the LNP also assists in the release of the modRNA from the endocytic compartment and into the

cytoplasm. In addition, Sattar et al. have detected both spike mRNA and spike protein in the nucleus of cells (See Sattar et al, 2022).[59] While the exact mechanism of this process is not fully defined, it has been suggested that the spike protein contains a "*nuclear localisation signal*" in its sequence, which allows for its transport into the nucleus. The authors propose that the spike mRNA can bind the spike protein, thereby "hitchhiking" a ride to the nucleus. The extent of function of the RNA in the nucleus is unknown. **This calls into question, the very vehement claims that the Pfizer and Moderna modRNA products do not enter the nucleus.**

26. It is important to note that a previous study demonstrated that the Pfizer modRNA (BNT162b2) can be reverse-transcribed in an *in vitro* cellular system (See Alden et al, 2022).[60] This process converted the RNA to DNA, which is the form of genetic material that is passed on from generation to generation. **Together, these studies place the LNP-modRNA complex as an agent for the transfer of genetic material.**

a) In less-scientific terms, the above means:

The LNP carries and transfers the RNA directly into each cell in the human body. The RNA can then be transported into different compartments of the cell, including the nucleus where the DNA is located. A study showed that modRNA could be converted into DNA, which raises the possibility that the modRNA could be inherited by following generations of people.

[59] Sarah Sattar, Juraj Kabat, Kailey Jerome, Friederike Feldmann, Kristina Bailey, Masfique Mehedi, Nuclear translocation of spike mRNA and protein is a novel pathogenic feature of SARS-CoV-2, bioRxiv 2022.09.27.509633; doi: https://doi.org/10.1101/2022.09.27.509633.

[60] Aldén, M.; Olofsson Falla, F.; Yang, D.; Barghouth, M.; Luan, C.; Rasmussen, M.; De Marinis, Y. Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line. *Curr. Issues Mol. Biol.* 2022, *44*, 1115-1126. https://doi.org/10.3390/cimb44030073.

Question 6

For the term 'gene technology', please consider only the following definition to be applicable for defining the term 'gene technology':

'any technique for the modification of genes or other genetic material'

Do the LNP-modRNA complexes contained in each of the Pfizer and Moderna Covid-19 vaccines satisfy this definition?

27. Yes.

Question 7

If yes to Question 6, specifically, what has been modified in respect of the LNP-modRNA complexes contained in each of the Pfizer and Moderna Covid-19 vaccines - genes or genetic material?

28. First, the sequence that encodes the entire modRNA is a fusion of several different sequences, which include a 5'-cap, a 5'-UTR, derived from the human alpha-globin gene, along with an optimised Kozak sequence (to assist in driving robust expression), a codon-optimised coding sequence (different from the original SARS-CoV-2 sequence), a 3'-UTR at the end, consisting of human gene sequences, and a poly-adenosine tail (to assist with stability of the mRNA) (See Nance and Meier, 2021; see Granados-Riveron, 2021).[61,62]

29. Once the modified DNA was created to include all the above mentioned features, the manufacturers utilise *in vitro transcription* (IVT) to create the modRNA molecules (See Nance and Meier, 2021).[63] During this process, they provided the M1□ in the mix, rather than the original Uracil. This rendered the resulting modRNA molecules

[61] Kellie D. Nance and Jordan L. Meier, Modifications in an Emergency: The Role of N1-Methylpseudouridine in COVID-19 Vaccines, ACS Central Science 2021 7 (5), 748-756
DOI: 10.1021/acscentsci.1c00197.

[62] Javier T. Granados-Riveron, Guillermo Aquino-Jarquin, Engineering of the current nucleoside-modified mRNA-LNP vaccines against SARS-CoV-2, Biomedicine & Pharmacotherapy, Volume 142, 2021, 111953, ISSN 0753-3322, https://doi.org/10.1016/j.biopha.2021.111953.

[63] Kellie D. Nance and Jordan L. Meier, Modifications in an Emergency: The Role of N1-Methylpseudouridine in COVID-19 Vaccines, ACS Central Science 2021 7 (5), 748-756 DOI: 10.1021/acscentsci.1c00197.

as highly modified versions compared with the SARS-CoV-2 mRNA encoding the spike protein.

a) In less-scientific terms the above means:

The sequence for the modRNA is significantly altered from the original viral mRNA. These modifications include differences to the sequence, differences to the nucleotides used (ie the incorporation of the N1-methylpseudouridine (M1□) instead of the uracil (U)), and addition of human sequence.

Question 8

Can the recombinant DNA discovered in each of the Pfizer and Moderna Covid-19 vaccine vials examined, be said to be vials containing 'LNP-modDNA complexes'?

30. Yes. The term modDNA is used to reflect the "*modified*" version of DNA that was engineered by Pfizer and Moderna for the purposes of developing the vaccine products. The circular, plasmid modDNA was produced by combining regulatory sequences from viruses (sequences that control the "switching on" of genes), such as the Simian Virus 40 (SV40) and the phage T7 promoter sequence. In addition, the modDNA contains a highly modified version of the gene encoding SARS-CoV-2 spike protein, and a bacterial gene encoding antibiotic resistance, contained within the plasmid vector sequence.

31. The work by Kevin McKernan et al demonstrated that in all the vials analysed from both Pfizer and Moderna, significant quantities of modDNA was DNAse I-resistant, demonstrating its protected localisation within the LNPs. Therefore, it is accurate to refer to the contents of the Pfizer and Moderna products as containing "LNP-modDNA complexes".

a) In less-scientific terms, the above means:

The modDNA discovered within the vials of Pfizer and Moderna products were the original modDNA sequences used to create the modRNA for the vaccine products. These modDNA sequences contain many modifications that

are different to the original SARS-CoV-2 viral spike sequence. The modDNA also contained sequences from other sources, such as viral sequences that instruct the modDNA to be "switched on" in the cell. In addition, the modDNA contains a bacterial gene that encodes for antibiotic resistance. Therefore, the modDNA found in these vials is referred to as "modified DNA" (modDNA).

The modDNA found in the Pfizer and Moderna vials was not susceptible to being destroyed by the DNA digestion enzyme DNAse I. This led to the conclusion that significant amounts of the modDNA is protected from the digestion by being on the inside of the LNP.

Question 9

For the term 'organism', please consider only the following definition to be applicable for defining the term 'organism':

'any biological entity'

Do the linear and plasmid LNP-modDNA complexes contained in each of the Pfizer and Moderna Covid-19 vaccines satisfy this definition?

32. Yes. As with the LNP-modRNA, the LNP contains many of the lipid molecules found on the cell surface. This allows the LNP to be readily taken up into any cell. The modDNA contained in the LNP is based on the viral sequence encoding the spike. The modDNA can be transcribed (read out in the form of a modRNA copy) and translated (converted to spike protein) in the host cell as any natural DNA would. Genetic material is a critical feature of all life.

Question 10

Please consider the following term:

'viable'

Are the linear or plasmid LNP-modDNA complexes contained in each of the Pfizer and Moderna Covid-19 vaccines viable?

33. In a strict biological definition, "*viable*" would refer to an organism that can maintain its own metabolism and has the capacity to reproduce. Viruses fall into a grey area as they require a host in order to reproduce themselves. In this way, the "LNP-modDNA" complex is highly analogous to a virus and is distinguishable from free DNA. Notably, the LNP provides the direct delivery of the modDNA to cells, rather than the modDNA being susceptible to degradation if injected without the protection of the LNP.

34. The full modDNA sequence has the capacity to be replication competent as it contains the origin (Ori) sequence that signals the starting point for replication of the modDNA plasmid. The presence of a natural SV40 viral infection (or similar virus such as JCV or BKV) in the same cell (of a human), would provide the enzyme to initiate the replication of the modDNA plasmid.

35. The modDNA also has the capacity to be integrated into the human genome, like viral sequence integration. If integration occurs, then the modDNA sequence would be replicated in perpetuity until that cell dies.

36. In light of the above mechanisms of replication the LNP-modDNA should be regarded as '*viable*'.

a) In less-scientific terms, the above means:

The "LNP-modDNA" complex is very similar to a virus in that it requires a "host" to carry out replication/reproduction. The information contained in the modDNA sequence allows for it to reproduce/replicate under the correct conditions. In addition, if the modDNA was to become integrated within

human genomic DNA, this would also lead to its replication and continuity. The LNP-modDNA has the ability to be *viable* within humans.

Question 11

Please consider the following phrase:

'capable of transferring genetic material'

Are the linear or plasmid LNP-modDNA complexes contained in each of the Pfizer and Moderna Covid-19 vaccines capable of transferring genetic material?

37. **Answer:** Yes.

Question 12

If yes to Question 11, how do the linear and plasmid LNP-modDNA complexes transfer genetic material?

38. The LNP acts as a *transfectant*, which enables the delivery of the modRNA across the membrane of human cells into the cytoplasm of cells. The design of the LNP also assists in the release of the modDNA from the endocytic compartment and into the cytoplasm. The presence of the SV40 *enhancer* sequence facilitates the transfer of the modDNA from the cytoplasm to the nucleus (Dean'99).[64] This colocalises the modDNA with the cellular machinery found in the nucleus that leads to the "expression" or "switching on" of genes. Therefore, the modDNA, and the information encoded in its sequence, is efficiently *transferred* to and within cells within the human body.

[64] David A. Dean, Brenda S. Dean, Susanne Muller, and Louis C. Smith, Sequence requirements for plasmid nuclear import Exp Cell Res. 1999 Dec 15; 253(2): 713–722. doi: 10.1006/excr.1999.4716 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4152905/.

a) In less-scientific terms, the above means:

The LNP carries and transfers the modDNA directly into each cell in the human body. The modDNA can then be transported into the nucleus of the cell, alongside the genomic DNA. The modDNA can then be "switched on" and active within the cell.

Question 13

For the term 'gene technology', please consider only the following definition to be applicable for defining the term 'gene technology':

'any technique for the modification of genes or other genetic material'

Do the linear and plasmid LNP-modDNA complexes contained in each of the Pfizer and Moderna Covid-19 vaccines satisfy this definition?

39. Yes.

Question 14

If yes to Question 13, specifically, what has been modified in respect of the LNP-modDNA complexes contained in each of the Pfizer and Moderna Covid-19 vaccines - genes or genetic material?

40. The modifications described for the modRNA sequence apply to the modDNA as it encodes the modRNA. To this end, the modDNA contains the fusion of several different sequences, making it *chimeric*, including: a 5'-cap; a 5'-UTR, derived from the human alpha-globin gene; an optimised Kozak sequence (to assist in driving robust expression); a codon-optimised coding sequence (different from the original SARS-CoV-2 sequence); a 3'-UTR at the end, consisting of human gene sequences; and, a poly-adenosine tail (to assist with stability of the mRNA) (See Nance and Meier, 2021; see Granados-Riveron, 2021).[65,66]

[65] Kellie D. Nance and Jordan L. Meier, Modifications in an Emergency: The Role of N1-Methylpseudouridine in COVID-19 Vaccines, ACS Central Science 2021 7 (5), 748-756
DOI: 10.1021/acscentsci.1c00197.

[66] Javier T. Granados-Riveron, Guillermo Aquino-Jarquin, Engineering of the current nucleoside-modified mRNA-LNP vaccines against SARS-CoV-2, Biomedicine & Pharmacotherapy, Volume 142, 2021, 111953, ISSN 0753-3322, https://doi.org/10.1016/j.biopha.2021.111953.

41. In addition to the sequence that encodes the modRNA, the plasmid modDNA also encodes sequence originating from the SV40 virus (promoter and enhancer), T7 phage promoter, a bacterial antibiotic resistance gene, and other plasmid vector sequence that links all the other sequences together in a complete circle (McKernan'23).

42. The linear and plasmid modDNA sequences do not resemble any naturally occurring sequences. Rather, they are highly engineered and modified sequences, such as that encoding the spike protein, in combination with a range of other sequences in an engineered plasmid construct. The modDNA draws from human, viral, bacterial, and newly created synthetic constructs, making it therefore, *chimeric*.

a) In less-scientific terms, the above means:

The sequence of the modDNA that encodes the spike protein is significantly altered from the original viral sequence. In addition, the modified spike sequence has been combined with other modDNA sequences from human, viral, and bacterial origins, that instruct the localisation and activation of the modDNA when it enters the host cell in the human body.

Question 15

Having considered paragraphs 4 through 7 of the Opening Statement above, and the complete findings and data in the references provided, do you agree with the concerns identified by Palmer and Gilthorpe in paragraph 6, as regards the presence of linear and plasmid DNA in the Pfizer and Moderna products?

If yes, which parts of their analysis do you agree with?

If yes, are there any further issues or concerns not discussed by Palmer and Gilthorpe?

43. Yes, I agree with the entire analysis and all the concerns the authors have identified.

44. The products developed by Pfizer (BNT162b2) and Moderna (mRNA-1273) were marketed as messenger RNA (modRNA), packaged in lipid vesicles (called Lipid NanoParticles; LNPs). Following an intramuscular injection into a human's arm it

was said to be taken up by local cells, which would switch on the spike gene and mount an immune response.

45. Recently, new data have come to light, demonstrating that modDNA is also contained within the LNPs. This raises a number of red flags as there are now extra risks to consider with these products. It is also clear that the quality control from both Pfizer and Moderna was woefully inadequate, and the assessment of these products by regulatory agencies was done, bereft of critical information. Thus, it appears that BNT162b2 and mRNA-1273 contain highly modified versions of both RNA (modRNA), and DNA (modDNA), contained within a transfection-ready LNP, which travels widely in the human body, transfecting cells of most major organs including the brain, bone marrow, heart, lungs, pancreas, Pituitary gland, spinal cord, Ovaries and Testes (TGA FOI Nonclinical Evaluation Report 2389-6, page 45).[67]

46. The data shared by Kevin McKernan et al., indicate the unexpected presence of DNA in both a linear form, as well as a circular (plasmid) form. The evidence that supports the presence of modDNA is as follows:

a) The use of deep-sequencing technology to "read" the nucleic acids present. The use of an enzyme called RNAse A, which breaks up (and effectively dissolve away) all the modRNA in the samples, allowing any modDNA present to be identified and sequenced to determine its nature (structure and composition).

b) To measure and read the nucleic acids (modDNA or modRNA), they had to be copied many times in order to detect them – this process is called amplification. Two methods were used to amplify the nuclei acids: qPCR can amplify DNA, but not RNA; RT-qPCR will amplify both DNA and RNA. McKernan et al. could amplify significant amounts of modDNA with the qPCR technique after a cycle threshold (Ct) of approximately 24. This is well within the optimal detection limits of this technique, demonstrating a significant quantity of modDNA present. This was true for both Pfizer and Moderna products.

[67] https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf

c) The contents of the Pfizer and Moderna products could successfully transform bacteria and allow them to grow in Kanamycin-infused agar. This means that the bacteria were made to take up the contents of the Pfizer or Moderna products, then could grow successfully in jelly-like agar, which contained the antibiotic Kanamycin. That bacteria successfully grew in these dishes, is testament that they were successful in taking up a circular (plasmid) form of modDNA that contained the genetic instructions for Kanamycin resistance. This confirmed the presence of plasmid modDNA and was consistent with the sequencing that returned information regarding the Kanamycin resistance gene present.

d) Using an enzyme that breaks up the modDNA (DNAse I), Kevin McKernan et al. treated the contents of the Pfizer and Moderna vials with DNAse I and left some untreated as a control. The DNAse would degrade all free-floating modDNA (not encapsulated in LNP) that could be contained in the vial; however, any modDNA contained in the LNP would be protected from DNAse digest. After the DNAse dissolved any free-floating modDNA, qPCR (which amplifies DNA but not RNA) was undertaken and successfully amplified modDNA, demonstrating that modDNA was present in significant quantities inside the LNPs (estimated at over half the modDNA contamination). Thus, modDNA will get "*transfected*" directly into cells, along with the modRNA.

47. For clarity, the modDNA found in these products is what is referred to as "*transgenic*" material. This modDNA is a highly modified, man-made sequence, which utilises sections of sequence from a number of different sources, including human, viral and bacterial sequences. Part of this modDNA sequence encodes a synthetic version of the viral Spike protein originating from the SARS-CoV-2 virus, although the modDNA sequence was altered to "optimise" the letter code (termed "codon optimisation"). The modDNA sequence also contains sections derived from other viruses (eg Simian Virus 40; SV40), and another gene sequence such as the Kanamycin antibiotic resistance gene sequence (NeoR/KanR). For these reasons, the DNA found in these products is referred to as modDNA (modified DNA).

48. The construction of such a set of sequences into a circular (plasmid) format is to facilitate the transformation of E.coli bacteria. This process allows the plasmid to be taken up and replicated many, many times within each bacterium. This phenomenon is coupled with the fact that E.coli rapidly divide themselves with a doubling of bacteria numbers approximately every 20min or so. This allows researchers or manufacturers (like Pfizer and Moderna) to rapidly produce a huge number of plasmid modDNA copies. These plasmids of modDNA are the very first step in the manufacturing process to produce the modRNA products (BNT162b2 or mRNA-1273) for injection.

49. The following steps outline a highly simplified workflow that would be used to produce modRNA from the modDNA:

a) E.coli bacteria are transformed with plasmid modDNA encoding the spike protein gene. Bacteria are grown to produce many copies of the plasmid modDNA within many, many bacteria growing and dividing in broth under laboratory conditions.

b) E-coli are broken open so that the plasmid modDNA can be isolated.

c) Isolated modDNA plasmids are treated with an enzyme to cut the circular, plasmid modDNA into a linear modDNA format.

d) Linear modDNA is combined with enzymes and nucleotides in a reaction called *in vitro transcription* (IVT). This is the step where the modRNA strand is produced and when the synthetic nucleotide N1-methyl-pseudouridine can be incorporated into the modRNA.

e) modDNA needs to be "purified" away from the modRNA for final packaging. This may involve enzymes that digest/fragment the modDNA and/or purification steps to isolate the modDNA to separate it away from the modRNA, leaving only modRNA.

f) The “purified” or “isolated” modRNA is combined with the LNPs for the final packaging process, ready for injection.

50. Kevin McKernan’s data point to contamination, originating from the step described in paragraph 6(c) above, and carrying right through to the final step of packaged LNPs (paragraph 6(f)). How much contamination is there? The European Medicines Agency (EMA) clearly states the limits of contamination that are allowed in these products as a ratio of only 1 nanogram (ng; 1 billionth of a gram) of DNA for every 3,030 ng of RNA (or 330ng/mg DNA:RNA). Importantly, the EMA limit was set under the auspices that any contamination would be “naked” or “free” DNA, which is readily “mopped up” by our immune system when detected in the blood. Crucially, naked DNA has no intrinsic ability to cross cell membranes and enter cells. In contrast, DNA encapsulated in LNPs evade immune attack and possess a high transfection efficiency (ie a very high likelihood that they will directly enter cells). Consequently LNP-modDNA manufacturing contamination should have required much more stringent limits on contamination. Unfortunately, these significant risks of DNA transfection were not addressed by regulators. Guidance from the TGA[68] states contamination be less than or limited to 10ng per dose. McKernan's data shows Pfizer's Bivalent product contains modDNA contamination from 44-339 times over the limit; the Moderna Bivalent product is 52-476.

51. McKernan used several techniques to measure this modDNA contamination. I have reanalysed the data contained within the preprint, to elaborate on ratios of RNA:DNA as well as amounts of RNA and DNA contained within each dose of Pfizer (300ul injection) and Moderna (500ul injection):

[68] https://www.tga.gov.au/sites/default/files/pm-argpm-guidance-18.pdf

Table 1.

McKernan et al. (2023) Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose

Agilent Tape Station™ data

Manufacturer	Sample ID	Agilent DNA (ng/ul)	DNA per dose (ng)	No. of multiples over DNA contamination limit	Agilent RNA (ng/ul)	RNA per dose (ug)	% of expected dose of RNA
Pfizer	**Pbiv2-km**	11.3	3390	**339 x**	23.7	7.11	**24**
Pfizer	**Pbiv2-yh**	8.19	2457	**246 x**	28.3	8.49	**28**
Moderna	**Mod2-km**	9.51	4755	**476 x**	25.7	12.85	**13**
Moderna	**Mod2-yh**	7.5	3750	**375 x**	55.9	27.95	**28**

Manufacturer	Sample ID	Current RNA:DNA	Predicted RNA:DNA ratio*
Pfizer	**Pbiv2-km**	2	**9**
Pfizer	**Pbiv2-yh**	3	**12**
Moderna	**Mod2-km**	3	**21**
Moderna	**Mod2-yh**	7	**27**

* This predicted value is based on recalculating the ratio of RNA:DNA if we assumed there had been no degradation of RNA

Table 2.

McKernan et al. (2023) Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose

Qubit™ data

Manufacturer	Sample ID	Agilent DNA (ng/ul)	DNA per dose (ng)	No. of multiples over DNA contamination limit	Agilent RNA (ng/ul)	RNA per dose (ug)	% of expected dose of RNA
Pfizer	**Pbiv1**	2.81	843	**84 x**	30	9	**30**
Pfizer	**Pbiv2**	1.47	441	**44 x**	52.8	15.84	**53**
Moderna	**Mod1**	2.67	1335	**134 x**	21.8	10.9	**11**
Moderna	**Mod2**	1.04	520	**52 x**	49	24.5	**25**

Manufacturer	Sample ID	Current RNA:DNA	Predicted RNA:DNA ratio*
Pfizer	**Pbiv1**	11	**36**
Pfizer	**Pbiv2**	36	**68**
Moderna	**Mod1**	8	**75**
Moderna	**Mod2**	47	**192**

* This predicted value is based on recalculating the ratio of RNA:DNA if we assumed there had been no degradation of RNA

Table 3.

McKernan et al. (2023) Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram

Data taken directly from Table 3. of McKernan et al. (2023): Analysis of 8 vials of Pfizer monovalent product

RATIO RNA/DNA	Vial 1	Vial 2	Vial 3	Vial 4	Vial 5	Vial 6	Vial 7	Vial 8	STDEV
Replicate 1	107	61	147	84	91	159	161	63	41.54
Replicate 2	80	67	61	51	81	70	121	134	29.25
Replicate 3	80	67	43	84	70	83	136	145	34.79
STDEV	15.5	3.3	55.8	19.2	10.4	47.9	20.3	44.6	

52. Several take-home messages may be inferred from these data:

a) In the final column, I have calculated the % of expected dose of modRNA. For Pfizer the expected dose is 30 ug, while it is 100 ug for Moderna. McKernan et al. report that the vials they received were out of date and they did not know the provenance of the vials. Therefore, it is not unexpected to have RNA values measured significantly below the expected amounts, due to degradation of the RNA molecules through incorrect storage or expiration. For this reason, I considered recalculating the ratio of RNA:DNA as this would be underestimated due to possible RNA degradation. It is assumed here that very little, if any, DNA degradation would have taken place, given the extremely stable nature of DNA. In the recalculations, the predicted ratios still returned ratios that far exceed the limits set by the European Medicines Agency (3,030:1 RNA:DNA). This means, for every 'ng' of DNA, there should be 3,030 ng of RNA (or 3.03 ug RNA), rather than only the 36-192 ng of RNA to every ng of DNA, according to the Qubit analysis. This means the quantity of modDNA present in the Pfizer and Moderna Bivalent products is 15-84 times above the limit set by the EMA and TGA.

b) The TGA and FDA has issued guidance that each dose should not contain more than 10ng of DNA. From the analysis above, it is clear that different amounts of modDNA were detected using the different techniques. Irrespective, all samples showed modDNA contamination to far exceed the dose limit by more than two orders of magnitude. At the very least, Pfizer and Moderna did not have sufficient quality control measures to prevent this from occurring.

c) The variation amongst batches and vials is significant. While these experiments are not extensive to address the magnitude of inter-batch variation, this again raises a red flag on the quality assurance of these products manufactured by Pfizer and Moderna.

53. Importantly, there is a discrepancy between what was "thought" to be (scenario I, figure 1), and what "actually is" (scenario II, figure 1), in the products. Figure 1 below summarises these differences:

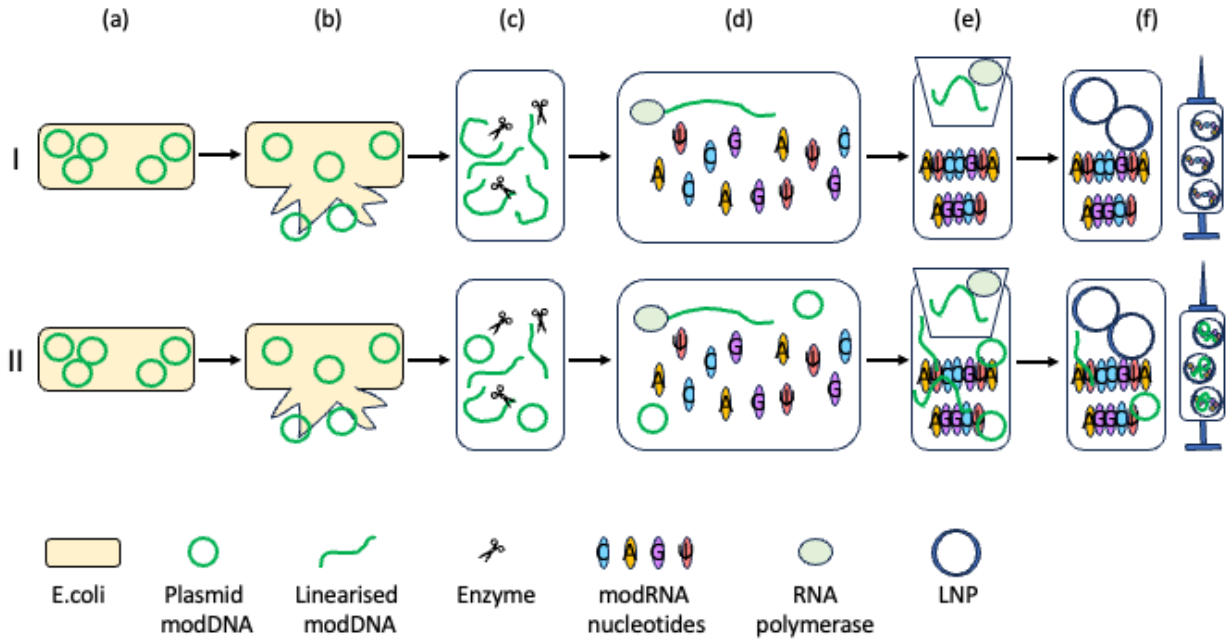

Figure 1. two scenarios are depicted: scenario I is what was thought to be in the injections; scenario II is what has been found in the injections. Steps (a-f) are explained in paragraph 49 of this report.

54. In summary, significant amounts of modDNA material from the early phases of product manufacture have been quite possibly carried forward into the final product that has been injected in the arms of millions to billions of men, women and children, worldwide.

55. With the knowledge of modDNA present in both linear and circular (plasmid) form, Michael Palmer, MD and Jonathon Gilthorpe, PhD, among others, have raised several concerns in their report (Palmer and Gilthorpe'23).[69] Those concerns include the destination of this modDNA, and what the implications are for health and disease in human patients receiving these injectable products. A number of these points, and others, will be elaborated upon and discussed further below.

[69] Michael Palmer, MD and Jonathan Gilthorpe, PhD, COVID-19 mRNA vaccines contain excessive quantities of bacterial DNA: evidence and implications, Doctors for COVID Ethics, https://doctors4covidethics.org/covid-19-mrna-vaccines-contain-excessive-quantities-of-bacterial-dna-evidence-and-implications/

56. In the case of these injectable products containing modDNA, there are two pools of modDNA to consider. First, the modDNA that is not contained within an LNP would likely cause localised inflammation in the arm where it is injected, whereby the body's immune system would come and "mop up" the foreign material. On the other hand, the modDNA contained within the LNP is distributed to organs and cells throughout the human body.

57. It is known from the Pfizer biodistribution study that the LNP particles can readily distribute within a rodent, including to the ovaries and testes, uterus, bone marrow, heart, lungs, brain, pancreas, liver, adrenal glands, spleen, and the bloodstream (FOI-2389-06-Non-clinical evaluation report pp44-45).[70] There is no reason to suspect this is any different in humans. In fact, spike modRNA or protein has been detected in a number of human organs such as liver (Martin-Navarro'23),[71] as free circulating spike protein in blood plasma (Ogata'22; Yonker'23)[72,73] and within a single patient, in both the brain and heart, following autopsy (Morz'22).[74]

58. Whereas free-floating modDNA would trigger an immune response and lead to its rapid "clean up" and degradation, the modDNA contained within the LNP will be shipped throughout the body, with a clear delivery and disembarkation inside many different cells in the human body. This is analogous to "*transfection*" of DNA into cells – a common laboratory technique that transfers genetic material and drives a

[70] https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf

[71] Martin-Navarro L, de Andrea C, Sangro B, Argemi J. In situ detection of vaccine mRNA in the cytoplasm of hepatocytes during COVID-19 vaccine-related hepatitis. Journal of Hepatology. 2023 Jan;78(1):e20-e22. DOI: 10.1016/j.jhep.2022.08.039. PMID: 36116717; PMCID: PMC9474959 https://europepmc.org/article/PMC/9474959.

[72] Alana F Ogata and others, Circulating Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccine Antigen Detected in the Plasma of mRNA-1273 Vaccine Recipients, Clinical Infectious Diseases, Volume 74, Issue 4, 15 February 2022, Pages 715–718, https://doi.org/10.1093/cid/ciab465

[73] Lael M. Yonker, Zoe Swank, Yannic C. Bartsch, Madeleine D. Burns, Abigail Kane, Brittany P. Boribong, Jameson P. Davis, Maggie Loiselle, Tanya Novak, Yasmeen Senussi, Chi-An Cheng, Eleanor Burgess, Andrea G. Edlow, Janet Chou, Audrey Dionne, Duraisamy Balaguru, Manuella Lahoud-Rahme, Moshe Arditi, Boris Julg, Adrienne G. Randolph, Galit Alter, Alessio Fasano and David R. Walt, Circulating Spike Protein Detected in Post–COVID-19 mRNA Vaccine Myocarditis, Jan 2023https://doi.org/10.1161/CIRCULATIONAHA.122.061025Circulation. 2023;147:867–876.

[74] Mörz, M. A Case Report: Multifocal Necrotizing Encephalitis and Myocarditis after BNT162b2 mRNA Vaccination against COVID-19. Vaccines 2022, 10, 1651. https://doi.org/10.3390/vaccines10101651.

new function or identity for that cell. With this in mind, Palmer and Gilthorpe discuss several specific issues arising from these new findings.

Palmer and Gilthorpe section 4.1: Extended duration of spike protein expression.

59. Palmer and Gilthorpe raise the issue of extended synthetic spike protein expression, which further comes into focus when considering the widespread distribution of the LNP-modDNA. This amplifies the risks of extended expression.

60. Palmer and Gilthorpe correctly point out the relatively short half-life of natural mRNA (ie within 4.5 days), which represents the amount of time for half of the mRNA to degrade in the cell. The modRNA contained in these products has the capacity to produce many times more spike protein per modRNA molecule (covered in section 3(i-iv) at paragraph 9 of this report). However, the life-time of the modRNA is finite and therefore, the production of synthetic spike from a given modRNA is finite. DNA on the other hand is much more stable and can be retained for much longer periods of time.

61. A number of studies point to extended periods of time whereby synthetic spike protein is still being detected in individuals. Fertig et al. (2022) demonstrated that BNT162b2 remained in blood plasma for at least 2 weeks following vaccination (Fertig'22).[75] Following the development of *myositis* (inflammation in the muscle, causing pain and weakness) in an otherwise healthy 34 year-old woman, BNT162b2 modRNA was discovered in her quadricep muscle (in her thigh) one month after receiving the Pfizer injection (Magen'22).[76] It is of particular note that the modRNA was located in the thigh muscle, which is quite distant from the original site of injection (shoulder muscle). This individual's condition deteriorated such that she required mechanical ventilation and a feeding tube, and finally a tracheostomy (surgical incision through the neck into the trachea, where a tube is fitted to allow a

[75] Fertig, T.E.; Chitoiu, L.; Marta, D.S.; Ionescu, V.-S.; Cismasiu, V.B.; Radu, E.; Angheluta, G.; Dobre, M.; Serbanescu, A.; Hinescu, M.E.; Gherghiceanu, M. Vaccine mRNA Can Be Detected in Blood at 15 Days Post-Vaccination. Biomedicines 2022, 10, 1538. https://doi.org/10.3390/biomedicines10071538.

[76] Magen, E.; Mukherjee, S.; Bhattacharya, M.; Detroja, R.; Merzon, E.; Blum, I.; Livoff, A.; Shlapobersky, M.; Baum, G.; Talisman, R.; et al. Clinical and Molecular Characterization of a Rare Case of BNT162b2 mRNA COVID-19 Vaccine-Associated Myositis. Vaccines 2022, 10, 1135.

patient to breath) (Magen'22).[77] A separate study by Roltgen et al. showed both modRNA and spike protein from BNT162b2, present in lymph nodes up to 60 days post injection (Roltgen'22).[78]

62. The greatly extended time periods of modRNA expression are very surprising given that the half-life of natural RNA is so short. What accounts for this extended period of modRNA and synthetic spike protein observed in these patients? Palmer and Gilthorpe discuss some of the design features of the modDNA and how this affects its location and expression within cells.

Palmer and Gilthorpe Section 4.2 Risks associated with SV40-derived regulatory DNA sequences.

63. When plasmid modDNA is contained in E.coli bacteria, the plasmid can be reproduced many times. This phenomenon is termed "replication competent". This requires the correct enzyme to bind to the *origin of replication* (Ori) to begin making an exact duplicate of the plasmid. This raises the concern that the plasmid modDNA is not strictly inert but has the capacity to be "viable" by reproducing itself within the "host cell", including human host cells. This scenario is highly analogous to viral infection, whereby a virus seeks to hijack the "molecule machinery" in an infected host cell to replicate and perpetuate itself.

64. The Pfizer modDNA plasmid contains an Ori under the control of the SV40 *promoter*. This just requires the SV40 virus to also be present in the cell (ie in the case of an SV40 infection), then all the ingredients would be present for the plasmid modDNA to be duplicated and perpetuated *in vivo*. Studies have measured the prevalence of

[77] Ibid.

[78] Katharina Röltgen, Sandra C.A. Nielsen, Oscar Silva, Sheren F. Younes, Maxim Zaslavsky, Cristina Costales, Fan Yang, Oliver F. Wirz, Daniel Solis, Ramona A. Hoh, Aihui Wang, Prabhu S. Arunachalam, Deana Colburg, Shuchun Zhao, Emily Haraguchi, Alexandra S. Lee, Mihir M. Shah, Monali Manohar, Iris Chang, Fei Gao, Vamsee Mallajosyula, Chunfeng Li, James Liu, Massa J. Shoura, Sayantani B. Sindher, Ella Parsons, Naranjargal J. Dashdorj, Naranbaatar D. Dashdorj, Robert Monroe, Geidy E. Serrano, Thomas G. Beach, R. Sharon Chinthrajah, Gregory W. Charville, James L. Wilbur, Jacob N. Wohlstadter, Mark M. Davis, Bali Pulendran, Megan L. Troxell, George B. Sigal, Yasodha Natkunam, Benjamin A. Pinsky, Kari C. Nadeau, Scott D. Boyd, Immune imprinting, breadth of variant recognition, and germinal center response in human SARS-CoV-2 infection and vaccination, Cell, Volume 185, Issue 6, 2022, Pages 1025-1040.e14, ISSN 0092-8674, https://doi.org/10.1016/j.cell.2022.01.018.

SV40 infection in humans with estimates ranging between 2% to 23% in different demographic populations (Butel '12).[79] Additionally, in a population with low SV40 prevalence (2%), there was a very high prevalence of related polyomaviruses JCV (39%) and BKV (82%) (Kean'09).[80] Therefore, modDNA entering cells in such persons carries the significant risk of becoming "replication competent" and making many copies of itself within the nucleus, thus rendering the modDNA *viable* within these human cells.

65. Separate to reproducing the whole plasmid modDNA sequence, the genes encoded by the modDNA can then be "expressed" or "switched on". If there was an increased number of plasmids due to replication, then increased gene expression would be expected from these plasmids within a human host.

66. The modDNA sequence contained in the Pfizer product contains a region called the SV40 *promoter*, which is a partial sequence derived from the SV40 virus. This region assists the cell's machinery in knowing where to start "reading" the genetic code to "switch it on" or "express" the gene. McKernan made the discovery that the Pfizer modDNA contains a very specific section of code comprising two copies of a 72-base sequence, referred to as the SV40 *enhancer*. Previous studies have revealed the importance of this region in allowing the DNA to move from the cytoplasm into the nucleus of a cell (Dean'99).[81] The SV40 is also relevant in an *in vivo* context, as a study demonstrated that the SV40 *enhancer* led to significant differences in gene expression in blood vessels of a rat (Young'03).[82]

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[79] Butel JS. Patterns of polyomavirus SV40 infections and associated cancers in humans: a model. Curr Opin Virol. 2012 Aug;2(4):508-14. doi: 10.1016/j.coviro.2012.06.004. Epub 2012 Jul 6. PMID: 22771310; PMCID: PMC3422415.

[80] Kean JM, Rao S, Wang M, Garcea RL. Seroepidemiology of human polyomaviruses. PLoS Pathog. 2009 Mar;5(3):e1000363. doi: 10.1371/journal.ppat.1000363. Epub 2009 Mar 27. PMID: 19325891; PMCID: PMC2655709.

[81] David A. Dean, Brenda S. Dean, Susanne Muller, and Louis C. Smith, Sequence requirements for plasmid nuclear import Exp Cell Res. 1999 Dec 15; 253(2): 713–722. doi: 10.1006/excr.1999.4716 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4152905/

[82] J L Young 1 , J N Benoit, D A Dean, Effect of a DNA nuclear targeting sequence on gene transfer and expression of plasmids in the intact vasculature. Gene Ther. 2003 Aug;10(17):1465-70. doi: 10.1038/sj.gt.3302021. https://pubmed.ncbi.nlm.nih.gov/12900761/.

67. The presence of SV40 *enhancer* sequence is highly significant because it is pivotal in transferring the modDNA into the nucleus. Many different sequences can be used to "promote" the expression of genes in plasmids, such as the human cytomegalovirus (CMV) or Rous sarcoma virus long terminal repeat (RSV LTR) *promoter* regions. However, they are insufficient to transfer the DNA into the nucleus (Dean'99).[83] Instead, they rely on the cell undergoing mitosis (cell division), whereby the nuclear envelope temporarily breaks down while the cell splits into two daughter cells, followed by the reformation of the nuclear envelope. This renders CMV and RSV LTR regions as significantly more restrictive in the ability of the DNA to get to the nucleus. Instead, the Pfizer modDNA can access the nucleus very efficiently in any cell that has finished dividing. This means the entry of this modDNA to the nucleus is highly likely in a vast number and type of cells.

68. Why did Pfizer choose the SV40 promoter, containing the 72-base pair *enhancer* region to drive expression in their plasmid modDNA, when the technology was meant to be centred around delivering a modRNA product to a cell, not a modDNA product to the nucleus? Pfizer have not explained the unnecessary and high-risk presence of the enhancer.

Palmer and Gilthorpe Section 4.3 Genomic insertion of the plasmid DNA

69. An alternate method for the modDNA (plasmid or linear) to be perpetuated is for it to be integrated into the genomic DNA, contained within the cell nucleus. This ensures that every time the cell divides, an entire copy is made of the genomic DNA (including the integrated modDNA) and inherited by the daughter cells derived from that cell. The prospect of modDNA integration into the genomic DNA opens a plethora of concerns, some of which were expressed by Palmer and Gilthorpe.

70. The risks associated with integration of foreign DNA include, but are not limited to: insertion in the genome leading to disruption of normal gene expression; inheritance of the foreign DNA by offspring (ie the babies of individuals, conceived from sperm

[83] David A. Dean, Brenda S. Dean, Susanne Muller, and Louis C. Smith, Sequence requirements for plasmid nuclear import Exp Cell Res. 1999 Dec 15; 253(2): 713–722. doi: 10.1006/excr.1999.4716 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4152905/ .

or eggs containing the integrated modDNA); and, a range of immunological issues. Each of these issues will be addressed in more detail below.

Location of modDNA insertion into the genome

71. The location of exogenous DNA integration is often random. A study by Wang et al.[84] used an intramuscular injection in mice, followed by a technique called electroporation to transfer plasmid DNA into cells. The electroporation step is used here instead of the LNP (as in the Pfizer and Moderna products) for the transmission of genetic material into cells. Wang et al. could detect four different locations where the plasmid modDNA had integrated in the mouse genome, demonstrating that the integration site may be random (Wang'04).[85] The more modDNA delivered to a cell and the more that is transferred to the nucleus, the higher the probability of a modDNA integration event.

72. If modDNA was to integrate in a range of genomic locations, coupled with the uptake in many different cell types, this could give rise to *mosaicism*. This means that integration in one cell could give rise to a colony of cells through cell division, whereby the daughter cells would contain that same integrated modDNA. Depending on the location and function of the integration, this colony may have a different identity or growth pattern to the neighbouring cells, leading to tissue abnormalities. A number of pathological conditions have been ascribed to *mosaicism* through postzygotic (after the sperm and egg meet, and therefore not inherited) mutations (Queremel-Milani'22).[86] These mosaic conditions are often characterised by

[84] Z Wang, P J Troilo, X Wang, T G Griffiths, S J Pacchione, A B Barnum, L B Harper, C J Pauley, Z Niu, L Denisova, T T Follmer, G Rizzuto, G Ciliberto, E Fattori, N L Monica, S Manam, B J Ledwith, Detection of integration of plasmid DNA into host genomic DNA following intramuscular injection and electroporation Gene Ther. 2004 Apr;11(8):711-21. doi: 10.1038/sj.gt.3302213. https://pubmed.ncbi.nlm.nih.gov/14724672/.

[85] Z Wang, P J Troilo, X Wang, T G Griffiths, S J Pacchione, A B Barnum, L B Harper, C J Pauley, Z Niu, L Denisova, T T Follmer, G Rizzuto, G Ciliberto, E Fattori, N L Monica, S Manam, B J Ledwith, Detection of integration of plasmid DNA into host genomic DNA following intramuscular injection and electroporation Gene Ther. 2004 Apr;11(8):711-21. doi: 10.1038/sj.gt.3302213 https://pubmed.ncbi.nlm.nih.gov/14724672/.

[86] Daniel A. Queremel Milani; Pradip R. Chauhan, Genetics, Mosaicism, StatPearls https://www.ncbi.nlm.nih.gov/books/NBK559193/.

asymmetric growth of tissues and organs (Moog'20).[87] Mosaicism is also a hallmark of cancerous tissues (Thorpe'20).[88]

73. The effect of mosaicism depends on a number of factors including the location of the genetic disruption and the age of the individual. The younger the individual, the greater the proportion of cells that may be affected. This, in turn, may affect a greater number of tissues and organs. In an older individual, the effects of mosaicism may manifest as cancer development and/or progression. The risks associated with Pfizer or Moderna modDNA integrating in different locations in different people is that a wide variety of mosaic conditions may result. This is particularly alarming given the application of the Pfizer and Moderna products to babies as young as 6 months old.

74. Not all DNA integration is random in its location of the genome. Several studies have demonstrated that certain viruses have a propensity to integrate in certain locations (Berry'06).[89] For example, the Human Immunodeficiency Virus (HIV), tends to integrate at sites of active gene transcription (Schroder).[90] This observation is significant because only about 1.5% of our genome encodes for protein-coding genes (ie. genes that produce proteins). So rather than a "random" integration only having a 1.5% chance of occurring near a protein-coding region, the integration within or adjacent to a gene becomes much more likely. By virtue of integration at "active" sites, this concentrates the risks further, as the genes that are relevant to the health of that cell are the ones that are being actively transcribed for the creation of proteins.

75. Insertion of foreign DNA in actively transcribed protein-coding regions, poses a real risk of disrupting key genes important to that tissue. Alternatively, the integration may

[87] Ute Moog, Prof. Dr. Dr. med., Ute Felbor, Prof. Dr. med., Cristina Has, Prof. Dr. med., and Birgit Zirn, Prof. Dr. med. Dr. rer. Nat. Disorders Caused by Genetic Mosaicism, Dtsch Arztebl Int. 2020 Feb; 117(8): 119–125. Published online 2020 Feb 21. doi: 10.3238/arztebl.2020.0119.

[88] Jeremy Thorpe, Ikeoluwa A. Osei-Owusu, Bracha Erlanger Avigdor, Rossella Tupler, and Jonathan Pevsner, Mosaicism in Human Health and Disease. Annu Rev Genet. 2020 Nov 23; 54: 487–510. Published online 2020 Sep 11. doi: 10.1146/annurev-genet-041720-093403.

[89] Charles Berry, Sridhar Hannenhalli, Jeremy Leipzig, Frederic D Bushman, Selection of Target Sites for Mobile DNA Integration in the Human Genome. Plos Computational Biology, November 24, 2006 https://doi.org/10.1371/journal.pcbi.0020157.

[90] Schröder AR, Shinn P, Chen H, Berry C, Ecker JR, Bushman F. HIV-1 integration in the human genome favors active genes and local hotspots. Cell. 2002 Aug 23;110(4):521-9. doi: 10.1016/s0092-8674(02)00864-4. PMID: 12202041.

occur in regulatory "control" sequences, which could lead to the gene(s) in that region being overexpressed. Given the highly active SV40 and T7 promoter sequences found in the Pfizer products, another risk is whether these promoter sequences may insert upstream of key oncogenes (genes that regulate cell growth and cancer). Either scenario can lead to deleterious consequences such as cancer formation.

76. It is not clear where the BNT162b2 or mRNA-1273 modDNA may integrate in the genome. Indeed, it has also been suggested that the modRNA from each of these products may be reverse-transcribed and integrated into the genome via a LINE-1-dependent mechanism (Doerfler'21; Alden'22; Domazet-Loso'22).[91,92,93] This provides two routes of possible genomic integration. Importantly, Palmer and Gilthorpe point out in their report that the EMA documents state no genotoxicity studies were performed by either Pfizer or Moderna. This means that genomic integration may have occurred, and Pfizer and Moderna have not even attempted to look for this possibility, nor have regulators required these critical safety studies which were routinely undertaken prior to Covid.

77. How much genomic integration of their products could there be in the billions of injected men, women and children? Some simplified calculations highlight the severity of the situation:

a) It is claimed that a single Pfizer BNT162b2 dose (of 30 ug) contains **$1.3x10^{13}$ modRNA molecules**, which equates to **13 trillion (**Domazet-Loso'22).[94]

[91] Walter Doerfler, Adenoviral Vector DNA- and SARS-CoV-2 mRNA-Based Covid-19 Vaccines: Possible Integration into the Human Genome - Are Adenoviral Genes Expressed in Vector-based Vaccines? Virus Research Volume 302, September 2021, 198466. https://www.sciencedirect.com/science/article/pii/S0168170221001738?via%3Dihub.

[92] Aldén, M.; Olofsson Falla, F.; Yang, D.; Barghouth, M.; Luan, C.; Rasmussen, M.; De Marinis, Y. Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line. *Curr. Issues Mol. Biol.* 2022, *44*, 1115-1126. https://doi.org/10.3390/cimb44030073.

[93] Domazet-Lošo T. mRNA Vaccines: Why Is the Biology of Retroposition Ignored? *Genes*. 2022; 13(5):719. https://doi.org/10.3390/genes13050719.

[94] Ibid.

b) The number of LNPs within a single dose is reported to be between 10-50 billion (McKernan'23).[95] For a simple calculation if we assume **13 billion LNPs**, then this equates to **1,000 modRNA molecules encapsulated in each LNP**.

c) The data from McKernan et al. demonstrated that the ratio of RNA:DNA could be as low as 9 (Table 1. Agilent Tape Station), and only as high as 68 (Table 2. Qubit data). Therefore, if there are 1,000 molecules of modRNA, then there could be anywhere from approximately **15-100 molecules of modDNA in each and every LNP**.

d) If 15-100 molecules of modDNA are in each LNP, then there could be anywhere between 195 billion (15 x 13 billion) to 1.3 trillion molecules (100 x 13 billion) of modDNA being introduced in a single injection bolus of BNT162b2.

e) A study by Wang et al. demonstrated an integration rate of 0.0003 to 0.05 per cell (or 1 integration for every 20-33,000 cells) using an adenovirus delivery system at 100 billion virus particles in one injection (Wang'22).[96] This is a ten fold higher number of virus particles compared with the expected number of LNPs; however, the LNPs are transfection-ready and adept at avoiding immune surveillance. Whereas one adenovirus particle may carry around 20-40 thousand base pairs (kbp) of DNA, the LNPs are carrying 1,000 copies or fragments of the same ~8,000 bp length of DNA, which multiplies the chances of a given fragment of DNA integrating in the genomic DNA of the human host cell.

[95] K McKernan, Nuclear permeability during cell division Flattening the "won't get to the nucleus" canard, Nepetalactone Newsletter Substack https://anandamide.substack.com/p/nuclear-permeability-during-cell.

[96] Wang, Z., Troilo, P.J., Griffiths, T.G. et al. Characterization of integration frequency and insertion sites of adenovirus DNA into mouse liver genomic DNA following intravenous injection. Gene Ther 29, 322–332 (2022). https://doi.org/10.1038/s41434-021-00278-2.

f) If we allow for a 10-fold difference in adenovirus (Wang'22)[97] vs LNP dosage, the modDNA may **integrate in 1 cell out of every 200 – 330,000** cells that it enters.

g) If the cell is quiescent (not dividing), then only the modDNA fragments that contain the SV40 promoter and enhancer region would be transported to the nucleus. However, in actively dividing cells, the nuclear membrane breaks down and all modDNA fragments would have the potential to locate within a nucleus during the cell division process.

h) The calculations above have been estimated on the Pfizer BNT162b2 dosage. These numbers can be multiplied by more than 3 to account for the larger dosage of Moderna mRNA-1273 (100 ug), assuming the mRNA-1273 product is packaged similarly.

i) Of note, the estimated number of virions present at the peak of a SARS-CoV-2 infection is approximately 1-100 billion (Sender'21).[98] The infection is largely localised to the lungs and upper airways. However, a single injection of BNT162b2 is injecting a bolus of between 10-50 billion LNPs to inside a human body, bypassing all the mucosal immune defences. This represents a very significant difference in the exposure to foreign nucleic acids, in particular exposure of the cell nuclei within the human body.

78. Kevin McKernan cites similar calculations for the quantities of modRNA and modDNA being packaged within LNPs (McKernan'23).[99] McKernan also highlights the ease with which modDNA could be amplified from 1/300th of a Pfizer dose (ie. 1 ul out of a 300 ul dose). modDNA could be clearly detected at a cycle threshold (Ct) of approximately 20. This contrasts with the extremely high Ct value of 35-40 to detect SARS-CoV-2 infection, in some instances. A difference of 20 Cts represents a

[97] Ibid.

[98] Ron Sender, Yinon M. Bar-On, Shmuel Gleizer, and Ron Milo, The total number and mass of SARS-CoV-2 virions June 3, 2021 118 (25) e2024815118 https://doi.org/10.1073/pnas.2024815118.

[99] K McKernan, Nuclear permeability during cell division Flattening the "won't get to the nucleus" canard, Nepetalactone Newsletter Substack https://anandamide.substack.com/p/nuclear-permeability-during-cell.

2^20 or approximately 1,000,000 fold difference in quantities. This means that the amount of modDNA detected is orders of magnitude more (~x10^6) than the amount of viral RNA detected and declared a positive case using Covid PCR tests.

79. The number and range of adverse events reported after use of BNT162b2 and mRNA-1273 has been astronomical. Upon interrogation of the DAEN database, there are a total of 18,151 reported adverse event notifications, including 58 deaths, over a period of 50 years before the rollout of Covid products. In the period between 22 February 2021 and 22 May 2023, since the rollout of the Covid products, there have been 89,159 adverse event reports, including 473 deaths reported, for just the Pfizer and Moderna Covid products combined. This is an indictment on the claim of "safe" (DAEN database[100]: input tradenames 'Comirnaty' and 'Spikevax'). The incidence of genotoxicity as one possible cause of these adverse events requires significant attention and investigation. The sheer quantity of modDNA contamination is a very concerning with the prospect of genotoxicity leading to cancer.

Genomic Integration of modDNA and Risk of Cancer

80. There are locations in the genome where it would be deleterious for foreign modDNA to be inserted. When extraneous DNA is inserted in the normal sequence of genes, the "message" contained within that gene is disrupted, thereby "disabling" the function of the protein encoded by that gene. One significant risk is the incorporation of modDNA into a gene that is a master regulator of cell growth and proliferation. Oncogenes are genes that assist in proper, controlled growth and development of cells, tissues and organs. When these genes are disrupted in some way, this can result in the formation of cancer.

81. While gene therapy is aimed at correcting faulty genetic sequence, one of the big drawbacks to this technology is the risk of cancer formation. In clinical trials that sought to treat *X-linked severe combined immunodeficiency* (SCID) with gene therapy, a number of patients developed a form of leukaemia (Hacein-Bey-Abina'03;

[100] https://www.tga.gov.au/safety/safety/safety-monitoring-daen-database-adverse-event-notifications/database-adverse-event-notifications-daen-medicines.

Staal'08).[101,102] Additionally, a gene therapy trial for *Wiskott-Aldrich syndrome* led to 7 out of 10 patients developing leukaemia, of which 2 died (Kumar'16).[103] These outcomes highlight the very real risks associated with manipulating or introducing genetic code, and the formation of cancers.

82. To date, a number of case reports discuss close temporal relationships with Covid injections and blood and lymphoid cancers (Goldman'21; Zamfir'22; Sekizawa'22; Bresler'22).[104,105,106,107] It should be noted that no carcinogenicity studies were conducted by Pfizer or Moderna (EMA doc pp18-19).

[101] Hacein-Bey-Abina S, von Kalle C, Schmidt M, Le Deist F, Wulffraat N, McIntyre E, Radford I, Villeval JL, Fraser CC, Cavazzana-Calvo M, Fischer A. A serious adverse event after successful gene therapy for X-linked severe combined immunodeficiency. N Engl J Med. 2003 Jan 16;348(3):255-6. doi: 10.1056/NEJM200301163480314. PMID: 12529469.

[102] Staal FJ, Pike-Overzet K, Ng YY, van Dongen JJ. Sola dosis facit venenum. Leukemia in gene therapy trials: a question of vectors, inserts and dosage? Leukemia. 2008 Oct;22(10):1849-52. doi: 10.1038/leu.2008.219. Epub 2008 Sep 4. PMID: 18769449.

[103] Kumar SR, Markusic DM, Biswas M, High KA, Herzog RW. Clinical development of gene therapy: results and lessons from recent successes. Mol Ther Methods Clin Dev. 2016 May 25;3:16034. doi: 10.1038/mtm.2016.34. PMID: 27257611; PMCID: PMC4879992.

[104] Serge Goldman, Dominique Bron, Thomas Tousseyn, Irina Vierasu, Laurent Dewispelaere, Pierre Heimann, Elie Cogan and Michel Goldman, Rapid Progression of Angioimmunoblastic T Cell Lymphoma Following BNT162b2 mRNA Vaccine Booster Shot: A Case Report, Front. Med., 25 November 2021 Sec. Pathology, Volume 8 - 2021 | https://doi.org/10.3389/fmed.2021.798095.

[105] Zamfir, M.-A.; Moraru, L.; Dobrea, C.; Scheau, A.-E.; Iacob, S.; Moldovan, C.; Scheau, C.; Caruntu, C.; Caruntu, A. Hematologic Malignancies Diagnosed in the Context of the mRNA COVID-19 Vaccination Campaign: A Report of Two Cases. Medicina 2022, 58, 874. https://doi.org/10.3390/medicina58070874

[106] Sekizawa A, Hashimoto K, Kobayashi S, Kozono S, Kobayashi T, Kawamura Y, Kimata M, Fujita N, Ono Y, Obuchi Y, Tanaka Y. Rapid progression of marginal zone B-cell lymphoma after COVID-19 vaccination (BNT162b2): A case report. Front Med (Lausanne). 2022 Aug 1;9:963393. doi: 10.3389/fmed.2022.963393. PMID: 35979213; PMCID: PMC9377515.

[107] Scott C. Bresler MD, PhD, Tyler D. Menge MD, Trilokraj Tejasvi MD, Shannon A. Carty MD, Alexandra C. Hristov MD Two cases of challenging cutaneous lymphoid infiltrates presenting in the context of COVID-19 vaccination: A reactive lymphomatoid papulosis-like eruption and a bona fide lymphoma, Journal of Cutaneous Pathology Volume50, Issue 3 https://doi.org/10.1111/cup.14371.

Genomic Integration and Inheritance of modDNA in Offspring

83. Palmer and Gilthorpe raise the concern about genomic integration of the modDNA into oocytes (egg cells in the ovary), or spermatocytes (sperm cells in the testes). Indeed, the LNPs can biodistribute to testes and, to a much greater extent, ovaries (FOI-2389-06-Non-clinical evaluation report pp44-45).[108] If the modDNA was to integrate in either of these cells and give rise to a baby, the modDNA would then be inherited by that baby in all the baby's cells.

84. An important study by Bansal et al. showed the presence of Spike protein on the surface of exosomes in vaccinated patients' blood (Bansal'21).[109] Exosomes are very small lipid vesicles produced by budding off cells, therefore reflecting the contents of the cells from which they originated. Exosomes can contain DNA, RNA and other small bioactive molecules and act as couriers that can transfer the contents of one cell to another, for example, modDNA or modRNA. This raises the plausible scenario that LNP-modDNA/modRNA could be distributed to offspring via exosomes through the placenta or breastmilk.

85. In a recent study, Swingle et al. demonstrated the use of LNPs in the delivery of modRNA to the placenta (Swingle'23).[110] If the Pfizer and Moderna LNP-modDNA/modRNA do in fact traverse the placental barrier, then the baby would receive a dose of these products *in utero*. Hanna et al. importantly showed that modRNA from either Pfizer or Moderna products was found in extracellular vesicles (exosomes are a type of extracellular vesicle) in breastmilk up to 48h post-vaccination. This suggests an infant would receive some dose of these products in

[108] https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf.

[109] Sandhya Bansal, Sudhir Perincheri, Timothy Fleming, Christin Poulson, Brian Tiffany, Ross M. Bremner; Thalachallour Mohanakumar, Cutting Edge: Circulating Exosomes with COVID Spike Protein Are Induced by BNT162b2 (Pfizer–BioNTech) Vaccination prior to Development of Antibodies: A Novel Mechanism for Immune Activation by mRNA Vaccines, J Immunol (2021) 207 (10): 2405–2410. https://doi.org/10.4049/jimmunol.2100637.

[110] Swingle KL, Safford HC, Geisler HC, Hamilton AG, Thatte AS, Billingsley MM, Joseph RA, Mrksich K, Padilla MS, Ghalsasi AA, Alameh MG, Weissman D, Mitchell MJ. Ionizable Lipid Nanoparticles for In Vivo mRNA Delivery to the Placenta during Pregnancy. J Am Chem Soc. 2023 Mar 1;145(8):4691-4706. doi: 10.1021/jacs.2c12893. Epub 2023 Feb 15. PMID: 36789893; PMCID: PMC9992266.

transfection-ready extracellular vesicles (similar to the LNPs).[111] Together, these scenarios are additional routes of "*transfection*" of babies and infants with the modDNA.

Angela Jeanes,
6 July 2023

[111] Hanna N, Heffes-Doon A, Lin X, et al. Detection of Messenger RNA COVID-19 Vaccines in Human Breast Milk. *JAMA Pediatr.* 2022;176(12):1268–1270. doi:10.1001/jamapediatrics.2022.3581.

No. of 20

Federal Court of Australia

District Registry: Victoria

Division: Commercial and Corporations NDA

Sub-area: Regulator and Consumer Protection

Dr Julian Fidge

Applicant

Pfizer Australia Pty Limited

First Respondent

Moderna Australia Pty Limited

First Respondent

This is the annexure marked **"AJ-2"** referred to in the affidavit of Dr Angela Jeanes affirmed before me on 6 July 2023 at [redacted]

Signature of witness:

CL Ashby-Koppens
185 Corlette Street, The Junction, NSW 2291
An Australian legal practitioner within the meaning
of the Legal Profession Uniform Law (NSW)

"AJ-2"

Curriculum Vitae

Angela Jeanes

Contact Details:

Email: [redacted]
ResearcherID:
OrcID:
Scopus:

Personal Summary:

I completed my PhD at the Institute for Molecular Bioscience within The University of Queensland. Over the course of 16 years I developed a range of research projects focussing on the molecular, cellular and environmental aspects of health and disease, specifically relating to embryonic development. I have presented my work at national and international conferences, including in Italy, Japan and the USA, to audiences including both academics and clinicians. Following my tenure as a research-focussed academic, I undertook a position in research grants administration, which gave me insight into the governance and legal aspects of research grant management. My work experiences have led me to acquire highly developed communication skills, both in written and oral form. I have highly trained analytical and problem-solving skills, which have been applied to the biomedical literature, and a range of data types.

Education:

2005 – 2009 **PhD – Institute for Molecular Bioscience,**
University of Queensland. *Field of Study: Molecular Cell Biology*
Supervisor: Prof. Alpha Yap; *Associate Supervisor:* Assoc. Prof. Carol Wicking
NHMRC Dora Lush Biomedical Research Scholarship

2004 **BSc. (Hons) Class I – Institute for Molecular Bioscience,**
University of Queensland. *Field of Study: Developmental Biology/Embryology*
Supervisors: Prof. Peter Koopman and Assoc. Prof. Dagmar Wilhelm.

2000 – 2002 **BSc. – Faculty of Biological and Chemical Sciences,**
University of Queensland. *Field of Study: Molecular and Cellular Biology*

Employment History:

Mar 2021 – Sep 2021 **Research Administration Officer**
Research Office, UQ.
Manager: Dr Lucy Buzacott

May 2016 – Dec 2019 **Postdoctoral Research Fellow**
Institute for Molecular Bioscience, UQ.
Supervisor: Assoc. Prof. Kelly Smith
- ***Cardiovascular Development***

Jan 2014 – Dec 2014: **Postdoctoral Research Fellow/Assistant Lecturer** (0.8 FTE)
School of Biomedical Sciences, UQ.

Jan 2011 – Dec 2013: **Postdoctoral Research Fellow**
School of Biomedical Sciences, University of Queensland
Supervisors: Prof. Stephen Taylor and Prof. Trent Woodruff
- ***Neural Tube Development***

Apr 2009 – Dec 2010: **Research Officer**
Centre for Integrated Preclinical Drug Development (CIPDD)/ TetraQ,
Supervisor: Prof. Rodney Minchin
- ***Morphometric analysis of melanoma***
- ***Analysis of the xenobiotic metabolising enzyme N-acetyltransferase 1 in folate metabolism and cancer***

Jan 2003 – Dec 2003: **Research Assistant/Personal Assistant**
Institute for Molecular Bioscience, University of Queensland
Supervisors: Prof. Peter Koopman and Assoc. Prof. Dagmar Wilhelm.
- ***Gonadal Development***

Scholarships/Awards:

2018: Receipt of the **Travel Award** for the **Weinstein Cardiovascular Development and Regeneration Meeting**, Nara, Japan.

2011: Receipt of the **Marcy Speer Memorial Award for best Trainee presentation** at the 7th International Conference on Neural Tube Defects, Austin, TX, USA.

2006 – 2008: **NHMRC Dora Lush Biomedical Research Scholarship** – IMB, University of Queensland.

2005: **Institute for Molecular Bioscience Postgraduate Research Scholarship** – IMB, University of Queensland.

2006: **Student Scholarship, half registration cost**
Live Cell Imaging Workshop, Monash University, Melbourne.

2001 – 2002: **Summer Vocation Research Scholarship** – School of Biomedical Sciences, University of Queensland.

Funding Support:

2013: SBMS (UQ)/OSMS (Otago) Grant for International Collaboration ($16,000; CIB)

2013: SBMS – Molecular Pathways in Human Disease Program travel award ($2000; CIA)

2011: Travel Funding: School of Biomedical Sciences - assistance to attend 7th International NTD Meeting in Austin, Texas, USA. ($1,500; CIA)

2006 – 2008: NHMRC Dora Lush Biomedical Research Scholarship – IMB, University of Queensland. ($54,255)

PUBLICATIONS:

1. Charlotte D Koopman*, Jessica De Angelis*, Swati P Iyer*, Arie O Verkerk, Jason Da Silva, **Angela Jeanes**, Gregory J Bailey, Cas Simons, Irina Vetter, Benjamin M Hogan, Jeroen Bakkers and Kelly A Smith (2021) The zebrafish *grime* mutant uncovers an evolutionarily conserved role for Tmem161b in the control of cardiac rhthym. ***Proceedings of the National Academy of Sciences*** 118(9), e2018220118 (IF 11.2; 9 citations)
2. Nicholas J. Hudson, Antonio Reverter, William J. Griffiths, Eylan Yutuc, Yuqin Wang, **Angela Jeanes**, Sean McWilliam, David W. Pethick, Paul L. Greenwood (2020) Gene expression identifies metabolic and functional differences between intramuscular and subcutaneous adipocytes in cattle. ***BMC Genomics*** 21:77 (IF 4.0; 12 citations)
3. M. Mahmoudi, **Angela Jeanes**, L. Kidd, D. Poppi, S. Quigley, N.J. Hudson. (2019) Development of a molecular assay to estimate mitochondrial content in cattle tissues. ***EAAP Scientific Series*** 138:401-2.
4. Daniela R. Grassini, Anne K. Lagendijk, Jessica E. De Angelis, Jason Da Silva, **Angela Jeanes**, Neil I. Bower, Benjamin M. Hogan, Kelly A Smith. (2018) Nppa and Nppb act redundantly during zebrafish cardiac development to confine AVC marker expression and reduce cardiac jelly volume. ***Development*** 145(12): dev160739 (IF 6.9; 30 citations)
5. Liam Coulthard, Owen Hawksworth, Rui Li, Anushree Balachandran, John Lee, Farshid Sepehrband, Nyoman Kurniawan, **Angela Jeanes**, David Simmons, Ernst Wolvetang, and Trent Woodruff (2017) Complement C5aR1 Signaling Promotes Polarization and Proliferation of Embryonic Neural Progenitor Cells through PKCζ ***Journal of Neuroscience*** 37(22):5595-5407 (IF 6.2; 51 citations)
6. Kerina J Denny, Christina Kelly, Vinod Kumar, Katey Witham, Robert Cabrera, Richard H Finnell, Stephen M Taylor **Angela Jeanes*,** Trent M Woodruff***** (2016) Autoantibodies Against Homocysteinylated Protein in a Mouse Model of Folate Deficiency-Induced Neural Tube Defects. ***Birth Defects Research: Part A*** *106(3):201-207* (IF 2.7; 15 citations)
7. Trent M Woodruff, Mike CL Wu, Michael Morgan, Nathan T Bain, **Angela Jeanes**, Jeffrey Lipman, Michael J Ting, Andrew W Boyd, Stephen M Taylor, Mark G Coulthard (2016). Epha4-fc treatment reduces ischemia/reperfusion-induced intestinal injury by inhibiting vascular permeability. ***Shock*** *45(2):184-191* (IF 3.5; 15 citations)
8. **Angela Jeanes***, Liam G Coulthard*, Susanna Mantovani, Kathryn Markham, Trent M Woodruff (2015). Co-ordinated expression of innate immune molecules during mouse neurulation. ***Molecular Immunology*** *68(2):253-260* (IF 4.4; 18 citations)
9. Aaron B Ingham, Simone A Osborne, Moira Menzies, Suzie Briscoe, Wei Chen, Kritaya Kongsuwan, Antonio Reverter, **Angela Jeanes**, Brian P Dalrymple, Gene Wijffels, Robert B Seymour and Nicholas J Hudson (2014). Rnf14 is a regulator of mitochondrial and immune function in muscle. ***BMC Systems Biology*** *8(1):10* (IF 4.4; 3 citation)
10. Kerina J Denny*, **Angela Jeanes***, Kristin Fathe, Richard H Finnell, Stephen M Taylor, Trent M Woodruff. (2013) Neural Tube Defects, Folate and Immune Modulation. ***Birth Defects Research: Part A*** *97(9):602-609* (IF 2.7; 28 citations)
11. Kerina J Denny, Liam G Coulthard, **Angela Jeanes**, Steven Lisgo, David G Simmons, Leonie K Callaway, Bogdan Wlodarczyk, Richard H Finnell, Trent M Woodruff, Stephen M Taylor. (2013) C5a Receptor Signaling Prevents Folate Deficiency-Induced Neural Tube Defects in Mice. ***Journal of Immunology*** *190(7):3493-9* (IF 5.4; 37 citations)
12. Jack T.H. Wang, Markus C. Kerr, Seetha Karunaratne, **Angela Jeanes**, Alpha S. Yap and Rohan D. Teasdale. (2010) The SNX-PX-BAR family in macropinocytosis: the regulation of macropinosome formation by SNX-PX-BAR proteins. ***PLoS ONE*** *5(10):e13763* (IF 3.2; 49 citations)

13. **Angela Jeanes**, Michael Smutny, Joanne M. Leerberg, and Alpha S. Yap. (2009) Phosphatidylinositol 3'-Kinase signalling supports cell height in established epithelial monolayers. ***Journal of Molecular Histology*** *40:395-405* (IF 2.6; 21 citations)
14. **Angela Jeanes**, Cara J. Gottardi, Alpha Yap. (2008) Cadherins and cancer: how does cadherin dysfunction promote tumor progression? ***Oncogene*** *27(55):6920-9* (IF 9.9; 638 citations)
15. Haley L. Bennett, Tilman Brummer, **Angela Jeanes**, Alpha S. Yap, Roger J. Daly. (2008) Gab2 and Src co-operate in human mammary epithelial cells to promote growth factor independence and disruption of acinar morphogenesis. ***Oncogene*** *27(19):2693-704* (IF 9.9; 37 citations)
16. **Angela Jeanes**, Dagmar Wilhelm, Megan J. Wilson, Josephine Bowles, Peter J. McClive, Andrew H. Sinclair, Peter Koopman. (2005) Evaluation of candidate markers for the peritubular myoid cell lineage in the developing mouse testis. ***Reproduction*** *130(4):509-16* (IF 3.9; 41 citations)

Citations: 1004 (Scopus); h-index: 12

Attendance at Conferences and Workshops:

2018: The Weinstein Cardiovascular Development and Regeneration Meeting: Nara, Japan. ***Poster Presentation***

2017: The Hunter Meeting Australia: Hunter Valley, NSW. ***Poster Presentation***

2014: The 7th Australian Developmental Biology Workshop: Tangalooma, Moreton Island, Queensland. ***Selected as 1 of 20 participants*** *from Australia and New Zealand*.

Brisbane Cell and Developmental Biology Meeting: TRI, UQ, Brisbane ***Abstract selected for oral presentation***

Australian Physiological Society (AuPS): UQ, Brisbane, Australia ***Organiser***

2013: The 8th International Conference on Neural Tube Defects: Austin, Texas, USA. ***Invited speaker***

Queensland Physiology Interest Group (QPiG), The University of Queensland: "New tricks for ancient molecules: Novel roles for the complement system in mammalian development" ***(Departmental Seminar)***

2012: Brisbane Cell and Developmental Biology Meeting: IMB, UQ, Brisbane ***Poster Presentation***

3rd Brisbane Early Career Researcher Symposium: UQ, Brisbane, Australia ***Organiser***

Australian Society for neuroscience – Satellite Meeting: Neuronal polarity, cytoskeleton and vesicular trafficking in health and disease. QBI, UQ, Brisbane

2011: The 7th International Conference on Neural Tube Defects: Austin, Texas, USA. ***Invited speaker***

The Brisbane Cell and Developmental Biology Meeting: Brisbane. ***Abstract selected for oral presentation***

School of Biomedical Sciences Pharmacology Retreat: Brisbane. ***Oral presentation, Organiser***

2007: Gordon Research Conference: Cell Contact and Adhesion, Il Ciocco, Italy, ***Poster presentation***

2006: ComBio, Brisbane.

2005: The 15th International Society for Developmental Biologists congress: Sydney, ***Poster presentation***

2004: Inaugural Sex Development Workshop: Flowerdale, Victoria, ***Oral presentation***

Science Communication and Engagement:

2017: Panel Member for the public launch of the UQ Centre for Cardiac and Vascular Biology (CCVB), Customs House, Brisbane.

Professional and Personal Development:

2012: Early Career Academic Development Program, University of Queensland.

2009: Women in Technology (WiT): "The Truth About Grant Applications" workshop, Institute of Health and Biomedical Innovation (IHBI), Kelvin Grove, QLD.

2008: IMBcom Biobusiness Retreat, Noosa Springs Resort, Noosa Heads, QLD. A 3-day workshop on the commercialisation of intellectual property arising from scientific research.

2007: Zeiss Confocal Microscopy Advanced Imaging Workshop, IMB, UQ.
Scientific Writing Workshops, IMB, UQ.

2006: Live Cell Imaging Workshop, Monash University, Melbourne.
Hugh Kearns workshop: work management and personal development

2005: 8-Week Course: Introduction to Statistics, IMB, UQ
Science Writing Workshop
IMBcom Biobusiness Workshop on the Commercialisation of Scientific Research, IMB, UQ.

Membership to Professional Societies:

2014 – 2019: Australian Physiological Society
2013 – 2019: Australian & New Zealand Society for Cell and Developmental Biology
International Society for Developmental and Comparative Immunology

2005 – 2006: Australian Society for Biochemistry and Molecular Biology

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Service:

Service within my discipline:-

Manuscript review: *PLoS One*
BMJ Open
Thyroid
The Journal of Immunology
International Journal of Cell Biology and Biochemistry

Grant review: The National Health and Medical Research Council of Australia (2017 – 1 grant, external reviewer)

The "Wellbeing of Women" Charity – UK (2014)

Conference organisation: Brisbane Cell and Developmental Biology Meeting, TRI, Brisbane, 2017 *(Member of organising committee)*

Australian Physiological Society (AuPS) conference, The University of Queensland, 2014 *(Member of organising committee)*

3rd Brisbane Early Career Researcher Symposium, 2012 *(Member of organising committee)*

School of Biomedical Sciences Pharmacology Retreat: Brisbane, 2011 *(Co-organiser)*

Academic Service:-

PhD thesis committee member for:

- Swati Iyer – "The role of Crim1 in heart development" (2014), SBMS, UQ
- Jamileh Nabizadeh – "The Role of Complement Components C3a and C5a in Melanoma" (2012 – 2015), AIBN, UQ

2014: Honours program – written and oral proposal examiner
Group leader – Honours Effective Communication Workshop
Group leader – Honours Journal Club

2013 – Sem2: Chair: Honours proposal seminars – SBMS
Examiner of Honours proposal/thesis

2013 – Sem1: Group leader – Honours Effective Communication Workshop
Chair: Honours proposal seminars – Developmental Biology, SBMS

2012: Organising committee for the 3rd Brisbane Early Career Researcher Poster Symposium
Examiner for Honours proposal/thesis
Host for an external academic speaker in the SBMS Seminar Series

2011: Co-organiser of the SBMS Pharmacology Retreat

Other service within UQ:-

2014: Member of the Early Career Researcher (ECR) Committee, SBMS, UQ.

2006: Member of the Early Career Researcher (ECR) Committee, IMB, UQ.

2006: Student Representative Member on panels for Academic Reappointment interviews, Levels C-E, IMB, UQ.

2006: Co-organiser of Yap Laboratory Retreat

2005 – 2006: President, Students of IMB Association (SIMBA)

LECTURING:

2014: **DEVB3002** – Molecular Mechanisms of Development (*3 lectures*)
(SECaT score = 4.64/5.00)
BIOL2200 – Cell Structure and Function *(2 lectures x 2 streams)*

2013: **DEVB3002** – Molecular Mechanisms of Development (*3 lectures*)
BIOM3402 – Advanced Pharmacology (*1 lecture*)

2012: **BIOM3402** – Advanced Pharmacology (*1 lecture*)

2011: **BIOM3402** – Advanced Pharmacology (*1 lecture*)

PRACTICAL DEMONSTRATING:

2017: **BIOM2208** – Differentiation and Development *(Prac co-ordinator and further development of new prac material)*

2016: **BIOM2208** – Differentiation and Development *(Prac co-ordinator and further development of new prac material)*

2015: **BIOM2208** – Differentiation and Development *(Prac co-ordinator)*

2014: **BIOM3014** – Molecular and Cellular Physiology *(Tutor)*

BIOM2011 – Integrative Cell and Tissue Biology *(Tutor)*

BIOM2208 – Differentiation and Development *(Prac co-ordinator)*

Other Teaching:

2017: **DEVB3002** – Stem Cells and Regenerative Medicine (*6 journal club classes*)

Student supervision:

2018: Poise Aula – *Master of Molecular Biology (Thesis received Distinction)*

2014: Jennifer Keil – *Honours (Class I)*
Chaseleigh Bradley – *Honours (Mid-year completion; Class I)*

2013: Simone Minnie – *undergraduate*

2012: Alexander Samuelowicz-Foster – *Honours (Class I)*
Chaseleigh Bradley – *undergraduate*

2011-2012: Azhar Bin Hamden –*undergraduate*

2010: Gwillym Whittaker – *undergraduate*

No. of 20

Federal Court of Australia

District Registry: Victoria

Division: Commercial and Corporations NDA

Sub-area: Regulator and Consumer Protection

Dr Julian Fidge

Applicant

Pfizer Australia Pty Limited

First Respondent

Moderna Australia Pty Limited

First Respondent

This is the annexure marked **"AJ-3"** referred to in the affidavit of Dr Angela Jeanes affirmed before me on 6 July 2023 at [redacted]

Signature of witness:

CL Ashby-Koppens
185 Corlette Street, The Junction, NSW 2291
An Australian legal practitioner within the meaning
of the Legal Profession Uniform Law (NSW)

"AJ-3"

PJ O'Brien & Associates
185 Corlette Street
The Junction
NSW 2291

3 May 2023

Dr Angela Jeanes

By email only: [redacted]

Dear Dr Jeanes

Letter of Instruction

We act on behalf of Dr Julian Fidge, GP and Pharmacist (**Applicant**).

The Applicant is considering a proposed injunction application pursuant to section 147 of the Gene Technology Act 2000. Such application would be in the Federal Court and be against Moderna and Pfizer for failure to obtain the necessary licences to deal with Genetically Modified Organisms in Australia.

We propose to engage you to produce an expert report to be filed in the proposed action. In your report we ask you to consider and respond to the questions set out in **Schedule 1** to this letter.

As an expert witness you are required to comply with the Expert Code of Conduct set out in the Federal Court Expert Evidence Practice Note (GPN-EXPT), which is hyperlinked but we have also included as **Schedule 2** to this letter. Please confirm as a part of your report that you have read, understand and agree to comply with that Practice Note. Please also include with your report include copy of your current CV.

Once you have had an opportunity to consider this letter and schedules, could you please contact us so we may discuss timing and next steps.

Kind regards

Katie Ashby-Koppens
PJ O'Brien &
Associates
+61 435 791 200

Schedule 1 – Questions posed of you

Part 1 – Do the Pfizer and Moderna 'vaccines for SARS-CoV-2 contain Genetically Modified Organisms

Questions to be Answered

Please begin by considering the following Opening Statement.

Opening Statement (provided)

1. Covid-19 vaccine manufacturers Pfizer and Moderna have taken the SARS-CoV-2 virus and analysed its genomic code (made of RNA).
2. Once understanding the elemental construction for that genomic code, they identified that portion of the genomic code required for the production of the Spike protein part of the SARS-CoV-2 virus,, and then separately they used techniques to produce from scratch, a mo*di*fie*d version* of that isolated genome sequence that encodes for the Spike protein,, to produce the modRNA (nucleoside-modified messenger RNA)) that is subsequently encapsulated in Lipid Nanoparticles (LNP)) found in vials of Pfizer and Moderna Covid-19 vaccines.. This can be understood as the "'LNP-modRNA complex' contained in each vial of thee Pfizer and Moderna Covid-19 vaccines.
3. The modifications from the natural genome sequence involved first isolating that part of the SARS-CoV-2 genome which codes for the Spike protein. Upon mapping and understanding that section of the genome,, the manufacturers then reproduced in the laboratory the same section of the genome that translates to the Spike protein of the virus,, but instead made the following modifications from the natural version, being:

   (i) Pseudouridylation —— being, the replacement of existing uracil nucleotides within the genomic sequence with N1-Methyllpseudouridine for the purpose of stabilising the modRNA against degradation;

   (ii) Codon Optimisation —— being, the exchange of the nucleotides from the original natural mRNA sequence for alternate coding nucleotides which in theory does not change the protein sequence,, where in this instance,, by the inclusion of G-C nucleotides led to an increase in the amount of the protein product translated,, or produced, namely, the Spike protein;

   (iii) 3'UTR modification using a novel 3'UTR specifically targeted to induce exaggerated induction of protein —— being,, the terminal end of the coding sequence of the modRNA is designed in such a way that its modification results in a far higher production of protein from the same modRNA sequence, than could ever be expected in the natural environment.. In this instance the modification to the 3'UTR acts as a biological version of an adjuvant or stimulant.

<u>Question 1</u>

Having considered paragraphs 1 through 3 of the Opening Statement above,, do you agree with the statement? If not, pleaser explain.

Question 2

Having considered the modifications mentioned in paragraph 3(i), (ii), and (iii) above, have these modifications any known risks, and/or have they produced any known risks you are aware of?

Question 3

For the term 'organism', please consider only the following definition to be applicable for defining the term 'organism':

'any biological entity''

Do the LNP-modRNA complexes contained in each of the Pfizer and Moderna Covid-19 vaccines satisfy this definition?

Question 4

Please consider the following phrase:

'capable of transferring genetic material'

Are the LNP-modRNA complexes contained in each of the Pfizer and Moderna Covid-19 vaccines *capable off transferring genetic material?*

Question 5

If yes to Question 4, how does the LNP-modRNA complex transfer genetic material?

Question 6

For the term 'gene technology', please consider only the following definition to be applicable for defining the term 'gene technology':

'any technique for the modification of genes or other genetic material'

Do the LNP-modRNA complexes contained in each of the Pfizer and Moderna Covid-19 vaccines satisfy this definition?

Question 7

If yes to Question 6, specifically, what has been modified in respect of the LNP-modRNA complexes contained in each of the Pfizer and Moderna Covid-19 vaccines - genes or genetic material?

Section 2 – synthetic DNA present in the Pfizer and Moderna Covid-19 vaccines

Opening Statement (provided)

4. Within a preprint paper dated 11 April 2023 titled ***Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose***[1], the study authors disclose the following findings:

> Several methods were deployed to assess the nucleic acid composition of four expired vials of the Moderna and Pfizer bivalent mRNA vaccines.
>
> Multiple assays support DNA contamination that exceeds the European Medicines Agency (EMA) 330ng/mg requirement and the FDAs 10ng/dose requirements.
>
> These data conclude that all Pfizer vectors contain a homoplastic 2 copy 72bp SV40 Enhancer associated with more robust expression and nuclear localization.
>
> Agilent Tape Station™ electrophoresis reveal 7.5 - 11.3 ng/µl of dsDNA compared to the 23.7 -55.9ng/µl of mRNA detected in each 300µl sample. Qubit™ 3 fluorometry estimated 1-2.8ng/µl of DNA and 21.8ng - 52.8ng/µl of RNA. There is higher fragmentation seen in the DNA electrophoresis. The total RNA levels are less than the anticipated 30ug (100ng/µl) and 100ug (200ng/µl) doses suggesting a loss of yield in DNA and RNA isolation, manufacturing variance or RNA decay with expired lots.
>
> This work was further validated by testing 8 unopened Pfizer monovalent vaccines with both qPCR and RT-qPCR.
>
> Multiple methods highlight high levels of DNA contamination in the both the monovalent and bivalent vaccines.
>
> .. it is orders of magnitude higher than the EMAs limit of 330ng DNA/ 1mg RNA.
>
> dsDNA contamination of sequence encoding the spike protein wouldn't require LINE-1 for Reverse Transcription and the presence of an SV40 nuclear localization signal in Pfizer's vaccine vector would further increase the odds of integration.
>
> This also brings into focus if these EMA limits took into consideration the nature of the DNA contaminants. Replication competent DNA should arguably have a more stringent limit. DNA with mammalian promoters or antibiotic resistance genes may also be of more concern than just random background *E.coli* genomic DNA from a plasmid preparation (Sheng-Fowler et al. 2009). Background *E.coli* DNA was measured with qPCR and had CT over 35.

[1] McKernan, K., Helbert, Y., Kane, L. T., & McLaughlin, S. (2023, April 10). Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose. https://doi.org/10.31219/osf.io/b9t7m

> While the sequencing delivered full coverage of the plasmid backbones, it is customary to assemble plasmids from DNase I fragmented libraries. These methods have not discerned the ratio of linear versus circular DNA in the vials. While plasmid DNA is more competent and stable, linear DNA may have higher genome integration risks.

5. Concerning the testing of 8 unopened Pfizer monovalent vaccines the lead author for the above preprint, Kevin McKernan, published his findings on 30 March 2023 in an article titled ***DNA contamination in 8 vials of Pfizer monovalent mRNA vaccines***[2], with results evidencing:

> 8/8 monovalent vaccines sourced from a single case from a single lot of Pfizer monovalent vaccines all fail the EMA specification of 3030:1 RNA:DNA (330ng/mg DNA/RNA). They are over the limit by an order of magnitude (18-70 fold). The DNA contamination is very consistent and the vial to vial ratio of RNA:DNA is very consistent within the same lot of monovalent vaccines.

6. The following indented section heavily summarises the recent paper by Palmer (MD) and Gilthorpe (PhD), *COVID-19 mRNA vaccines contain excessive quantities of bacterial DNA: evidence and implications*, analysing the data returned by Kevin McKernan and presented in three articles[3] prior to publication of the preprint in paragraph 4 above:

> Nucleic acids were extracted from the Pfizer and Moderna vaccine samples.
>
> The nucleic acids were mixed with a suspension of *E. coli* cells that had been rendered competent for DNA uptake.
>
> The *E. coli* were spread onto Petri dishes filled with solidified growth medium containing kanamycin.
>
> Kanamycin will kill any *E. coli* cells that do not contain a resistance gene to it.
>
> Observed growth of bacterial colonies on those Petri dishes confirmed acquired resistance to kanamycin by taking up and propagating plasmid DNA.
>
> This was observed with both the Pfizer and the Moderna vaccine samples.
>
> Only circular plasmid DNA molecules, but not linearized DNA, can be efficiently introduced into *E. coli*, evidencing therefore plasmid DNA had escaped the linearization step during manufacturing by Pfizer and Moderna.

---

[2] McKernan, 30 March 2023: DNA contamination in 8 vials of Pfizer monovalent mRNA vaccines; see also McKernan,25 March 2023: DNA contamination in Pfizer monovalent vaccines.

[3] K. McKernan, 16 February 2023: *Deep sequencing of the Moderna and Pfizer bivalent vaccines identifies contamination of expression vectors designed for plasmid amplification in bacteria*;
K. McKernan, 9 March 2023: *Pfizer and Moderna bivalent vaccines contain 20-35expression vector and are transformation competent in E.coli*;
K. McKernan, 30 March 2023: *DNA contamination in 8 vials of Pfizer monovalent mRNA vaccines*.

The number of bacterial colonies observed in this experiment was not high, indicating an unknown quantity of the DNA had been linearized.

The exact proportions of circular and linear DNA in the mixtures remains to be determined.

Additionally, quantitation by *multiplex* PCR of both DNA and mRNA contained in the Pfizer and Moderna vaccines was undertaken to determine the abundance of DNA contamination, targeting the Spike protein gene (in the mRNA and plasmid DNA) and the kanamycin resistance gene (in the plasmid DNA only).

The DNA contamination is likely causing extended duration of spike protein expression.

Multiple studies[4] on vaccinated individuals evidence that both the spike protein itself and the modRNA encoding it can be detected in the bloodstream and in various organs, for weeks and even months after the injection.

For the bacterial plasmid DNA to support prolonged expression of the spike protein, two conditions must be fulfilled:

1. the plasmid DNA must persist inside our body cells, and
2. the spike protein gene on that plasmid must be transcribed into mRNA by our own cellular RNA polymerase II.

Recombinant plasmids expressing coagulation factor IX have been found to persist in the liver cells of experimental animals at stable levels for up to 1.5 years[5].

Recombinant viral DNA has been shown to persist in linear form within animals for equally long periods of time[6], which suggests that the same can occur with the linearised plasmid DNA of both Pfizer and Moderna.

---

[4] S. Bansal et al.: *Cutting Edge: Circulating Exosomes with COVID Spike Protein Are Induced by BNT162b2 (Pfizer-BioNTech) Vaccination prior to Development of Antibodies: A Novel Mechanism for Immune Activation by mRNA Vaccines*. J. Immunol. 207 (2021), 2405– 2410; J. A. S. Castruita et al.: *SARS-CoV-2 spike RNA vaccine sequences circulate in blood up to 28 days after COVID-19 vaccination*. APMIS 131 (2023), 128–132; T. E. Fertig et al.: *Vaccine mRNA Can Be Detected in Blood at 15 Days Post-Vaccination*. Biomedicines 10 (2022), 1538; E. Magen et al.: *Clinical and Molecular Characterization of a Rare Case of BNT162b2 mRNA COVID-19 Vaccine-Associated Myositis*. Vaccines 10 (2022); K. Röltgen et al.: *Immune imprinting, breadth of variant recognition and germinal center response in human SARS-CoV-2 infection and vaccination*. Cell (2022).

[5] C. H. Miao et al.: *Long-term and therapeutic-level hepatic gene expression of human factor IX after naked plasmid transfer in vivo*. Mol. Ther. 3 (2001), 947–57; X. Ye et al.: *Complete and sustained phenotypic correction of hemophilia B in mice following hepatic gene transfer of a high-expressing human factor IX plasmid*. J. Thromb. Haemost. 1 (2003), 103–11.

The spike protein gene contained in Pfizer's and Moderna's expression plasmids is under the control of a T7 bacteriophage promoter. It has been experimentally confirmed[7] that the T7 promoter also binds the cellular RNA polymerase II and causes protein expression in mammalian cells.

As such the possibility that the observed long-lasting expression of spike protein is caused by the plasmid DNA contained in the mRNA vaccines must be taken seriously, and creates an altogether unacceptable safety risk.

Pfizer's bivalent vaccine plasmid DNA contamination also contains the Simian Virus 40 (SV40) DNA sequence for promoting antibiotic resistance. The protein encoded by this resistance gene will be expressed in any cell containing this DNA. Like the spike protein, this protein is a foreign antigen and may therefore trigger an immune attack on the cells expressing it.

The SV40 promoter also includes an internal origin of replication that can potentially cause copies of the plasmid to be made inside human cells. This replication would require either the SV40 virus itself, which already infects a minority of humans, or by the human BK or JC polyomaviruses[8]. Any additional copies of the plasmid DNA generated would amplify the risk of genomic integration with human DNA and increase the risk of malignant tumours associated[9] with the SV40 virus.

This detection of copious amounts of plasmid DNA in both manufacturers' vaccines obviates the need to make that case genomic insertion of the plasmid DNA is occurring, as no specific sequence features are necessary for such integration to occur.

The stable chromosomal integration of a bacterial plasmid into the chromosomal DNA of mammalian cells was demonstrated as early as 1982[10]. The plasmid in question shares multiple features with those used in the production of Moderna's and Pfizer's mRNA bivalent vaccines.

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[6] L. Jager and A. Ehrhardt: *Persistence of high-capacity adenoviral vectors as replication-defective monomeric genomes in vitro and in murine liver*. Hum. Gene Ther. 20 (2009), 883–96.
[7] Y. Q. Li et al.: *The function of T7 promoter as cis-acting elements for polymerase II in eukaryotic cell*. Yi Chuan Xue Bao 27 (2000), 455–61.
[8] J. A. DeCaprio and R. L. Garcea: *A cornucopia of human polyomaviruses*. Nat. Rev. Microbiol. 11 (2013), 264–76; I. Hussain et al.: *Human BK and JC polyomaviruses: Molecular insights and prevalence in Asia*. Virus Res. 278 (2020), 197860.
[9] J. C. Rotondo et al.: *Association Between Simian Virus 40 and Human Tumors*. Front. Oncol. 9 (2019), 670.
[10] P. J. Southern and P. Berg: *Transformation of mammalian cells to antibiotic resistance with a bacterial gene under control of the SV40 early region promoter*. J. Mol. Appl. Genet. 1 (1982), 327–41.

The introduction of foreign or modified genes into mammalian cells using this and similar techniques has since become commonplace in experimental research and in biotechnology. The methodology is referred to as *transfection*, and organisms modified in this manner as *transgenic*. Stable integration can occur with both linear and circular plasmid DNA[11].

In this context, further consideration of the study previously published by Aldén *et al*[12], who detected DNA copies of the spike protein gene in a human liver cells exposed to the Pfizer monovalent mRNA vaccine, must, in light of McKernan's discovery that Pfizer vaccine vials contain substantial amounts of DNA, consider it equally possible that the observations by Aldén *et al* indicated the cellular uptake of this DNA contamination.

When genomic integration of exogenous recombinant DNA occurs at the wrong place within the genome, it frequently induces malignant diseases, especially leukemia[13].

The human genome contains multiple genes which may give rise to cancer if their expression level - the rate at which mRNA and protein molecules are synthesized from them - is altered by integrated foreign DNA which causes their expression levels to become too low or too high. A foreign DNA molecule may insert directly into such a gene and knock it out altogether, potentially halting the tumour suppressor function of a gene. These effects have been seen not only with viral DNA but also with bacterial plasmid DNA[14].

Oocytes – immature ovum - can be transfected (with foreign DNA) in the body at certain stages of maturation[15], and so can sperm-producing cells within the testes[16]. In the latter case, the offspring of such treatment were shown to be transgenic. It can therefore not be ruled out that persons injected with mRNA vaccines that also contain DNA will subsequently give rise to transgenic children. DNA insertion into germline cells might also interfere with early intrauterine development and thereby induce miscarriages or malformations.

---

[11] G. Stuchbury and G. Münch: *Optimizing the generation of stable neuronal cell lines via pre- transfection restriction enzyme digestion of plasmid DNA*. Cytotechnology 62 (2010), 189–94.
[12] M. Aldén et al.: *Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line*. Curr. Issues Mol. Biol. 44 (2022), 1115–1126.
[13] F. J. T. Staal et al.: *Sola dosis facit venenum. Leukemia in gene therapy trials: a question of vectors, inserts and dosage? Leukemia* 22 (2008), 1849–1852.
[14] W. Doerfler et al.: Inheritable epigenetic response towards foreign DNA entry by mammalian host cells: a guardian of genomic stability. Epigenetics 13 (2018), 1141– 1153.
[15] A. Laurema et al.: *Transfection of oocytes and other types of ovarian cells in rabbits after direct injection into uterine arteries of adenoviruses and plasmid/liposomes*. Gene Ther. 10 (2003), 580–4.
[16] S. Dhup and S. S. Majumdar: *Transgenesis via permanent integration of genes in repopulating spermatogonial cells in vivo*. Nat. Methods 5 (2008), 601–3.

> In the study by Wang *et al*[17], significant plasmid DNA transfection into cells was observed after intramuscular injection followed by electroporation [electric field applied to promote transfection/entry of plasmid DNA into cells] – up to a 34 fold increase.
>
> While electroporation did increase the cellular uptake of the injected DNA, it was likely much less effective in this regard than the lipid nanoparticles contained in the mRNA vaccines would be[18], due to the extensive bio-distribution LNPs achieve throughout the human body, enabling magnitudes more DNA plasmids to be presented to magnitudes more cell varieties, which DNA plasmids are then aided by the transfection properties of the LNPs, for cellular entry throughout the human body.

7. In a follow-up article by lead author Kevin McKernan to the preprint in paragraph 4, titled ***LNP packaging of dsDNA***[19], McKernan further tested the same Covid-19 vaccines and was able to demonstrate:

> Over half of the DNA contamination in the vaccines is DNaseI resistant. This implies the DNA is protected by the LNPs and the DNA is packaged in the LNPs.
>
> This data also suggests some of the DNA is not packaged.

Question 8

Can the recombinant DNA discovered in each of the Pfizer and Moderna Covid-19 vaccine vials examined, be said to be vials containing 'LNP-modDNA complexes'?

Question 9

For the term 'organism', please consider only the following definition to be applicable for defining the term 'organism':

'any biological entity'

Do the linear and plasmid LNP-modDNA complexes contained in each of the Pfizer and Moderna Covid-19 vaccines satisfy this definition?

[17] Z. Wang et al.: *Detection of integration of plasmid DNA into host genomic DNA following intramuscular injection and electroporation*. Gene Ther. 11 (2004), 711–21.
[18] Tanaka et al: *Improvement of mRNA Delivery Efficiency to a T Cell Line by Modulating PEG-Lipid Content and Phospholipid Components of Lipid Nanoparticles*. Pharmaceutics. 2021 Dec; 13(12): 2097.
[19] McKernan, 27 APRIL 2023: LNP packaging of dsDNA.

Question 10

Please consider the following term:

'viable'

Are the linear or plasmid LNP-modDNA complexes contained in each of the Pfizer and Moderna Covid-19 vaccines viable?

Question 11

Please consider the following phrase:

'capable of transferring genetic material'

Are the linear or plasmid LNP-modDNA complexes contained in each of the Pfizer and Moderna Covid-19 vaccines capable of transferring genetic material?

Question 12

If yes to Question 11, how do the linear and plasmid LNP-modDNA complexes transfer genetic material?

Question 13

For the term 'gene technology', please consider only the following definition to be applicable for defining the term 'gene technology':

'any technique for the modification of genes or other genetic material'

Do the linear and plasmid LNP-modDNA complexes contained in each of the Pfizer and Moderna Covid-19 vaccines satisfy this definition?

Question 14

If yes to Question 13, specifically, what has been modified in respect of the LNP-modDNA complexes contained in each of the Pfizer and Moderna Covid-19 vaccines - genes or genetic material?

Question 15

Having considered paragraphs 4 through 7 of the Opening Statement above, and the complete findings and data in the references provided, do you agree with the concerns identified by Palmer and Gilthorpe in paragraph 6, as regards the presence of linear and plasmid DNA in the Pfizer and Moderna products?

If yes, which parts of their analysis do you agree with?

If yes, are there any further issues or concerns not discussed by Palmer and Gilthorpe?

Schedule 2 – Expert Code of Conduct

Expert Code of Conduct

ANNEXURE 2

Human Rights Violations

1. 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.

2. 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.

3. 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.**

4. 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.

5. 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.

6. 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.

7. 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.

8. 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.