

4 July 2023

**U R G E N T**

Secretary, Department of Health  
Department of Health and Aged Care  
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**By email only:**

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Attention: Dr Brendan Murphy

Dear Dr Murphy,

**Failure to obtain the necessary licences to deal with Genetically Modified Organisms in Australia: Pfizer and Moderna Monovalent and Bivalent Covid-19 products.**

**Excessive synthetic modDNA contamination in the Pfizer and Moderna Monovalent and Bivalent Covid-19 products.**

1. We act for Dr Julian Fidge.
2. We refer to the provisional approvals and consequential supply of the Pfizer and Moderna Covid-19 vaccines:
  - a) COMIRNATY (tozinameran, original) (Monovalent); and
  - b) COMIRNATY Original/Omicron BA.4-5 COVID-19 vaccine (Bivalent); and
  - c) SPIKEVAX (elasomeran, original) (Monovalent); and
  - d) SPIKEVAX Original/Omicron vaccine (Bivalent),(together the **Products**).
3. On instruction, we demand the Therapeutics Goods Administration (**TGA**) immediately cause Pfizer and Moderna to cease *dealing* with the Covid-19 Products in Australia on the basis that:

- a) Pfizer and Moderna have not obtained the necessary licences to deal with the Products as they constitute 'genetically modified organisms' (**GMO**) in Australia; and
- b) the Products are contaminated with cell-substrate modDNA grossly in excess of acceptable levels.

Each of these matters give rise to breaches of the *Gene Technology Act 2000* (**GT Act**) and *Therapeutic Goods Act 1989* (**TG Act**). We deal with each, under their own headings below.

## **Part A.**

### **The Pfizer and Moderna Covid-19 modRNA Products are Genetically Modified Organisms that are being Supplied in Australia without the appropriate Licence**

#### **The LNP-modRNA Complexes**

4. Pfizer and Moderna know the Products contain GMOs and are therefore in breach of sections [32](#) and [33](#) GT Act.
5. In order to deal with GMOs in Australia, Pfizer and Moderna were required to apply for the necessary licences from the Gene Technology Regulator under section [40](#) of the GT Act (as AstraZeneca did for its Covid-19 vaccine).
6. The GT Act [defines](#) a GMO as an organism that has been modified by gene technology where an 'organism' means any biological entity that is capable of transferring genetic material.
7. The transferred genetically modified material is the nucleoside-modified messenger Ribonucleic Acid (**modRNA**) that is encapsulated in Lipid Nanoparticles (**LNPs**) of the Products, which together form LNP-modRNA complexes. The modRNA is the modified genomic code for the Spike protein from the Ribonucleic Acid (**RNA**) of the SARS-CoV-2 virus.
8. For the purposes of the GT Act, the Pfizer and Moderna Products are GMO/s as the LNP-modRNA complex variously transfers the synthetic modRNA throughout the Human body as follows:
  - a) The LNP-modRNA complex transfers the modRNA from the injection site throughout the human body, bio-distributing to virtually all organs.
  - b) The LNP-modRNA complex then transfers the modRNA genetic material across and through the cell membranes of the cells composing affected organs, delivering the modRNA into the cytoplasm of cells.

- c) The modRNA is then further transferred from the cytoplasm into the cell nucleus where human Deoxyribonucleic Acid (**DNA**) is located, due to the Nuclear Localisation Signal (**NLS**) sequence contained within the Spike protein translated by the modRNA.<sup>1</sup>
- d) On entering the cell nucleus the modRNA from the Products have been observed to reverse-transcribe into human DNA.<sup>2</sup> This is supported by previous work on the molecular and evolutionary aspects of retroposition in murine and human populations, which clearly documents the frequent integration of modRNA molecules into genomes, including in the clinical context.<sup>3</sup>
- e) Once in the nucleus the modRNA is further transferred and integrated with chromosomal DNA, as evidenced by mice pre-exposed to the modRNA-LNP platform passing down acquired immune traits to their offspring.<sup>4</sup>

## ii. The LNP-plasmidDNA & LNP-truncatedDNA Complexes

- 9. Both the Monovalent and Bivalent Products are contaminated with and contain whole plasmid modDNA and truncated/linear forms of the same plasmid modDNA, the further details of which are contained in Part B.
- 10. By virtue of the contents of this letter, or prior to receipt of this letter, Pfizer and Moderna know/knew the Products contain whole plasmid modDNA and truncated forms of the same plasmid modDNA that are GMOs and therefore are in breach of sections 32 and 33 GT Act.
- 11. In order to deal with GMOs in Australia, Pfizer and Moderna were required to apply for the necessary licences from the Gene Technology Regulator under section 40 of the GT Act (as AstraZeneca did for its Covid-19 vaccine).
- 12. The GT Act defines a GMO as an organism that has been modified by gene technology where an 'organism' means any biological entity that is viable and capable of transferring genetic material. As the identified plasmid modDNA can possibly become replication competent after transfection, it must be deemed to be 'viable' until conclusively proven otherwise.

<sup>1</sup> See 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.

<sup>2</sup> See 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; and Jiang, Hui, and Ya-Fang Mei. 2021. "[SARS-CoV-2 Spike Impairs DNA Damage Repair and Inhibits V\(D\)J Recombination In Vitro](#)" *Viruses* 13, no. 10: 2056. <https://doi.org/10.3390/> (this latter paper was only withdrawn after inappropriate pressure was exerted upon the authors).

<sup>3</sup> See Domazet-Lošo, T. [mRNA Vaccines: Why Is the Biology of Retroposition Ignored?](#) *Genes* 2022, 13, 719.

<sup>4</sup> See Zhen Qin, Aurélie Bouteau, Christopher Herbst, Botond Z. Igyártó [Pre-exposure to mRNA-LNP inhibits adaptive immune responses and alters innate immune fitness in an inheritable fashion](#) (September 2022).

13. The transferred genetically modified organism is the wholly synthesized cell-substrate modDNA (**plasmid modDNA**) used for the production of the modRNA, and truncated forms of the same plasmid modDNA, which whole and truncated modDNA is encapsulated in the LNPs of the Products, which together form LNP-modDNA complexes.
14. For the purposes of the GT Act, the Pfizer and Moderna Products are GMO/s as the LNP-modDNA complexes variously transfers this cell-substrate modDNA throughout the Human body as follows:
  - a) The LNP-modDNA complex transfers the whole and truncated modDNA from the injection site throughout the human body, bio-distributing to virtually all organs.
  - b) The LNP-modDNA complex then transfers the whole and truncated modDNA genetic material across and through the cell membranes of the cells of affected organs, delivering the modDNA into the cytoplasm of cells.
  - c) The modDNA is then further transferred from the cytoplasm into the cell nucleus where human DNA is located.
15. There is long established science of LNPs encapsulating plasmid DNA, transfecting human cells. The LNPs used by Pfizer and Moderna in the Products readily encapsulate both the truncated and whole plasmid modDNA, for efficient transfection into human cells. Once within the cytoplasm this modDNA gains entry to the nucleus via nuclear envelope reformation at telophase, or with the assistance of the NLS sequence forming part of the Spike protein created by the synthetic modRNA also transfected into cells along with the truncated and plasmid modDNA, or with the assistance of the SV40 sequence contained within the plasmid modDNA which has long been known to assist nuclear transport. The scientific literature is abundant on the subject of LNP encapsulated plasmid DNA transfection into mammalian cells, and the subsequent localization into the cell nucleus, showing transgene expression in all major organs including heart, lung, liver, spleen, and kidney.<sup>5</sup>
16. After entry into the nucleus, of the truncated/linear and plasmid modDNA:
  - a) The plasmid modDNA can become replication competent, meaning it self-replicates independently of any chromosomal replication<sup>6</sup>.
  - b) Subsequent copies of that plasmid modDNA (replications) are able to transcribe further modRNA for the translation of further quantities of synthetic Spike protein<sup>7</sup>.
  - c) The plasmid modDNA is able to integrate into chromosomal DNA<sup>8</sup>, where:

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<sup>5</sup> See the peer reviewed literature in Schedule 1.

<sup>6</sup> Ibid.

<sup>7</sup> Ibid.

<sup>8</sup> Ibid.

- i) Further transcription of modRNA for further synthetic Spike protein can occur.
  - ii) Integration near oncogenes threatens to stimulate cancer in otherwise healthy humans.
  - iii) Integration near tumour suppressor genes such as P53 and other immune-related genes threatens to reduce the effectiveness of innate tumour suppression.
  - iv) The integrated plasmid modDNA with significant probability will likely be inherited by offspring.
- d) The truncated/linear modDNA is able to integrate into chromosomal DNA<sup>9</sup>, where:
- i) Integration near oncogenes threatens to stimulate cancer in otherwise healthy humans.
  - ii) Integration near tumour suppressor genes such as P53 and other immune-related genes threatens to reduce the effectiveness of innate tumour suppression.
  - iii) The integrated truncated/linear modDNA with significant probability will likely be inherited by offspring.

17. The above is all information known to the TGA, Office of the Gene Technology Regulator (**OGTR**), the Gene Technology Regulator (**GTR**), the Gene Technology Technical Advisory Committee (**GTTAC**), Pfizer and Moderna or should have been known to the TGA, OGTR, the GTR, the GTTAC, Pfizer and Moderna before and at the time of the respective applications ('the applications') to the TGA for provisional approval of the Products. If the TGA, OGTR, the GTR, the GTTAC, Pfizer and Moderna did not know before or at the time:

- a) In respect of the LNP-modRNA GMOs:
- i) It was criminally reckless and/or criminally negligent for Pfizer and Moderna to not be aware before or at the time of the applications; and
  - ii) It was reckless and/or negligent for the TGA to not be aware before or at the time of the applications, or the TGA knowingly allowed these products to contain GMOs (LNP-modRNA). We note you and your office received sworn affidavit evidence of these LNP-modRNA GMOs during High Court proceedings S162/2022 on or about 21

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<sup>9</sup> Ibid.

December 2021, and that you chose not to act on that information;  
and

- iii) Before the Secretary of Health could evaluate Pfizer and Moderna under section 25(1)(d) of the *TG Act* before deciding to grant provisional registration under section 25(3) for the entry of Pfizer and Moderna onto the Australian Register of Therapeutic Goods (ARTG), the Secretary of Health was first required to give written notice to the Gene Technology Regulator under [section 30C\(2\)](#), seeking advice from the Gene Technology Regulator, as the Products contain a 'genetically modified organism' (LNP-modRNA) under [section 30C\(1\)\(a\)](#). The Secretary of Health failed to give written notice under section 30C(2); and
- iv) The subsequent peer reviewed papers of early 2022 to date informed the TGA, OGTR, the GTR, the GTTAC, Pfizer and Moderna, and confirmed the Products contain GMOs.

b) In respect of the LNP-modDNA GMOs:

- i) It was criminally reckless and/or criminally negligent for Pfizer and Moderna to not be aware before or at the time of the applications; and
- ii) It was reckless and/or negligent for the TGA to not be aware before or at the time of the applications, or the TGA knowingly allowed these products to contain GMOs (LNP-modDNA); and
- iii) Before the Secretary of Health could evaluate Pfizer and Moderna under section 25(1)(d) of the *TG Act* before deciding to grant provisional registration under section 25(3) for the entry of Pfizer and Moderna onto the Australian Register of Therapeutic Goods (ARTG), the Secretary of Health was first required to give written notice to the Gene Technology Regulator under [section 30C\(2\)](#), seeking advice from the Gene Technology Regulator, as the Products contain a 'genetically modified organism' (LNP-modDNA) under [section 30C\(1\)\(a\)](#). The Secretary of Health failed to give written notice under section 30C(2); and
- iv) The subsequent information published by Kevin McKernan informed Pfizer and Moderna and confirmed the Products contain synthetic modDNA GMOs (see Part B); and

- v) By receipt of this letter the TGA, OGTR, the GTR, the GTTAC, Pfizer and Moderna have been informed the Products contain synthetic modDNA GMOs.

18. Therefore, Pfizer and Moderna have contravened and satisfied both sections [32](#) and [33](#) of the GT Act, in that Pfizer and Moderna have dealt with the Products:

- a) Knowing they are GMOs (either knowingly or were reckless as to that fact or were negligent in not becoming aware of the fact);
- b) They did so without a GMO licence; and
- c) There was no emergency dealing determination, nor a notifiable low risk dealing, an exempt dealing, and the dealing was not included on the GMO Register.

19. In respect of paragraphs 17 and 18, a further legal assessment is required for determining whether the TGA has also committed the offence of *Complicity and common purpose* under [section 11.2](#) of the [Criminal Code Act 1995](#).

## **Part B.**

### **The Pfizer and Moderna Covid-19 Products contain Dangerously Excessive DNA Contamination**

20. The Products contain cell-substrate modDNA contamination, where:

- a) The cell-substrate modDNA contamination grossly exceeds *per dose* limits published by the TGA<sup>10</sup> of less than or limited to 10ng per dose.
- b) The Monovalent Product of Pfizer has been found to contain consistently high levels of contamination in excess of 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)**”<sup>11</sup>;
- c) The Bivalent Products contain higher contamination. The TGA states contamination be less than or limited to 10ng per dose, whereas:
  - i) The Moderna Bivalent product has been found<sup>12</sup> to contain modDNA contamination from 52-479 times over the limit; and

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<sup>10</sup> TGA: [Guidance 18: Impurities in drug substances and drug products](#).

<sup>11</sup> Supra n 15 in paragraph 24.

<sup>12</sup> Ibid.

- ii) The Pfizer Bivalent product has been found<sup>13</sup> to contain modDNA contamination from 54-476 times over the limit.

**Important Note:** The TGA and EMA limits were 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, modDNA encapsulated in LNPs evade immune attack and possess a high transfection efficiency, meaning, the LNP-modDNA complexes possess a very high likelihood that they will directly enter cells.

21. We repeat here sub-paragraphs 14(a), 14(b), 14(c), and paragraphs 15 and 16 above.

22. Further, excessive DNA contamination (exacerbated by repeated doses further multiplying the excessive quantities), is often associated with<sup>14</sup>, and will likely result in:

- a) Extended duration of synthetic Spike protein expression for an unknown period of time, possibly years;
- b) Promotion of antibiotic resistance within the human host and throughout communities;
- c) Replication of the plasmid modDNA within the human host;
- d) Genomic insertion of the truncated/linear and plasmid modDNA into human chromosomal DNA;
- e) Genomic integration inducing malignant diseases;
- f) Transfection into Oocytes and sperm-producing cells leading to:
  - i) Transgenic offspring;
  - ii) Interference with early intrauterine development;
  - iii) Induction of miscarriages and malformations.

23. The levels of contamination in the Products suggest that:

- a) Pfizer and Moderna failed to undertake simple, cheap, and quick testing necessary for quality control and quality assurance of the Products, or knowingly allowed these products to contain variable and publicly unspecified contaminants; and

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<sup>13</sup> Ibid.

<sup>14</sup> Schedule 2 provides peer reviewed literature in support of 22(a)-(f).



- b) The TGA failed to monitor the Products generally using simple, cheap, and quick testing, or knowingly allowed these products to contain variable and unspecified modDNA contaminants.

24. The identification of this significant modDNA contamination in the Products occurred in February 2023 by Kevin McKernan *et al*<sup>15</sup>, an expert in genomics and sequencing<sup>16</sup>, who is engaged in independent and ongoing analysis of vial contents of the Moderna and Pfizer Monovalent and Bivalent gene therapies.

## **Part C**

### **Sponsor Obligations to the Therapeutic Goods Administration**

25. Pursuant to sections [29A](#) and [29AA](#) of the TG Act, Pfizer and Moderna are required to provide to the TGA information it becomes aware of that:
- a) **contradicts** information already furnished by it in respect of therapeutic goods which are registered to Pfizer (ss 29AA(2)(a));
  - b) may have an unintended harmful effect (ss 29AA(2)(b));
  - c) indicates that the quality, safety or efficacy of the goods is unacceptable (ss 29AA(2)(c)).

As the contamination testing undertaken by McKernan *et al* clearly sets forth the methodology involved and only requires less than 2 hours to perform and validate, the TGA must immediately test the Pfizer and Moderna Products to confirm the modDNA contamination, where once confirmed, and in light of the modDNA and modRNA also satisfying the [Section 10](#) legal definitions for being deemed GMOs, will obligate the TGA to immediately cancel the provisional approvals of the Products granted to Pfizer and Moderna forthwith.

Kind regards



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<sup>15</sup> See Schedule 3 for the McKernan *et al* Preprint, methods, results, and references.

<sup>16</sup> Schedule 4 contains the Curriculum Vitae of Kevin McKernan.

CC:

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## Schedule 1 – Peer reviewed literature

- Liu *et al* 2021: [Gene Therapy with Plasmid DNA](#)
- Moreau *et al* 1985: [The SV40 72 base repair repeat has a striking effect on gene expression both in SV40 and other chimeric recombinants](#)
- Prasad *et al* 2005: [The role of plasmid constructs containing the SV40 DNA nuclear-targeting sequence in cationic lipid-mediated DNA delivery](#)
- Miller *et al* 2008: [Cell-specific nuclear import of plasmid DNA in smooth muscle requires tissue-specific transcription factors and DNA sequences](#)
- Young *et al* 2003: [Effect of a DNA nuclear targeting sequence on gene transfer and expression of plasmids in the intact vasculature](#)
- Escriou *et al* 1998: [Cationic lipid-mediated gene transfer: analysis of cellular uptake and nuclear import of plasmid DNA](#)
- Antonietta *et al* 1999: [Gene delivery: A single nuclear localization signal peptide is sufficient to carry DNA to the cell nucleus](#)
- Tseng *et al* 1999: [Mitosis enhances transgene expression of plasmid delivered by cationic liposome](#)
- Hwang *et al* 2001: [Liver-targeted gene transfer into a human hepatoblastoma cell line and in vivo by sterylglucoside-containing cationic liposome](#)
- Hong *et al* 1997: [Stabilization of cationic liposome-plasmid DNA complexes by polyamines and poly\(ethylene glycol\)-phospholipid conjugates for efficient in vivo gene delivery](#)
- Uyechi *et al* 2001: [Mechanism of lipoplex gene delivery in mouse lung: binding and internalization of fluorescent lipid and DNA components](#)
- Li *et al* 1997: [In vivo gene transfer via intravenous administration of cationic lipid-protamine-DNA \(LPD\) complexes](#)
- Liu *et al* 1997: [Factors controlling the efficiency of cationic lipid-mediated transfection in vivo via intravenous administration](#)

- Sakurai *et al* 2001: [Interaction between DNA-cationic liposome complexes and erythrocytes is an important factor in systemic gene transfer via the intravenous route in mice: the role of the neutral helper lipid](#)
- Zhang *et al* 1998: [Vector-specific complementation profiles of two independent primary defects in cystic fibrosis airways](#)
- Kariko *et al* 1998: [Phosphate-enhanced transfection of cationic lipid-complexed mRNA and plasmid DNA](#)
- Haraguchi *et al* 2022: [Transfected plasmid DNA is incorporated into the nucleus via nuclear envelope reformation at telophas](#)
- Zhu *et al* 2022: [Multi-step screening of DNA/lipid nanoparticles and co-delivery with siRNA to enhance and prolong gene expression](#)
- Sattar *et al* 2023: [Nuclear translocation of spike mRNA and protein is a novel feature of SARS-CoV-2](#)
- Midoux *et al* 2009: [Chemical vectors for gene delivery: a current review on polymers, peptides and lipids containing histidine or imidazole as nucleic acids carriers](#)
- Dean *et al* 1999: [Sequence Requirements for Plasmid Nuclear Import](#)

## Schedule 2 – Effects and Outcomes Associated with DNA Contamination

The following is a summary of the paper by Palmer (MD) and Gilthorpe (PhD), [COVID-19 mRNA vaccines contain excessive quantities of bacterial DNA: evidence and implications](#), analysing the data produced by Kevin McKernan *et al* set forth in Schedule 3.

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

Multiple studies<sup>17</sup> 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<sup>18</sup>.

Recombinant viral DNA has been shown to persist in linear form within animals for equally long periods of time<sup>19</sup>, 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<sup>20</sup> that the T7

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<sup>17</sup> 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).

<sup>18</sup> 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.

<sup>19</sup> 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.

<sup>20</sup> 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.

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<sup>21</sup>. 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<sup>22</sup> 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<sup>23</sup>. 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<sup>24</sup>.

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<sup>21</sup> 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.

<sup>22</sup> J. C. Rotondo et al.: [Association Between Simian Virus 40 and Human Tumors](#). Front. Oncol. 9 (2019), 670.

<sup>23</sup> 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.

<sup>24</sup> 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.

In this context, further consideration of the study previously published by Aldén *et al*<sup>25</sup>, 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 leukaemia<sup>26</sup>.

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<sup>27</sup>.

Oocytes – immature ovum - can be transfected (with foreign DNA) in the body at certain stages of maturation<sup>28</sup>, and so can sperm-producing cells within the testes<sup>29</sup>. 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*<sup>30</sup>, 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<sup>31</sup>, due to the extensive bio-distribution LNPs achieve throughout the

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<sup>25</sup> 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.

<sup>26</sup> 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.

<sup>27</sup> 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.

<sup>28</sup> 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.

<sup>29</sup> S. Dhup and S. S. Majumdar: [\*Transgenesis via permanent integration of genes in repopulating spermatogonial cells in vivo\*](#). *Nat. Methods* 5 (2008), 601–3.

<sup>30</sup> 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.

<sup>31</sup> 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.

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.

Accordingly, it must be expected that there will be chromosomal integration of the contaminating plasmid DNA within human recipients of the Pfizer and Moderna vaccines containing DNA contaminants.



### Schedule 3 – DNA Contamination Data

Preprint 10 April 2023

McKernan, Kevin, Yvonne Helbert, Liam T. Kane, and Stephen McLaughlin. 2023. “[Sequencing of Bivalent Moderna and Pfizer mRNA Vaccines Reveals Nanogram to Microgram Quantities of Expression Vector dsDNA Per Dose.](#)” OSF Preprints. April 10.

Preprint above drawing from the rolling data and methods published below.

- 16 February [Deep sequencing of the Moderna and Pfizer bivalent vaccines identifies contamination of expression vectors designed for plasmid amplification in bacteria](#)
- 9 March [Pfizer and Moderna bivalent vaccines contain 20-35% expression vector and are transformation competent in E.coli](#)
- 12 March [Sequencing of RNase A treated Pfizer bivalent vaccines reveals paired-end sequencing evidence of circular plasmids and an inter-vial 72bp variation in the SV40 promoter](#)
- 15 March [Failure of the linearization reaction in the Pfizer bivalent vaccine manufacturing process](#)
- 15 March [DNase and RNase qPCR examination of Pfizer and Moderna bivalent vaccines](#)
- 16 March [Fluorometer and UV spectra of purified Pfizer and Moderna vaccines](#)
- 19 March [The Med Gen qPCR assay for assessing Pfizer and Moderna DNA contamination](#)
- 23 March [Rapid Boil Prep for assessing the dsDNA contamination in the Pfizer and Moderna mRNA vaccines](#)
- 25 March [DNA contamination in Pfizer monovalent vaccines](#)
- 30 March [DNA contamination in 8 vials of Pfizer monovalent mRNA vaccines](#)
- 13 April [Sequencing the Pfizer monovalent mRNA vaccines also reveals dual copy 72-bp SV40 Promoter](#)
- 15 April [DNA-RNA hybrids, R-Loops and nuclease resistance of the mRNA vaccines](#)
- 27 April [LNP packaging of dsDNA](#)

29 April [Pfizer's own data implicates their contamination](#)

5 June [Nuclear permeability during cell division](#)

#### **Schedule 4 - Curriculum Vitae**

### **Kevin McKernan**

Mr. McKernan currently serves as the Founder and Chief Scientific Officer of Medicinal Genomics. In 2011, Medicinal Genomics was the first organization to publish the *Cannabis sativa L.* draft genome in effort to build a better scientific foundation for cannabis-based therapeutics, blockchain tracking of strains, and microbial-cannabis safety tests. In 2018, Medicinal genomics further refined this genome reference with the publication of the Jamaican Lion genome with DASH and Pacific Biosciences. To date this is the most contiguous Cannabis genome reference ever created and has aided in the design of high specificity qPCR assays for microbial contamination in cannabis. Medicinal Genomics now offers cannabis safety testing and strain tracking services in over 30 states and multiple countries.

Previously, Kevin worked as a Vice President and Director of R&D for Life Technologies where he oversaw the next generation SOLiD sequencing technology from 2006 to 2011. Integral to the SOLiD R&D process, Kevin oversaw over 100 research collaborations exploring the new biological frontiers with next generation sequencing. These collaborations gained traction in human tumor sequencing and resulted in hundreds of publications and 7 Journal covers from Science Translational Medicine, Genome Research, Clinical Chemistry, Nature Methods and Nature.

Prior to his work at ABI, Kevin was the President and CSO of Agencourt Personal Genomics, a startup company he co-founded in 2005 to develop SOLiD sequencing. This ligation based sequencing technology dropped the cost of sequencing a human genome from \$300M to \$3,000; a 100,000 fold improvement in sequencing speed and cost in a few years. Agencourt Personal Genomics was acquired by Applied Biosystems in 2006.

From 2000 to 2005, Kevin was the CSO of Agencourt Biosciences which was acquired by Beckman Coulter in 2005.

From 1996 to 2000 Kevin managed the Research and Development for the Human Genome Project at Whitehead Institute/MIT resulting in several patents for magnetic bead based nucleic acid purification. These purification tools have grown to comprise 37.9% of the nucleic acid purification market.

Kevin's peer reviewed publications have resulted in over 57,000 citations and 29 patents.

#### **Kevin's publications include:**

ORCID ID <https://orcid.org/0000-0002-3908-1122>

[https://scholar.google.com/citations?user=WKED1\\_sAAAAJ&hl=en](https://scholar.google.com/citations?user=WKED1_sAAAAJ&hl=en)

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#### Issued Patents

- 9822395 Methods for producing a paired tag from a nucleic acid sequence and methods of use thereof
- 9670545 Methods and kits for treating and classifying individuals at risk of or suffering from TRAP1 change-of-function
- 9512472 Method of amplifying nucleic acid sequences
- 9493830 Reagents, methods, and libraries for bead-based sequencing
- 9422594 Method of amplifying nucleic acid sequences
- 9309560 Methods for producing a paired tag from a nucleic acid sequence and methods of use thereof
- 9217177 Methods for bead-based sequencing
- 8486382 Method for treating cervical cancer
- 8431691 Reagents, methods, and libraries for bead-based sequencing
- 8329404 Reagents, methods, and libraries for bead-based sequencing
- 8058030 Methods of producing and sequencing modified polynucleotides
- 7993842 Directed enrichment of genomic DNA for high-throughput sequencing

- 7851158 Enrichment through heteroduplexed molecules
- 7645866 Methods of producing and sequencing modified polynucleotides
- 7527929 Methods of isolating nucleic acids using multifunctional group-coated solid phase carriers
- 6534262 Solid phase technique for selectively isolating nucleic acids

Patent Applications

- 20180163253 METHODS FOR PRODUCING A PAIRED TAG FROM A NUCLEIC ACID SEQUENCE AND METHODS OF USE THEREOF
- 20170081717 Reagents, Methods, and Libraries for Bead-Based Sequencing
- 20170073732 METHOD OF AMPLIFYING NUCLEIC ACID SEQUENCES
- 20160265034 METHODS FOR PRODUCING A PAIRED TAG FROM A NUCLEIC ACID SEQUENCE AND METHODS OF USE THEREOF
- 20160230223 Method Of Amplifying Nucleic Acid Sequences
- 20160186264 METHODS AND KITS FOR TREATING AND CLASSIFYING INDIVIDUALS AT RISK OF OR SUFFERING FROM TRAP1 CHANGE-OF-FUNCTION
- 20160177404 Cannabis genomes and uses thereof
- 20140342353 Reagents, Methods, and Libraries for Bead-Based Sequencing
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- 20140057251 Cannabis Genomes and Uses Thereof
- 20120191363 Reagents, Methods, and Libraries for Bead-Based Sequencing
- 20110257385 METHODS FOR FLIP-STRAND IMMOBILIZING AND SEQUENCING NUCLEIC ACIDS
- 20110257019 Directed Enrichment of Genomic DNA for High-Throughput Sequencing
- 20110081687 Enrichment Through Heteroduplexed Molecules
- 20110077169 Reagents, Methods, and Libraries for Bead-Based Sequencing
- 20100298551 Methods Of Producing And Sequencing Modified Polynucleotides
- 20100297628 Methods Of Producing And Sequencing Modified Polynucleotides
- 20100297626 Reagents, Methods, and Libraries for Bead-Based Sequencing
- 20100285461 Methods Of Producing And Sequencing Modified Polynucleotides
- 20100121044 SOLID PHASE TECHNIQUE FOR SELECTIVELY ISOLATING NUCLEIC ACIDS
- 20100120034 METHYLATION ANALYSIS OF MATE PAIRS
- 20100028888 METHODS FOR PRODUCING A PAIRED TAG FROM A NUCLEIC ACID SEQUENCE AND METHODS OF USE THEREOF
- 20090280540 DIRECTED ENRICHMENT OF GENOMIC DNA FOR HIGH-THROUGHPUT SEQUENCING
- 20090191566 Kits for Isolating Nucleic Acids Using Multifunctional Group-Coated Solid Phase Carriers
- 20090181860 Reagents, methods, and libraries for bead-based sequencing
- 20090181385 Reagents, methods, and libraries for bead-based sequencing
- 20090062129 REAGENTS, METHODS, AND LIBRARIES FOR GEL-FREE BEAD-BASED SEQUENCING

20090036325 Directed assembly of amplicons to enhance read pairing signature with massively parallel short read sequencers

20080274466 Enrichment Through Heteroduplexed Molecules

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20060177836 Methods of isolating nucleic acids using multifunctional group-coated solid phase carriers

20060078923 Method for isolating nucleic acids

20060024701 Methods and reagents for the isolation of nucleic acids

20060024681 Methods for producing a paired tag from a nucleic acid sequence and methods of use thereof

20060003357 Solid phase technique for selectively isolating nucleic acids

20050072674 Method and device for introducing a sample into an electrophoretic apparatus

20040214175 Solid phase technique for selectively isolating nucleic acids

20040197780 Method for isolating nucleic acids

20030235839 Solid phase technique for selectively isolating nucleic acids

### **Honors and Awards:**

- 1) Nominee- Aventis Innovative Investigator Award
- 2) Invitation to the Whitehouse, Human Genome Project Completion Celebration
- 3) Invitation to the House of Lords, Genomic Medicine
- 4) G35- Genome Technology, Most influential in Genomics under age 35
- 5) TR35 Nominee- MIT Technology Review
- 6) Beckman Coulter Game Ball- Most influential deal in Beckman Coulter in 2006
- 7) Most innovative patent of the year- Life Technologies 2008
- 8) Over a half dozen awards misdirected at me but really the ownership of the SOLiD team in Beverly, MA for the most innovative product in Nucleic Acid Sciences.