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4 July 2023

U R G E N T

Gene Technology Regulator (OGTR/GTR)
Office of the Gene Technology Regulator
Scarborough House
Atlantic Street
Phillip ACT 2606

By email only:
ogtr@health.gov.au

Attention: Dr Raj Bhula

Dear Dr Bhula,

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 OGTR 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**). 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.[1]

d) On entering the cell nucleus the modRNA from the Products have been observed to reverse-transcribe into human DNA.[2] 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.[3]

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.[4]

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

[1] 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.
[2] 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 paper was only withdrawn after inappropriate pressure was exerted upon the authors).
[3] See Domazet-Lošo, T. mRNA Vaccines: Why Is the Biology of Retroposition Ignored? *Genes* 2022, *13*, 719.
[4] 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).

competent after transfection, it must be deemed to be 'viable' until conclusively proven otherwise.

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 Lipid Nanoparticles (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.[5]

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[6].

[5] See the peer reviewed literature in Schedule 1.
[6] Ibid.

b) Subsequent copies of that plasmid modDNA (replications) are able to transcribe further modRNA for the translation of further quantities of synthetic Spike protein[7].

c) The plasmid modDNA is able to integrate into chromosomal DNA[8], where:

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[9], 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 Office of the Gene Technology Regulator (**OGTR**), the Gene Technology Regulator (**GTR**), the Gene Technology Technical Advisory Committee (**GTTAC**), the TGA, Pfizer and Moderna or should have been known to the OGTR, the GTR, the GTTAC, the TGA, Pfizer and Moderna before or at the time of the respective applications ('the applications') to the Therapeutic Goods Administration for provisional approval of the Products. If the OGTR, the GTR, the GTTAC, the TGA, Pfizer and Moderna did not know before or at the time:

a) In respect of the LNP-modRNA GMOs:

[7] Ibid.
[8] Ibid.
[9] Ibid.

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 OGTR/GTR to not be aware before or at the time of the applications, or the OGTR/GTR knowingly allowed these products to contain GMOs (LNP-modRNA). We note you and your office and all members of the GTTAC received from the law firm Maat's Method on 18 and 21 November 2022 the peer reviewed papers shown at footnotes 1 through 4 above, and the further peer reviewed papers at footnote 10 below[10], and that you chose not to act on that information; and

iii) The subsequent peer reviewed papers of early 2022 to date informed the OGTR, the GTR, the GTTAC, the TGA, 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 OGTR/GTR to not be aware before or at the time of the applications, or the OGTR/GTR knowingly allowed these products to contain GMOs (LNP-modDNA); and

iii) The subsequent information published by Kevin McKernan informed Pfizer and Moderna and confirmed the Products contain synthetic modDNA GMOs (see Part B); and

iv) By receipt of this letter the OGTR, the GTR, the GTTAC, the TGA, 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);

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[10] 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/; 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.

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 OGTR 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 Therapeutic Goods Administration[11] 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)**"[12];

c) The Bivalent Products contain higher contamination. The TGA states contamination be less than or limited to 10ng per dose, whereas:

i) The Pfizer Bivalent product has been found[13] to contain modDNA contamination from 44-339 times over the limit; and

ii) The Moderna Bivalent product has been found[14] to contain modDNA contamination from 52-476 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.

[11] TGA: Guidance 18: Impurities in drug substances and drug products.
[12] Supra n 16 in paragraph 24.
[13] Ibid.
[14] Ibid.

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

22. Further, excessive modDNA contamination (exacerbated by repeated doses further multiplying the excessive quantities), is often associated with[15], 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 modDNA 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

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*[16], an expert in genomics and sequencing[17], who is engaged in independent and ongoing analysis of vial contents of the Moderna and Pfizer Monovalent and Bivalent gene therapies.

[15] Schedule 2 provides peer reviewed literature in support of 21(a)-(f).
[16] See Schedule 3 for McKernan *et al* Preprint, methods, results, and references.
[17] Schedule 4 contains the Curriculum Vitae of Kevin McKernan.

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, and in light of the close relationship between the OGTR and the TGA, the OGTR is in a position to influence and demand the TGA 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 and empower the OGTR/GTR to immediately call for Pfizer and Moderna to cease dealing with the Products forthwith across Australia.

Kind regards

Katie Ashby-Koppens
PJ O'Brien & Associates
[redacted]

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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[18] 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[19].

Recombinant viral DNA has been shown to persist in linear form within animals for equally long periods of time[20], 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[21] that the T7

[18] 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).

[19] 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.

[20] 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.

[21] 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[22]. 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[23] 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[24]. 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[25].

[22] 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.

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

[24] 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.

[25] 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*[26], 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[27].

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[28].

Oocytes – immature ovum - can be transfected (with foreign DNA) in the body at certain stages of maturation[29], and so can sperm-producing cells within the testes[30]. 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*[31], 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[32], due to the extensive bio-distribution LNPs achieve throughout the

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[26] 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.

[27] 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.

[28] 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.

[29] 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.

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

[31] 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.

[32] 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 contaminates.

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

Bayes Lines Tool (BLT): a SQL-script for analyzing diagnostic test results with an application to SARS-CoV-2-testing

Aukema W, Malhorta BR, Goddek S et al F1000Research 2022

Pathogenic Enterobacteriaceae require multiple culture temperatures for detection in Cannabis sativa L.

McKernan KJ, Helbert Y, Kane LT. Zenodo 2022

A whole genome atlas of 81 Psilocybe genomes as a resource for psilocybin production.

McKernan KJ, Kane LT, Helbert Y. F1000Research 2021

Differences in Vaccine and SARS-CoV-2 Replication Derived mRNA: Implications for Cell Biology and Future Disease

McKernan KJ, Kyriakopoulos AM, McCullough PA. OSF 2021

Whole genome sequencing of colonies derived from cannabis flowers and the impact of media selection on benchmarking total yeast and mold detection tools [version 2; peer review: 2 approved]

McKernan KJ, Helbert Y, Kane LT. F1000Research 2021

A draft reference assembly of the Psilocybe cubensis genome [version 2; peer review: 2 approved]

McKernan KJ, Kane LT, Crawford S. F1000Research 2021

Addendum to the Corman-Drosten Review Report

Borger P, Malhotra BR , Yeadon M. OSF 2021

External peer review of the RTPCR test to detect SARS-CoV-2 reveals 10 major scientific flaws at the molecular and methodological level: consequences for false positive results

Borger P, Malhotra BR , Yeadon M. Zenodo 2020

Quantitative PCR for cannabis flower containing SARs-CoV-2

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Sequence and annotation of 42 cannabis genomes reveals extensive copy number variation in cannabinoid synthesis and pathogen resistance genes

McKernan KJ, Helbert Y, Kane LT. BioRxiv 2020

Genomic characterization of the complete terpene synthase gene family from Cannabis sativa

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Microbiological examination of nonsterile Cannabis products: Molecular Microbial Enumeration Tests and the limitation of Colony Forming Units.
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McKernan KJ, Spangler J, Zhang L et al.,F1000Research 2016, 4:1422 (doi: 10.12688/f1000research.7507.2)

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DREAMing of a patent-free human genome for clinical sequencing
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McKernan KJ, Spangler J, Zhang L, Tadigotla V, McLaughlin S, et al. (2014) Expanded Genetic Codes in Next Generation Sequencing Enable Decontamination and Mitochondrial Enrichment. PLoS ONE 9(5): e96492. doi: 10.1371/journal.pone.0096492

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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
20140335569	Method Of Amplifying Nucleic Acid Sequences
20140248610	Reagents, Methods, and Libraries for Bead-Based Sequencing
20140243232	NUCLEIC ACID COMPLEXITY REDUCTION
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
20080003571	Reagents, methods, and libraries for bead-based sequencing
20070231823	Directed enrichment of genomic DNA for high-throughput sequencing
20070054285	Method for isolating nucleic acids
20070026438	Methods of producing and sequencing modified polynucleotides
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.