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4 July 2023

URGENT

Pfizer Australia
Level 15-18
151 Clarence Street
Sydney
NSW 2000

By hand

Attention: Anne Harris, Managing Director ANZ

Dear Ms Harris

Immediate withdrawal of supply of Pfizer monovalent Comirnaty and bivalent booster products for failure to obtain the necessary licence/s to deal with genetically modified organisms in Australia

1. We act for Dr Julian Fidge.

2. We refer to the provisional approvals, and consequential supply of Pfizer's Covid-19 'vaccines':

    a) COMIRNATY (tozinameran) (mRNA) (**Monovalent**); and

    b) Bivalent (COMIRNATY Original/Omicron BA.4-5 COVID-19 vaccine) booster dose (**Bivalent**),

    (together the **Products**).

3. On instruction, we demand Pfizer immediately cease dealing with the Covid-19 Products in Australia on the basis that:

    a) Pfizer has not obtained the necessary licences to deal with 'genetically modified organisms' (**GMO**) in Australia; and

b) the Products are contaminated with cell-substrate deoxyribonucleic acid (**DNA**) grossly in excess of acceptable levels;

c) Pfizer has failed certain of its sponsor obligations to the Therapeutic Goods Administration.

4. 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.

Pfizer's Covid-19 mRNA Products are Genetically Modified Organisms that are being Supplied in Australia without the appropriate Licence

5. 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.

6. Pfizer knows the Products contain GMOs and therefore is in breach of sections 32 and 33 GT Act. The Products satisfy the GMO definition in at least two respects, as they:

i) transfer genetically modified material throughout the human body; and

ii) are contaminated with and contain whole plasmid DNA and truncated forms of the same plasmid DNA.

7. By virtue of the contents of this letter, or prior to receipt of this letter, Pfizer knows/knew the Products contain whole plasmid DNA and truncated forms of the same plasmid DNA that are GMOs and therefore is in breach of sections 32 and 33 GT Act.

8. In order to deal with GMOs in Australia, Pfizer was 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). Pfizer failed or refused to obtain the necessary licences.

i) The LNP-modRNA Complexes

9. For the purposes of the GT Act, the transferred genetically modified material is the nucleoside-modified messenger RNA (**modRNA**) that is encapsulated in Lipid Nanoparticles (**LNPs**) of the Products, which together form LNP-mRNA complexes. The modRNA is the modified genomic code for the Spike protein from the Ribonucleic Acid (**RNA**) of the SARS-CoV-2 virus.

10. Pfizer's Products are GMO/s as the LNP-mRNA complex variously transfers the synthetic modRNA throughout the human body as follows:

a) The LNP-mRNA complex transfers the modRNA from the injection site throughout the human body, bio-distributing to virtually all organs.

b) The LNP-mRNA 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 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 mRNA 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 mRNA-LNP platform passing down acquired immune traits to their offspring.[4]

ii) The LNP-plasmidDNA & LNP-truncatedDNA Complexes

11. In addition, both the monovalent and bivalent Products are contaminated with and contain whole plasmid DNA and truncated forms of the same plasmid DNA, the further details of which are contained in Part B.

12. For the purposes of the GT Act, the identified plasmid DNA is replication competent it is therefore 'viable'.

13. The transferred genetically modified organism is the wholly synthesized cell-substrate DNA (plasmid DNA) used for the production of the modRNA, and truncated forms of the same

[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).

plasmid DNA, which whole and truncated DNA is encapsulated in the LNPs of the Products, which together form LNP-DNA complexes.

14. For the purposes of the GT Act, Pfizer's Products are GMO/s as the LNP-DNA complexes variously transfers this cell-substrate DNA throughout the Human body as follows:

    a) The LNP-DNA complex transfers the whole and truncated DNA from the injection site throughout the human body, bio-distributing to virtually all organs.

    b) The LNP-DNA complex then transfers the whole and truncated DNA genetic material across and through the cell membranes of the cells of affected organs, delivering the DNA into the cytoplasm of cells.

    c) The DNA 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 LNP used by Pfizer in both its Products readily encapsulate both the truncated and whole plasmid DNA, for efficient transfection into human cells. Once within the cytoplasm this DNA 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 mRNA also transfected into cells along with the truncated and plasmid DNA, or with the assistance of the SV40 sequence contained within the plasmid DNA 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, plasmid DNA:

    a) Is replication competent, meaning it self-replicates independently of any chromosomal replication[6]; and

    b) All subsequent copies of that DNA (replications) are able to transcribe further modRNA for the translation of further quantities of Spike protein[7].

    c) Is able to integrate into chromosomal DNA[8], where

        i. Further transcription of modRNA for further Spike protein can occur.

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

ii. Integration near oncogenes and other genes, for example the tumour suppressor gene P53, threatens to stimulate cancerous tumour growth.

iii. The integrated plasmid DNA with significant probability will likely be inherited by offspring.

17. The above is all information known to Pfizer, or should have been known to Pfizer at the time of its respective applications to the Therapeutic Goods Administration for provisional approval of the Products. If Pfizer did not know at the time:

a) In respect of the LNP-modRNA:

i. It was criminally reckless and/or criminally negligent to not be aware at the time; and

ii. The subsequent peer reviewed papers of early 2022 to date informed Pfizer and confirmed the Products contain GMOs.

b) In respect of the LNP-DNA:

i. It was criminally reckless and/or criminally negligent to not be aware at the time; and

ii. The subsequent information published by Kevin McKernan informed Pfizer and confirmed the Products contain synthetic DNA GMOs (see Part B); and

iii. By receipt of this letter Pfizer has been informed the Products contain synthetic DNA GMOs.

18. Therefore, Pfizer has contravened and satisfied both sections 32 and 33 of the GT Act, in that Pfizer has dealt with the Products:

a) Knowing they are GMOs (either knowingly or was reckless as to that fact or was negligent in not becoming aware of the fact);

b) It 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.

Part B.

Pfizer's Covid-19 Products contain Dangerously Excessive DNA Contamination

19. Further to the above, the Products contain cell-substrate DNA contamination, where the cell-substrate DNA contamination grossly exceeds *per dose* limits published by the Therapeutic Goods Administration[9]. Namely:

a) The cell-substrate modDNA contamination grossly exceeds *per dose* limits published by the TGA of less than or limited to 10ng per dose.

b) The Monovalent Product have 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)****"*[10].

c) The Bivalent Product contain higher contamination. The TGA states contamination be less than or limited to 10ng per dose, whereas the Bivalent Product has been found[11] to contain modDNA contamination from 44-339 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.

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

21. Further, excessive DNA contamination (exacerbated by repeated doses further multiplying the excessive quantities), is often associated with[12], and will likely result in:

a) Extended duration of 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 DNA within the human host;

d) Genomic insertion of the plasmid DNA into human chromosomal DNA;

e) Genomic integration inducing malignant diseases;

[9] TGA: Guidance 18: Impurities in drug substances and drug products.
[10] Supra n 13 in paragraph 23.
[11] Ibid.
[12] Schedule 2 provides peer reviewed literature in support of 21(a)-(f).

f) Transfection into Oocytes and sperm-producing cells leading to:

i. Altered transgenic offspring;

ii. Interference with early intrauterine development;

iii. Induction of miscarriages and malformations.

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

a) Pfizer failed to undertake necessary quality control and quality assurance of the Products, or knowingly allowed these products to contain variable and publicly unspecified contaminants; and

b) Regulators failed to monitor the Products generally, or knowingly allowed these products to contain variable and unspecified contaminants.

23. The identification of this significant DNA contamination in the Products occurred in February 2023 by Kevin McKernan *et al*[13], an expert in genomics and sequencing, 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

24. Pursuant to sections 29A and 29AA of the TG Act, Pfizer is 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)).

25. We trust that Pfizer has been complying with this provision by supplying all new information to the TGA with respect to those matters outlined in A and B of this letter above. Failure to do so exposes both Pfizer's local and international executives to personal liability under section 54B of the TG Act. For this reason, we have cc'd your local and international executives into this letter of demand.

[13] See Schedule 3 for McKernan *et al* Preprint, methods, results, and references.

26. As the contamination testing undertaken by McKernan *et al* clearly sets forth the methodology involved requires less than 2 hours to perform and validate, Pfizer has until **3pm Thursday 6 July 2023** to respond to this letter, confirming it will cease dealing with these Products forthwith.

I phoned your office requesting an email address but was not provided one. Please email me as soon as possible after receipt and I will ensure you get an electronic version of this letter so you can review the hyperlinks.

We look forward to hearing from you.

Regards

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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[14] 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[15].

Recombinant viral DNA has been shown to persist in linear form within animals for equally long periods of time[16], 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[17] that the T7

[14] 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).

[15] 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.

[16] 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.

[17] 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[18]. 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[19] 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[20]. 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[21].

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[18] 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.

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

[20] 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.

[21] 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*[22], 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[23].

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[24].

Oocytes – immature ovum - can be transfected (with foreign DNA) in the body at certain stages of maturation[25], and so can sperm-producing cells within the testes[26]. 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*[27], 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[28], due to the extensive bio-distribution LNPs achieve throughout the

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[22] 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.

[23] 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.

[24] 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.

[25] 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.

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

[27] 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.

[28] 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