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Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
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Rockville, MD 20852

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE FOOD AND DRUG ADMINISTRATION

PETITION FOR ADMINISTRATIVE ACTION REGARDING COVID-19 modRNA VACCINES OF PFIZER & MODERNA	Docket No. _____

CITIZEN PETITION

On behalf of the Co-Signatories, the undersigned submit this petition under 21 C.F.R. § 10.30 and other applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Public Health Service Act (PHSA) to request that the Food and Drug Administration (FDA) and the Secretary of Health and Human Services take administrative actions outlined below.

We request the Commissioner of the FDA and the Secretary of Health and Human Services revoke or suspend by taking administrative actions in respect of the earlier emergency use authorizations (EUAs), biologics license applications (BLAs), and approvals of BLAs for all the modRNA-LNP based Covid-19 products of Pfizer (Comirnaty) and Moderna (Spikevax) pursuant to sections 501 (21 U.S.C. § 351), 505(e) (21 U.S.C. § 355(e)), and 701(a) (21 U.S.C. § 371(a)) of the FD&C Act and section 351 of the Public Health Service Act (42 U.S.C. § 262), and any other applicable provisions.

I. ACTIONS REQUESTED

The undersigned petitioners request that the FDA and the Secretary of Health and Human Services:

1. Revoke or suspend the Biologics License Applications (BLAs) granted to Pfizer-BioNTech (Comirnaty) and Moderna (Spikevax) for their modRNA Covid-19 products, pending investigations into the following grounds:

    a. **Wrongful and Illegal Categorical Exclusions from Environmental Assessments (EAs):** Both Pfizer and Moderna improperly sought and were improperly granted by the FDA categorical exclusions from submitting EAs under 21 CFR 25.31. This exclusion prevented their products from being reviewed by the Cellular, Tissue and Gene Therapies Advisory Committee (CTGTAC), the appropriate body for gene therapy evaluation.

    b. **Excessive Synthetic DNA Contamination:** Nine independent laboratories, including one supervised by FDA scientists, have confirmed excessive synthetic DNA contamination in the Pfizer and Moderna modRNA products at levels significantly exceeding regulatory thresholds. This DNA has been detected in vials and in the bloodstream of human recipients.

2. Investigate the regulatory processes and decisions that allowed for these violations, including:

    a. The illegal classification of these products as non-gene therapies.

b. The failure to ensure public disclosure and transparency about the gene therapy nature of these products, thereby denying legally valid Informed Consent.

3. Issue public guidance regarding the risks posed by excessive synthetic DNA contamination, including its potential for genomic integration, self-replication, and associated health consequences.

4. Mandate independent testing of existing stocks and retained samples for contamination and suspend further administration until safety can be assured.

5. Establish and develop testing to confirm synthetic DNA integration into human genomic DNA and replication within human cells including testing for self-replication of the synthetic DNA within human cancer tumours.

II. STATEMENT OF GROUNDS

A. Wrongful and Illegal Categorical Exclusions from Environmental Assessments (EAs)

Under 21 CFR 25.15, all applications requesting FDA action must include an Environmental Assessment (EA) or a claim of categorical exclusion.

Pfizer and Moderna sought categorical exclusions under 21 CFR 25.31, which the FDA wrongfully and illegally granted[1] despite clear legal and regulatory provisions showing ineligibility for such exclusions. This section explains the legal requirements for EAs, why the categorical exclusions were invalid, and the consequences of this regulatory failure.

[1] The FDA's Summary Basis for Regulatory Action in respect of Pfizer, dated 8 November 2021, states at page 14:

> **f. Environmental Assessment**
> The BLA included a request for categorical exclusion from an Environmental Assessment under 21 CFR 25.31. The FDA concluded that this request is justified, and no extraordinary circumstances exist that would require an environmental assessment.

The FDA's Summary Basis for Regulatory Action in respect of Moderna, dated 30 January 2022, states at page 13:

> **f. Environmental Assessment**
> The BLA included a request for categorical exclusion from an Environmental Assessment under 21 CFR 25.31. The FDA concluded that this request is justified, and no extraordinary circumstances exist that would require an environmental assessment.

1.0 Legal Requirements for Environmental Assessments

1.1 Under 21 CFR 25.15(a)[2], sponsors of applications, including Biologics License Applications (BLAs)[3], and including BLAs the subject of an Emergency Use Approval (EUA), are required to submit an EA unless the application qualifies for a categorical exclusion. To qualify for such an exclusion, the applicant must:

a. Include a statement confirming compliance with the categorical exclusion criteria, and

b. Certify that no extraordinary circumstances exist that may significantly affect the human environment.

1.2 Failure to submit an adequate EA, unless a valid categorical exclusion applies, is grounds for the FDA to refuse to file or approve the application. An EA must address all relevant environmental issues and contain sufficient information for the FDA to determine whether the proposed action significantly impacts the environment.

1.3 The term "environment" as it applies to Environmental Assessments (EAs) under 21 CFR Part 25 includes not only the external or ecological environment but also encompasses the human environment, including human health and safety[4].

[2] See 21 CFR 25.15(a).

[3] The FDA guidance titled *Environmental Assessment of Human Drug and Biologics Applications* (1998) clarifies that 21 CFR Part 25 also applies to biologics regulated under BLAs.
Extraordinary Circumstances Requirement: Even if the categorical exclusion provisions under 21 CFR 25.31(a) or (c) are interpreted narrowly to apply to NDAs, 21 CFR 25.21 states (in part): "As required under 40 CFR 1508.4, FDA will require at least an EA for any specific action that ordinarily would be excluded if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment ". The synthetic and recombinant nature of modRNA and lipid nanoparticles, which do not occur naturally in the environment, constituted extraordinary circumstances requiring an EA for both Pfizer and Moderna's BLAs.

[4] NEPA's Definition of "Human Environment" or "Environment" at 40 CFR 1508.1(r): "Human environment shall be interpreted comprehensively to include the natural and physical environment and the relationship of people with that environment". Noting in addition the definition of "Effects" at 1508.1(i). See also "human environment" within FDA guidance document *Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products*.

2. Criteria for Categorical Exclusion and Inapplicability

2.1 The FDA's regulations under 21 CFR 25.31(a) and 25.31(c) provide specific criteria for categorical exclusions. The claims submitted by Pfizer and Moderna under these provisions were invalid:

a. Section 25.31(a)[5]:

This provision applies only if the action does not increase the use of a new molecular entity. FDA guidance explicitly states[6] that new molecular entities are considered actions that increase use and are thus ineligible for this exclusion. The modRNA contained in the Pfizer and Moderna vaccines is a patented, novel molecular entity.

b. Section 25.31(c)[7]:

This provision applies to substances that occur naturally in the environment and do not significantly alter concentration or distribution in the environment. The modRNA and lipid nanoparticle (LNP) formulations used in these vaccines are synthetic and recombinant, created through advanced biotechnological processes, and do not occur naturally in the environment. FDA's own guidance[8] on Gene Therapies[9] is clear such products are not considered to occur naturally in the environment.

[5] Section 25.31(a): "Action on an NDA, abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications, or action on an OTC monograph, if the action does not increase the use of the active moiety."

[6] FDA *Guidance for Industry Environmental Assessment of Human Drug and Biologics Applications*, page 3: "Increased use of an active moiety may occur if the drug will be administered at higher dosage levels, for longer duration, or for different indications than were previously in effect, **or if the drug is a new molecular entity**."

[7] Section 25.31(c): "Action on an NDA, abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications, or action on an OTC monograph, for substances that occur naturally in the environment when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment."

[8] *Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products* page 5: "Specifically, a GTVV [gene therapies, vectored vaccines, and related recombinant viral or microbial products] that includes functional protein-coding sequences from a genus that is different from the organism that is expressing the sequences is not considered to "occur naturally in the environment" under 21 CFR 25.31(c)."

[9] 'Gene therapies' are defined in the FDA guidance document entitled, *Gene Therapy Clinical Trials – Observing Subjects for Delayed Adverse Events*, November 2006, page 4, as (emphasis added): "**All products that mediate their effects by** transcription and/or **translation of transferred genetic material** and/or by integrating into the host genome and **that are administered as nucleic acids**, viruses, or genetically engineered microorganisms. The products may be used to modify cells in vivo or transferred to cells ex vivo prior to administration to the recipient." The FDA website also provides the following definition capturing the action of the modRNA-LNP Covid-19 products (emphasis added): "**Human gene therapy seeks** to modify or manipulate the expression of a gene or **to alter the biological properties of living cells for therapeutic use**."

3. Regulatory Guidance for Gene Therapies and Advanced Biologics

3.1 FDA guidance on BLAs requiring Environmental Assessments for gene therapies[10] states:

a. Gene therapies that include synthetic sequences or recombinant molecules are not considered substances that occur naturally.

b. Products that contain novel coding sequences from recombinant sources require full environmental review.

3.2 Both Pfizer and Moderna's modRNA products meet the definition of gene therapy products as they mediate effects by translation of transferred genetic material and use recombinant nucleic acids, requiring at law full environmental review.

4. Consequences of Wrongful and Illegal Categorical Exclusions

4.1 By wrongly and illegally granting categorical exclusions, the FDA:

a. Failed to subject the applications to review by the Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC), the appropriate body for evaluating gene therapies.

b. Wrongfully, improperly, and illegally subjected the applications to the Vaccines and Related Biological Products Advisory Committee (VRBPAC).

c. Failed to ensure compliance with the National Environmental Policy Act (NEPA), which mandates public disclosure and a comment period for products requiring environmental assessments.

4.2 Had the FDA properly demanded Environmental Assessments from Pfizer and Moderna as required by law, the American public would have been informed of the gene therapy nature of the modRNA products during a public comment period, fulfilling legal obligations for transparency and enabling informed consent.

[10] *Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products* section IV.B.1, pages 5-6.

4.3 Had Pfizer and Moderna submitted Environmental Assessments the content[11] of those EAs would have relied upon the following FDA guidance[12]:

Guidance for Industry Environmental Assessment of Human Drug and Biologics Applications (1998)

Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products (2015)

5. Legal and Regulatory Impact

5.1 Without Environmental Assessments or legally valid categorical exclusions, the Biological Licence Applications for Comirnaty and Spikevax were unlawfully

[11] In the paper *Hurdles of environmental risk assessment procedures for advanced therapy medicinal products: comparison between the European Union and the United States*, Iglesias- Lopez et al (2019) set out in Table 2 the matters Pfizer and Moderna should have addressed in EAs submitted with their BLAs. Iglesias-Lopez et al further observe:

> The ERA [Environmental Assessments] in EU and the US is based on nonclinical and/or clinical data, which mainly includes: description of the biological properties of the product that may pose a hazard, pathogenicity, its genetic stability, replication competence, host range, tissue tropism, the ability of the virus vector to survive after being shed, or the clearance, persistence and latency, shedding and biodistribution (Anliker et al. 2010). Therefore, during the development of the product it is necessary to generate enough information to address all these issues and conduct a proper ERA.
>
> One of the most important factors to analyze consists in the shedding assessment, which is the dissemination of the virus/vector through secretions and/or excreta of the patient, i.e. saliva, sweat, urine, feces, nasopharyngeal fluids, blood, exudates from skin lesions, breast milk and semen.

Independent of the required EAs, and to date neither Pfizer nor Moderna have released any studies on shedding, or the pathogenicity, genetic stability, replication competence, host range, tissue tropism, or the clearance, persistence or latency of their products. Pfizer did disclose a single and inadequate biodistribution study when requested by Japanese authorities.

The essential nature of biodistribution studies were reinforced by Iglesias-Lopez et al as follows:

> Biodistribution assessments are also another key point for the ERA [EA], as they provide information about the dissemination of the recombinant vector from the site of administration. This fact may influence the routes of shedding of the virus from the recipient, and therefore, the likelihood of transmission to third parties, including vertical transmission. Similarly to shedding assessments, biodistribution is usually part of the pivotal study and there is a minimum panel of tissues to be analyzed, apart from the ones considered necessary depending on the product and route of administration, i.e. blood, injection site(s), gonads, brain, liver, kidneys, lung, heart, and spleen (FDA Center for Biologics Evaluation and Research (CBER) 2018). If vector is detected in gonads, germline transmission studies should be performed (EMEA/273974/20 2006).

[12] See footnotes 5 & 7.

approved. Section 25.15(a)[13] makes clear that the absence of an adequate EA is grounds for rejecting an application.

5.2 In the circumstances described above, no environmental assessment information was submitted by either Pfizer or Moderna, so the environmental assessment information required by law to form part of the consideration process of the FDA was absent, therefore the purported BLA approvals were always *void ab initio*, or void from the beginning.

5.3 With the BLA approvals being *void ab initio* the Acting Commissioner and Secretary of Health and Human Services are required to revoke or suspend the approvals of the BLAs for all the modRNA-LNP based Covid-19 gene therapy products of Pfizer and Moderna.

B. Synthetic DNA Contamination

6.0 Significant Evidence of DNA Contamination

6.1 Evidence from multiple independent studies confirms the presence of excessive levels of synthetic DNA contamination in the Pfizer and Moderna modRNA Covid-19 products. The studies, reports and key findings are:

a. A December 2024 peer-reviewed study[14] supervised by FDA scientists detected synthetic DNA contamination levels between 6 and 470 times above the regulatory safety threshold of 10 ng per dose, in both the Pfizer and Moderna Covid-19 products, including SV40 promoter and enhancer sequences.

This study confirmed the synthetic DNA contamination is encapsulated and protected by the Lipid Nanoparticles (LNPs) used to encapsulate, protect, and efficiently transfect the modRNA into human cells; therefore the synthetic

[13] Section 25.15(a) states (emphasis added):

> "All applications or petitions requesting agency action require the submission of an EA or a claim of categorical exclusion. A claim of categorical exclusion shall include a statement of compliance with the categorical exclusion criteria and shall state that to the applicant's knowledge, no extraordinary circumstances exist. **Failure to submit an adequate EA for an application or petition requesting action by the agency of a type specified in § 25.20**, unless the agency can determine that the action qualifies for exclusion under §§ 25.30, 25.31, 25.32, 25.33, 25.34, or 25.35 **is sufficient grounds for FDA to refuse to file or approve the application or petition. An EA adequate for filing is one that addresses the relevant environmental issues. An EA adequate for approval is one that contains sufficient information to enable the agency to determine whether the proposed action may significantly affect the quality of the human environment.**"

[14] Wang et al 2024, *A rapid detection method of replication-competent plasmid DNA from COVID-19 mRNA vaccines for quality control*. Review by McKernan confirming integrity of methodology and accuracy of quantified contamination: see *FDA White Oak Lab Finds 6X to 470X DNA contamination in mRNA vaccines*. Further analysis by Dr Maryanne Demasi *EXCLUSIVE: FDA lab uncovers excess DNA contamination in COVID-19 vaccines*.

DNA contamination is not "naked", where the safety threshold of 10 ng per dose only applies to "naked" and unprotected DNA able to be broken down quickly and efficiently by human blood.

b. South Australian researchers collected data[15] confirming synthetic plasmid DNA in the blood of 75 participants who received the Pfizer or Moderna Covid-19 products, including SV40 promoter and enhancer sequences.

c. A December 2024 peer-reviewed study[16] by German researchers detected synthetic DNA contamination levels between 3 to over 4 times above the regulatory safety threshold in the Pfizer Covid-19 products, including SV40 promoter and enhancer sequences.

This study confirmed the synthetic DNA contamination is encapsulated and protected by the Lipid Nanoparticles (LNPs) used to encapsulate, protect, and efficiently transfect the modRNA into human cells; therefore the synthetic DNA contamination is not "naked", where the safety threshold of 10 ng per dose only applies to "naked" and unprotected DNA able to be broken down quickly and efficiently by human blood.

This study confirmed the synthetic DNA is efficiently transfected into human cells, including transfection of SV40 promoter and enhancer sequences.

d. A November 2024 French study[17] detected excessive synthetic DNA contamination in the Pfizer Covid-19 drug.

This study confirmed the synthetic DNA contamination is encapsulated and protected by the Lipid Nanoparticles (LNPs) used to encapsulate, protect, and efficiently transfect the modRNA into human cells; therefore the synthetic DNA contamination is not "naked", where the safety threshold of 10 ng per dose only applies to "naked" and unprotected DNA able to be broken down quickly and efficiently by human blood.

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[15] Date re-analysed by Chakraborty 2024, *The bloodstream of mRNA vaccinated individuals (both Pfizer and Moderna) shows DNA expression vector contamination, including SV40 and kanamycin-resistant gene sequences*. Further analysis of data by Kevin McKernan et al confirming findings of Chakraborty, noting levels of DNA contamination detected likely to be under-quantified and significantly higher: see *Chakraborty Open Review* and *Chakraborty Part II: Odak et al*. Review of findings by Dr Maryanne Demasi, noting findings elevated to the attention of the Australian Prime Minister, Minister for Health, and Deputy Secretary of Health *PART 1: Blood samples contain DNA sequences from COVID-19 mRNA vaccine.*

[16] Kammerer et al 2024 *BioNTech RNA-Based COVID-19 Injections Contain Large Amounts Of Residual DNA Including An SV40 Promoter/Enhancer Sequence*. Analysis and validation of Kammerer et al paper by Kevin McKernan *The most comprehensive study on Vax DNA sails through peer review*.

[17] Raoult 2024 *Confirmation of the presence of vaccine DNA in the Pfizer anti-COVID-19 vaccine*. DNA contamination levels ranged between 216 ng and 5,160 ng per dose. Kevin McKernan noted RNaseA was not used to eliminate cross-talk with modRNA, which typically lowers DNA quantification 10x (ie for Raoult, to 21.6 ng – 516 ng per dose): see *More papers on DNA contamination emerge*.

e. A September 2024 expert report[18] prepared for Australian legal proceedings confirms synthetic DNA contamination levels between 7 and 145 time above the regulatory safety threshold in both the Pfizer and Moderna Covid-19 products, including SV40 promoter and enhancer sequences.

This study confirmed the synthetic DNA contamination is encapsulated and protected by the Lipid Nanoparticles (LNPs) used to encapsulate, protect, and efficiently transfect the modRNA into human cells; therefore the synthetic DNA contamination is not "naked", where the safety threshold of 10 ng per dose only applies to "naked" and unprotected DNA able to be broken down quickly and efficiently by human blood.

f. A May 2024 peer-reviewed study[19] by German researchers detected synthetic DNA contamination levels between 360 and 534 times above the regulatory safety threshold in the Pfizer Covid-19 drug, including SV40 promoter and enhancer sequences.

This study confirmed the synthetic DNA contamination is encapsulated and protected by the Lipid Nanoparticles (LNPs) used to encapsulate, protect, and efficiently transfect the modRNA into human cells; therefore the synthetic DNA contamination is not "naked", where the safety threshold of 10 ng per dose only applies to "naked" and unprotected DNA able to be broken down quickly and efficiently by human blood.

g. April 2024 preliminary findings[20] by US Professor of Molecular Biology & Genetics confirms synthetic DNA contamination in the Pfizer Covid-19 drug above the regulatory safety threshold.

[18] Expert report prepared by Dr David Speicher for use in Australian Federal Court proceedings alleging the Pfizer and Moderna Covid-19 products should have been processed under the Gene Technology Act 2000 and properly deemed GMOs. Study by Dr Speicher used RNaseA to eliminate modRNA cross-talk. Review of Speicher findings by journalist Rebekah Barnett *BREAKING: DNA contamination in Australian mRNA Covid shots up to 145 time regulatory limit, report shows*. Review of Speicher findings by former barrister Julian Gillespie *Australian DNA Contamination: The Final Report*.

[19] Konig et al 2024 *Methodological Considerations Regarding the Quantification of DNA Impurities in the COVID-19 mRNA Vaccine Comirnaty*. Methodology did not use RNaseA. Elimination of cross-talk from modRNA using RNaseA would have likely resulted in final DNA quantification at approximately 360 – 534 ng per dose.

[20] Professor Phillip Buckhaults X/Twitter post of preliminary findings. Formal paper being prepared.

h. An October 2023 study[21] by Speicher et al detected synthetic DNA contamination levels between 188 and 509 times above the regulatory safety threshold of 10 ng per dose, in both the Pfizer and Moderna Covid-19 products, including SV40 promoter and enhancer sequences.

i. A September 2023 study[22] by McKernan et al detected synthetic DNA contamination levels between 18 and 70 times above the regulatory safety threshold in both the Pfizer and Moderna Covid-19 products, including SV40 promoter and enhancer sequences.

j. Putative findings[23] have confirmed this synthetic DNA can and does integrate into human genomic DNA and can replicate within human cells. McKernan has further reported[24] early-stage evidence of self-replication of the synthetic DNA within human cancer tumours, demonstrating a capacity for independent propagation.

7.0 Legal and Regulatory Failures

7.1 There are numerous legal and regulatory failures for which EUA does not explain nor excuse, namely:

a. 42 U.S.C. § 262(a)(2)(C)(i)[25] requires applicants for a BLA to submit data to demonstrate that the biological product is safe, pure, and potent. The data to be provided by sponsors encompasses detailed information about the manufacturing process, which includes genetic materials like plasmid DNA used in production.

At no time when seeking BLA approval from the FDA did Pfizer disclose that its plasmid DNA used in the manufacture of its Covid-19 products, included and includes the SV40 promoter and enhancer sequences.

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[21] Speicher et al 2023 *DNA fragments detected in monovalent and bivalent Pfizer/BioNTech and Moderna modRNA COVID-19 vaccines from Ontario, Canada: Exploratory dose response relationship with serious adverse events*. Methodology did not use RNaseA to eliminate modRNA cross-talk. With RNaseA contamination levels more likely 18.8 – 50.9 times above the regulatory safety threshold.

[22] McKernan et al 2023 *Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose*. Triton-X was not used in the methodology. Triton-X is a detergent that breaks open the Lipid Nanoparticles (LNPs) that hold the modRNA and synthetic DNA. Use of Triton-X typically results in higher quantifications of synthetic DNA once the LNPs are removed.

[23] Study by Professor Phillip Buckhaults, preliminary findings posted to X/Twitter. Study by Kevin McKernan, preliminary findings in *SV40 origin of replication in mammalian cells in absence of SV40 Large T-Antigen*.

[24] Ibid.

[25] 42 U.S.C. § 262(a)(2)(C)(i).

b. 21 CFR 601.2[26] requires sponsors to provide a complete description of the manufacturing process, including detailed information about the genetic material used. Detailed plasmid DNA maps showing Open Reading Frames (ORFs), promoters, enhancers, and other genetic elements must be disclosed to ensure the integrity of the final product.

At no time when seeking BLA approval from the FDA did Pfizer provide a plasmid DNA map detailing the SV40 promoter and enhancer sequences forming part of the plasmid DNA used to manufacture its Covid-19 products, nor did Pfizer otherwise disclose that its plasmid DNA used in the manufacture of its Covid-19 products, included and includes the SV40 promoter and enhancer sequences.

c. FDA guidance[27] requires sponsors submit detailed plasmid DNA maps and descriptions of all sequences used in production, including Open Reading Frames (ORFs), promoters, and enhancers (e.g., SV40), to assess risks of unintended expression or other effects.

At no time when seeking BLA approval from the FDA did Pfizer provide a plasmid DNA map detailing the SV40 promoter and enhancer sequences forming part of the plasmid DNA used to manufacture its Covid-19 products, nor did Pfizer otherwise disclose that its plasmid DNA used in the manufacture of its Covid-19 products, included and includes the SV40 promoter and enhancer sequences.

d. At no time prior to or after the approvals of the BLAs for the Pfizer and Moderna Covid-19 products did the FDA consider the regulatory threshold of 10 ng per dose for "naked" synthetic DNA to have no meaning in the context of the Covid-19 products of Pfizer and Moderna which use LNPs capable of, and which in fact do encapsulate and protect residual DNA templates (synthetic DNA) so as to not be "naked", where the LNPs are capable of, and in fact do efficiently transfect (transfer) the synthetic DNA inside human cells, which transfection process "naked" DNA is unable to do without the aid of LNPs.

Consequently, the regulatory threshold of 10 ng per dose for "naked" DNA is entirely meaningless for the Covid-19 products of Pfizer and Moderna, where the safety threshold should have been (prior to any BLA approvals) and must be, revised significantly lower by the FDA.

[26] 21 CFR 601.2.

[27] FDA Guidance for Industry *Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs)* and *FOR THE SUBMISSION OF CHEMISTRY, MANUFACTURING, AND CONTROLS INFORMATION FOR A THERAPEUTIC RECOMBINANT DNA-DERIVED PRODUCT OR A MONOCLONAL ANTIBODY PRODUCT FOR IN VIVO USE*.

8.0 Health Risks posed by Synthetic DNA Contamination[28]

8.1 The following are just a number of the health risks posed by Synthetic DNA Contamination; there may be many more that have not yet been discovered:

a. **High Transfection Efficiency**: Encapsulation of synthetic DNA within lipid nanoparticles (LNPs) ensures efficient delivery to human cells. Unlike naked DNA, LNP-protected synthetic DNA bypasses immune detection, crosses cell membranes, and integrates into cells, including their nuclei.

b. **Systemic Distribution and Efficient Transfection by LNPs**: Recent research[29] has demonstrated the systemic distribution of lipid nanoparticles (LNPs) following injection, confirming their delivery of genetic material to cells across all major organs, including the brain, lungs, heart, liver, spleen, testes, and ovaries. This efficient transfection likely extends to the synthetic DNA contaminants encapsulated within these LNPs, as confirmed by earlier disclosures[30] made by Pfizer to Japanese regulatory authorities. The broad bio-distribution of these particles significantly amplifies the potential for synthetic DNA to integrate into diverse cellular environments throughout the human body.

c. **Integration into Genomic DNA**: Synthetic DNA can integrate into human chromosomal DNA during cell division or with the assistance of Simian Virus 40 (SV40) nuclear localisation sequences, present in the Pfizer vaccine. Such integration poses risks of genomic instability and insertional mutagenesis, which can trigger cancers, especially leukemia.

d. **Minimal Threshold for Cancer Risk**: Studies show that the insertion of as few as 3 - 10 SV40-enhanced synthetic DNA molecules into a single cell can provoke a malignant response. This contrasts starkly with the billions of SV40 molecules delivered in a contaminated dose, significantly amplifying cancer risks.

e. **Magnitude of Contamination**: Independent analyses have detected synthetic DNA levels in Pfizer and Moderna products exceeding regulatory thresholds

[28] Peer-reviewed support and references for each of 8.1(a) through 8.1(k) is contained in the *Science Summary* prepared by 52 co-signatories, presented to the Australian Prime Minister by Russell Broadbent MP under cover of letter dated 25 September 2024.

[29] Luo et al 2025, *Nanocarrier imaging at single-cell resolution across entire mouse bodies with deep learning*.

[30] Study by Acuitas Therapeutics Inc. who provided Pfizer and its partner BioNTech with proprietary LNP technology to encapsulate and deliver the mRNA in their COVID-19 products. See Table 1: *A Tissue Distribution Study of a [3 H]-Labelled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rats*.

by 6 to 534 times. Each contaminated dose contains approximately 60 billion to 575 billion SV40 molecules.

f. **Impact on Tumour Suppressors**: SV40 sequences in synthetic DNA bind to tumour suppressor protein p53, which is crucial for genome protection. This binding neutralizes p53's cancer-preventing role, enhancing the risk of tumour proliferation.

g. **SV40 Enhancers and Somatic Hypermutability**: The SV40 enhancer sequences found in synthetic DNA contaminants are now recognized[31] as somatic hypermutability elements. These sequence elements have been shown to actively promote genetic instability and enhance risks associated with oncogenesis. This evidence directly contradicts earlier claims[32] by regulatory agencies that these sequences were non-functional and underscores their role in elevating cancer risks through mutagenic activity.

h. **Heritable Genetic Changes**: Synthetic DNA can transfect germline cells, such as oocytes and sperm-producing cells, potentially creating transgenic offspring or causing early developmental disruptions, miscarriages, and malformations.

i. **Cytosolic Transfection and Oncogenesis**: Emerging evidence[33] highlights that cytosolic transfection of DNA alone - without genomic integration - can induce oncogenesis by triggering a robust interferon response. This immune reaction is a known precursor to inflammatory diseases and cancer. The presence of synthetic DNA contaminants encapsulated in LNPs exacerbates this risk, as their high transfection efficiency ensures widespread cytosolic presence, elevating the potential for oncogenic transformations even without direct genomic integration.

j. **Potential for Self-Replication**: SV40 genetic elements enable the synthetic DNA to replicate autonomously within human cells, compounding the risk of genomic integration and amplifying the chances of malignant transformations.

k. **Other Severe Risks**: Additional contaminants identified in these products, including synthetic RNA:DNA hybrids and double-stranded synthetic RNA, have been linked to severe diseases such as blood clots and immune disorders.

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[31] Senigi et al 2024, *The SV40 virus enhancer functions as a somatic hypermutation-targeting element with potential tumorigenic activity*.

[32] The Epoch Times *EXCLUSIVE: Health Canada Confirms Undisclosed Presence of DNA Sequence in Pfizer Shot*.

[33] Kwon et al 2018, *The Cytosolic DNA-Sensing cGAS-STING Pathway in Cancer*.

9.0 Scientific Support for Statements in 8.0

9.1. Contained in the ***Science Summary: Consequences of Synthetic DNA Contamination***[34] presented to the Australian Prime Minister on September 25, 2024.

C. Conclusion to Statement of Grounds

10.0 Protecting Public Health

The overwhelming scientific evidence presented in this petition demonstrates that the Pfizer and Moderna Covid-19 products fail to meet the basic safety and efficacy requirements expected of approved biological products. The risks of synthetic DNA contamination, genomic integration, and SV40 promoter sequences demand immediate regulatory action to safeguard public health. In addition, corroborative evidences from pharmacovigilance databases with respect to increasing rates of cancer reports (including rare cancers), also demand investigation - it is imperative that we determine if these products are causing cancer.

10.1 Compliance with Legal Standards

The FDA must adhere to its statutory obligations under the Federal Food, Drug, and Cosmetic Act (FDCA) and the Public Health Service Act (PHSA). Failure to require Environmental Assessments and the improper classification of these products circumvented critical legal safeguards, rendering previous authorizations and approvals invalid from inception.

10.2 Call for Transparency and Accountability

The misrepresentation of these modRNA products as vaccines rather than gene therapy products constitutes a severe breach of public trust. Acknowledging and rectifying these regulatory failures is essential to restoring faith in public health institutions.

10.3 Urgency of Action

The continued administration of these products without addressing their synthetic DNA contamination exposes millions to avoidable health risks, including cancer, genomic instability, and transgenerational genetic harm. This petition calls for an immediate suspension of approvals, comprehensive independent testing, and revised safety thresholds for DNA contaminants encapsulated in lipid nanoparticles.

[34] See footnote 28.

10.4 Global Implications

Beyond the United States, the international community relies on the FDA's regulatory rigor. Addressing these concerns now will set a global precedent for upholding the highest safety standards in the deployment of novel medical technologies.

III. ENVIRONMENTAL IMPACT

The actions requested herein are exempt from the requirement to prepare an Environmental Impact Statement or Environmental Assessment under 21 CFR 25.30 because they involve administrative and enforcement actions designed to protect public health.

IV. ECONOMIC IMPACT

No significant economic impact is anticipated from the requested actions. However, the failure to act could result in substantial costs to public health and the economy due to potential short-, medium-, and long-term health consequences of the synthetic DNA contamination.

V. CERTIFICATION

The undersigned certify that, to the best of their knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners that may be unfavourable to the petition.

Respectfully submitted,

/s/ Julian J Gillespie
Julian Gillespie, LLB BJuris

/s/ Kevin McKernan
Kevin McKernan BSc, former Team Leader, Research and Development Whitehead Institute/MIT Center for Genome Research, Human Genome Project; Chief Scientific Officer (CSO) and Founder of Medicinal Genomics.

/s/ David J. Speicher
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/s/ Jessica Rose

Dr Jessica Rose, PhD, Applied Mathematics, Immunology, Computational Biology, Biochemistry, Molecular Biology; Brownstone Fellow; IMA Senior Fellow.

/s/ L. Maria Gutschi

L. Maria Gutschi BScPhm, PharmD, Pharmacy Consultant.