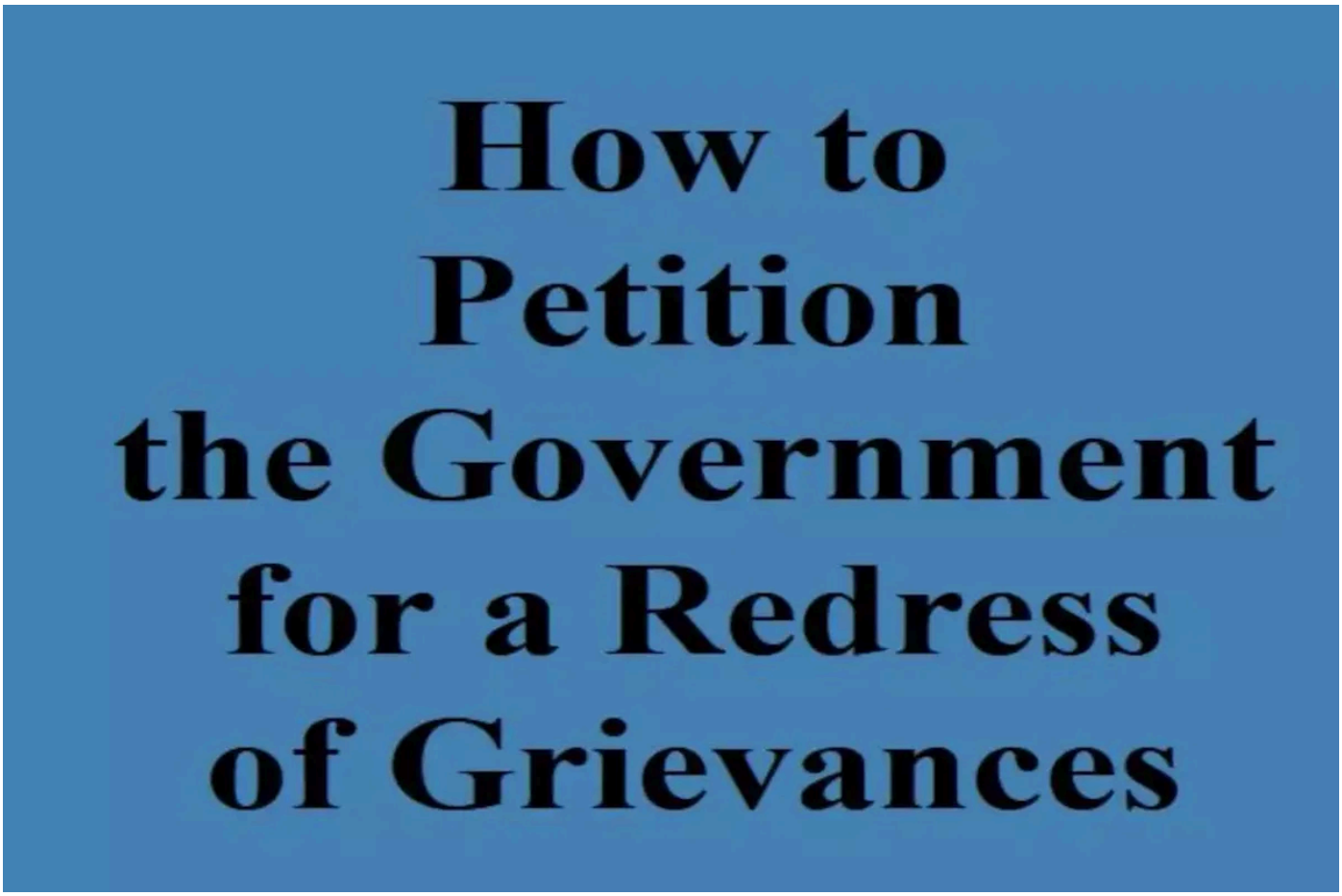
Submit Your Comment To The FDA

The FDA has received a Citizen Petition informing them that independent researchers around the world have found unacceptable levels of DNA contamination in the Pfizer-BioNTech and Moderna "vaccines."

JAMES ROGUSKI
FEB 02, 2025



Katie Ashby-Koppens of PJ O'Brien & Associates submitted a Citizen Petition to the FDA on January 21, 2025 on behalf of Julian J. Gillespi Kevin McKernan, David J. Speicher, Jessica Rose, and L. Maria Gutschi, ***requesting that the licenses and authorizations for the Pfizer-BionTech and Moderna mRNA products be REVOKED.***

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 levels significantly exceeding regulatory thresholds. This DNA has been detected in vials and in the bloodstream of human recipients.

Download and read the entire petition:

Citizen Petition From Pj Obrien And Associates On Behalf Of Multiple Clients
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https://www.regulations.gov/document/FDA-2025-P-0335-0001

Everyone on earth can submit a public comment to the FDA.

You do NOT need to be a citizen of the United States in order to subm a public comment.

EVERYONE ON EARTH may submit a text comment (up to 5,000 characters) and EVERYONE may also upload up to 20 files, each of wh may be up to 10MB.

Click on the link below to submit YOUR public comment:

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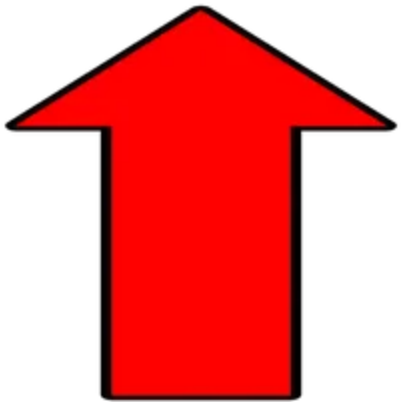

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or you can choose to submit your public comment anonymously.

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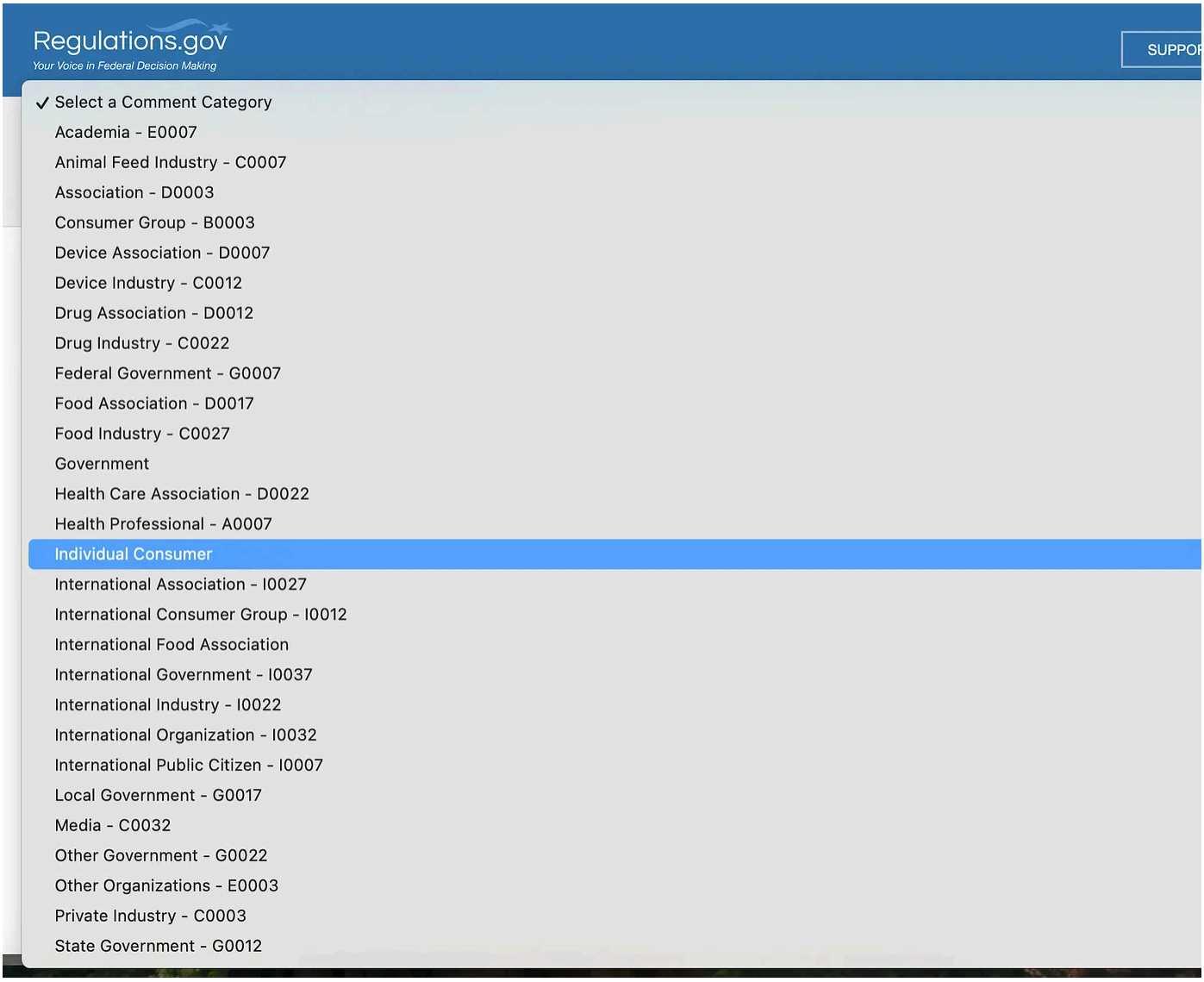

Click on the link below to read comments that have already been submitted and published.

https://www.regulations.gov/docket/FDA-2025-P-0335/comments

On the web page above, you WILL be able to read other people's comments, but it v
APPEAR that the comments have been closed. THAT IS NOT THE CASE. YOU C
MAKE A COMMENT. Be sure to click on the link above the red arrow above. The
Citizen Petition should be open for comments for 180 days.

Before you submit a public comment, please take the tim to read the details of the three sections of the Citizen Petition (below) that focus on the issue of DNA contamination which, in and of itself, should be adequat grounds for the licenses and authorizations to be revoke

CLICK HERE for additional details.

B. Synthetic DNA Contamination

6.0 Significant Evidence of DNA Contamination

6.1 Evidence from multiple independent studies confirms the presence of excessive level 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 safe threshold of 10ng per dose, in both the Pfizer and Moderna Covid-19 products, includin 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 t synthetic*

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

b. *South Australian researchers collected data* ***(15)*** *confirming synthetic plasmid DNA i 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 thresh in the Pfizer Covid-19 products, including SV40 promoter and enhancer sequences.

This study confirmed the synthetic DNA contamination is encapsulated and protected l the Lipid Nanoparticles (LNPs) used to encapsulate, protect, and efficiently transfect th modRNA into human cells; therefore the synthetic DNA contamination is not "naked", where the safety threshold of 10ng per dose only applies to "naked" and unprotected DN 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 the Pfizer Covid-19 drug.

This study confirmed the synthetic DNA contamination is encapsulated and protected l the Lipid Nanoparticles (LNPs) used to encapsulate, protect, and efficiently transfect th 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 DN able to be broken down quickly and efficiently by human blood.

e. A September 2024 expert report (18) prepared for Australian legal proceedings confirm 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 enhancer sequences.

This study confirmed the synthetic DNA contamination is encapsulated and protected l the Lipid Nanoparticles (LNPs) used to encapsulate, protect, and efficiently transfect th modRNA into human cells; therefore the synthetic DNA contamination is not "naked", where the safety threshold of 10ng per dose only applies to "naked" and unprotected DN 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 i the Pfizer Covid-19 drug, including SV40 promoter and enhancer sequences.

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

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 both the Pfizer and Moderna Covid-19 products, including SV40 promoter and enhance sequences.

i. A September 2023 study (22) by McKernan et al detected synthetic DNA contaminati levels between 18 and 70 times above the regulatory safety threshold in both the Pfizer a 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 humai 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 nc 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 provide by sponsors encompasses detailed information about the manufacturing process, which includes genetic materials like plasmid DNA used in production.

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, enhanc 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 DN 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 plasmid DNA used in the manufacture of its Covid-19 products, included and includes t 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 DN 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 plasmid DNA used in the manufacture of its Covid-19 products, included and includes t SV40 promoter and enhancer sequences.

d. At no time prior to or after the approvals of the BLAs for the Pfizer and Moderna Co 19 products did the FDA consider the regulatory threshold of 10ng per dose for "naked" synthetic DNA to have no meaning in the context of the Covid-19 products of Pfizer an Moderna which use LNPs capable of, and which in fact do encapsulate and protect resi 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, whic transfection process "naked" DNA is unable to do without the aid of LNPs.

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

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

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, LNI 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 t brain, lungs, heart, liver, spleen, testes, and ovaries. This efficient transfection likely exte 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 chromoson 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 - 1(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 le in Pfizer and Moderna products exceeding regulatory thresholds 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 synthetic DNA contaminants are now recognized* ***(31)*** *as somatic hypermutability eleme These sequence elements have been shown to actively promote genetic instability and enhance risks associated with oncogenesis. This evidence directly contradicts earlier cla (32) by regulatory agencies that these sequences were non-functional and underscores th role in elevating cancer risks through mutagenic activity.*

h. Heritable Genetic Changes: *Synthetic DNA can transfect germline cells, such as oocy 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 cytos 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 eve 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 integratio 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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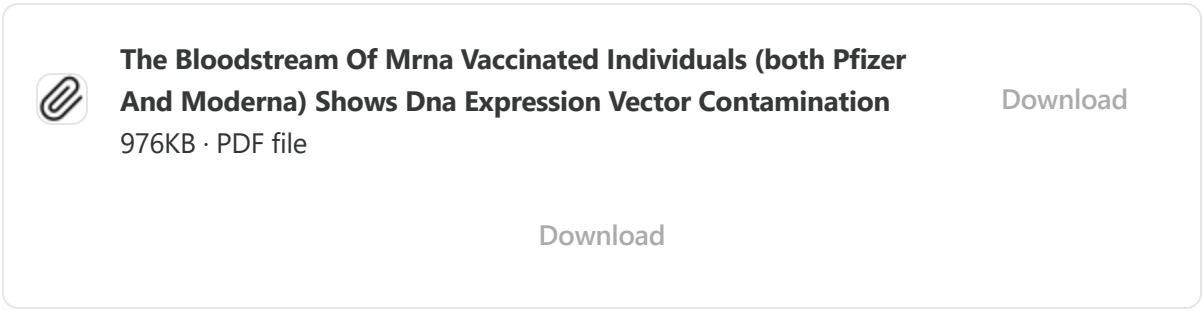

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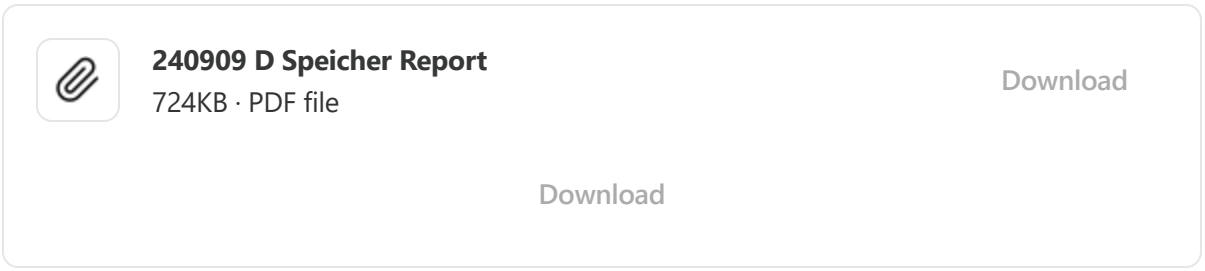

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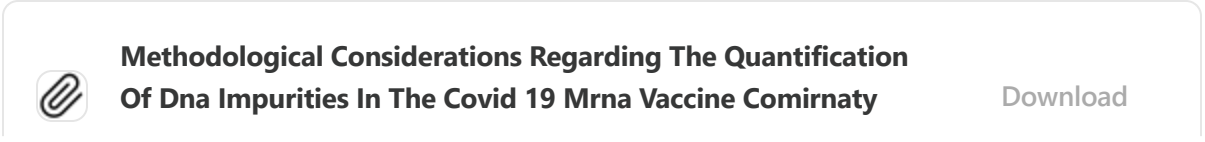

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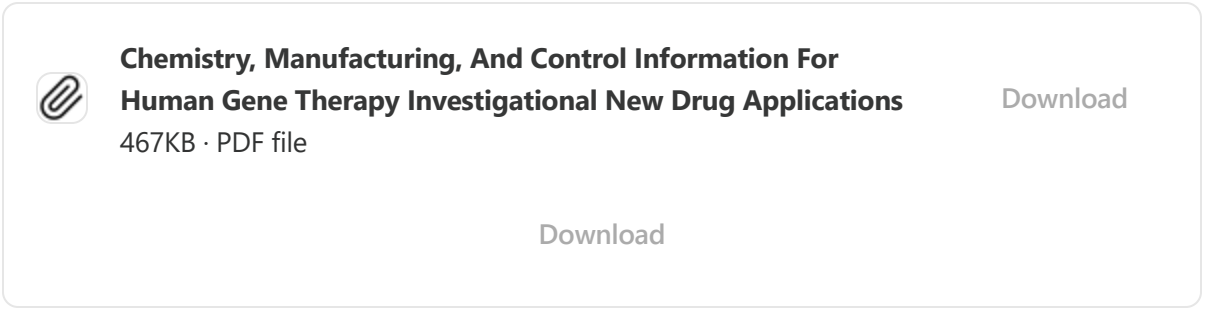

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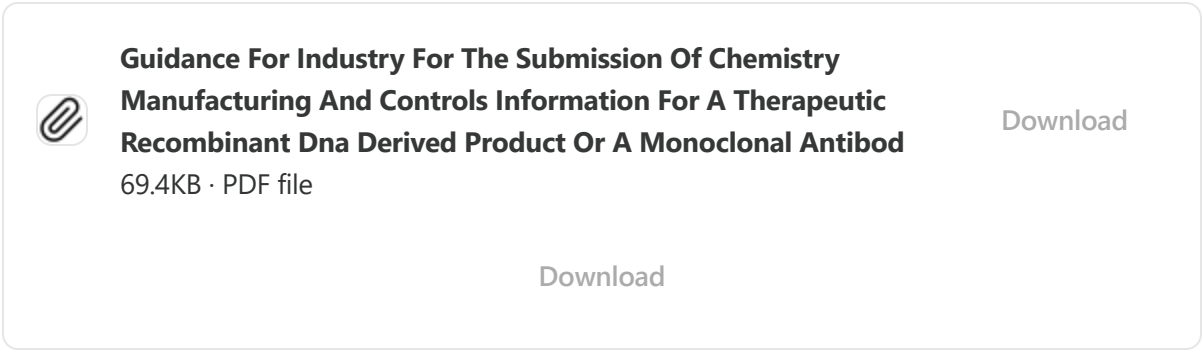

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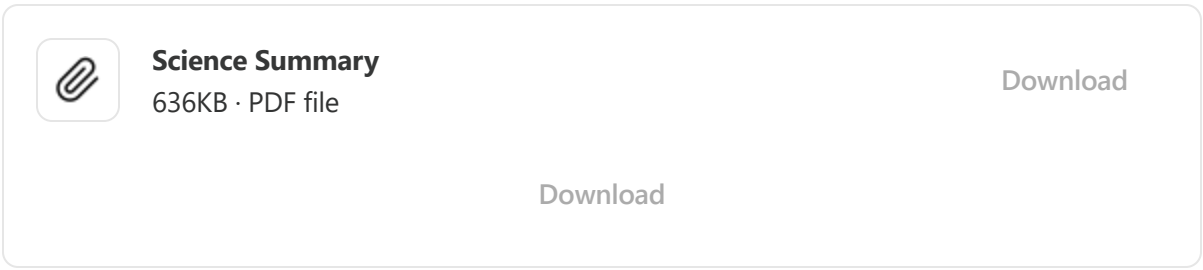

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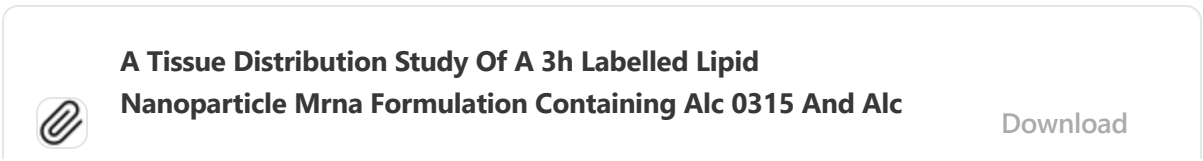

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Evidence of DNA Contamination

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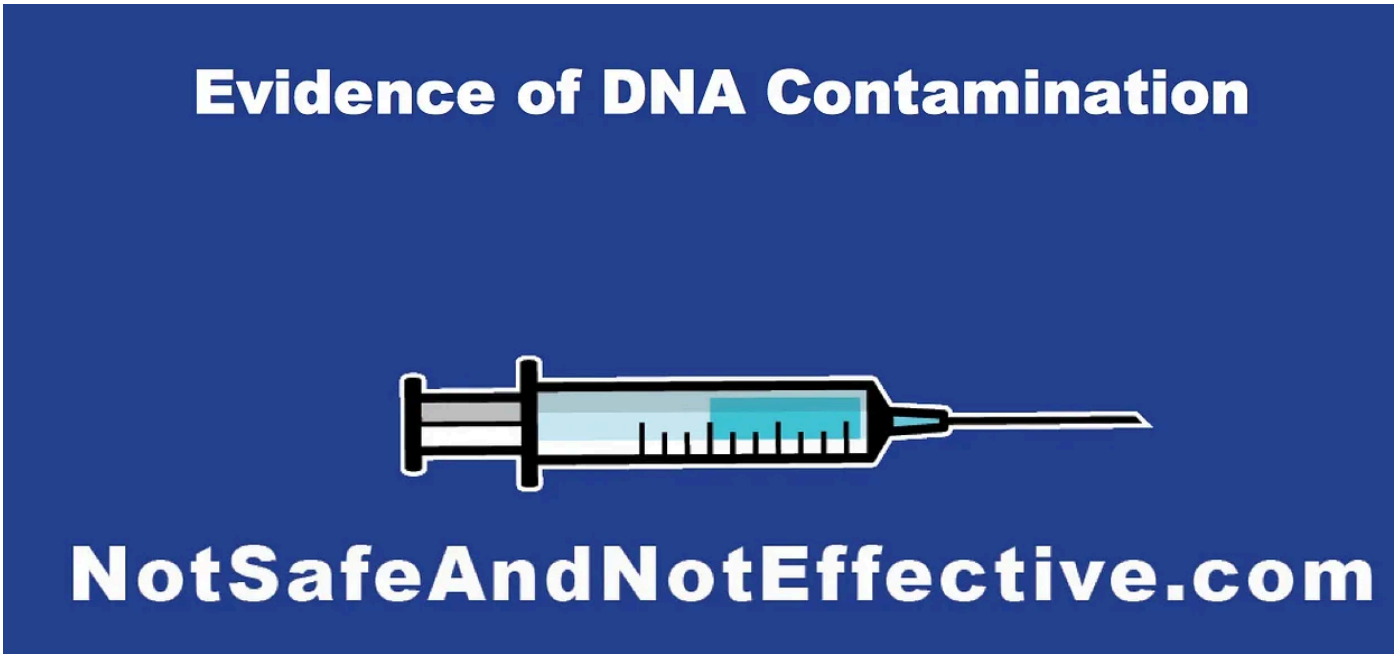

FOR COMPLETE DETAILS: NotSafeAndNotEffective.com

Read full story →

James Roguski

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Sharon olson Sharon olson 5d *Edited*

I have been licensed since 1983, doing integrated medicine and prevention. From what I have se medical practice, all vaccines should be stopped and the effects studied. I quit giving vaccines in If parents wanted vaccines for their children or adulst wanted them, I sent them to the health department. I believe the MRNA shots are contaminated and the additives are extremely toxic.

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3 replies

Stephanie Green Formerly Young Stephanie Green 4d

Liked by James Roguski

I will of course, be signing this. However, I truly believe the most impact will come from handing 'business cards'. Just as I did with pamphlets about the uselessness/ dangers of mask wearing, I i to strategically place them at doctors' offices, the grocery store, etc, and hand them directly to p firmly believe that the only way this ends, is with us. Politicians, law enforcement, government ag and hospitals are obviously not interested. I can't say thank you enough, James. Your work is stel

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