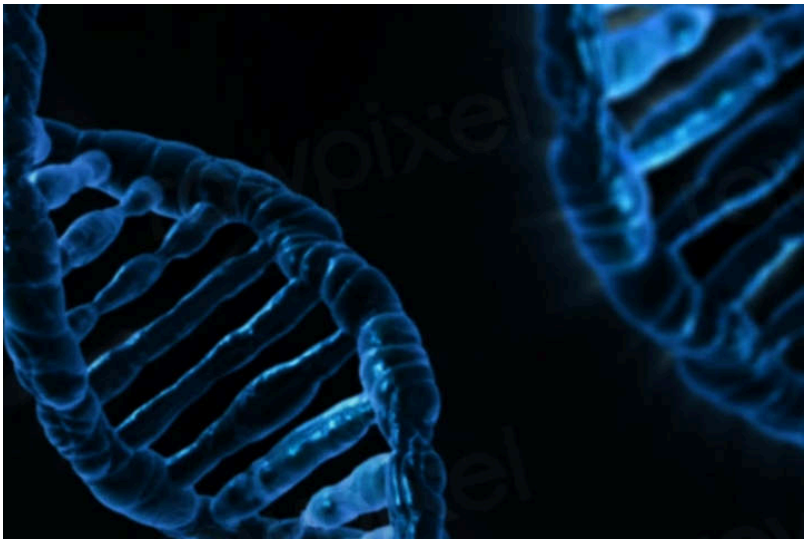
Written by **Dr. Robert Malone** on December 18, 2023

FDA Fails to Address DNA Adulteration Concerns



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The failure of government regulatory authorities to identify and disclose DNA fragment contamination of the Moderna and Pfizer/BioNTech COVID vaccine products prior to independent laboratories disclosing their contamination study findings has raised serious questions about quality control oversight of the manufacturing processes used to produce these products, as well as their overall safety. Rather than rigorously addressing specific safety questions concerning the previously undisclosed contamination or adulteration of both modified-mRNA vaccines, in a written Dec 14 reply to a prior Dec 06 inquiry, Dr. Peter Marks of the FDA Center for Biologics Evaluation and Research has resorted to redirecting, gaslighting and stonewalling the Surgeon General of the State of Florida.

Experts from around the world have raised concerns about the safety implications of DNA fragment contamination in COVID gene therapy-based "vaccine" products. Leading regulatory authorities have conceded that these rushed novel and complex biological products are contaminated, and deliver both synthetic modified messenger ribonucleic acid (mod-mRNA) and a wide variety of uncharacterized shorter DNA fragments into the cells and tissues of those who have accepted these product. The Biden administration has previously mandated and currently markets these products in the USA for Americans of all ages including during pregnancy, fraudulently claiming that they prevent SARS-CoV-2 infection and spread as well as COVID-19 disease and death.

These DNA fragments are left over contaminants from manufacturing the mod-mRNA "payload". The contamination was first detected and reported by experienced US and Canadian genomic researchers, and their findings have been replicated by many other laboratories.

To manufacture the COVID shots, both the DNA contaminants and the mod-mRNA are assembled into the most highly active lipid nanoparticle genetic delivery system ever developed, and this final drug product has been injected into over a billion human arms. After injection, the material distributes throughout the body and delivers both DNA and mod-mRNA to a wide variety of cells and tissues

including ovaries.

Both mRNA and DNA can control a wide variety of cell functions. The mod-mRNA directs cells and tissues of the recipient to produce genetically engineered SARS-CoV-2 spike protein (as well as other uncharacterized "frameshifted" proteins and peptides). The DNA fragments come from the circular bacterial DNA ("plasmids") used to manufacture the mod-mRNA. These plasmids include DNA sequences which can produce a variety of functions inside both bacterial and human cells; proteins which confer antibiotic resistance, sequences which guide DNA into the nucleus of cells, and highly active genetic switches for turning on adjacent genes in either bacterial or animal cells.

In a December 06 letter from Dr. Joe Ladapo MD, PhD sent to FDA director Robert Califf, the following questions concerning DNA contamination of these mod-mRNA products were posed:

1. Have drug manufacturers evaluated the risk of human genome integration or mutagenesis of residual DNA contaminants from the mRNA COVID-19 vaccines alongside the additional risk of DNA integration from the lipid nanoparticle delivery system and SV40 promoter/enhancer? Has FDA inquired any information from the drug manufacturers to investigate such risk?
2. Do current FDA standards for acceptable and safe quantity of residual DNA (present as known contaminants in biological therapies) consider the lipid nanoparticle delivery system for the mRNA COVID-19 vaccines?
3. Considering the potentially wide biodistribution of mRNA COVID-19 vaccines and DNA contaminants beyond the local injection site, have you evaluated the risk of DNA integration in reproductive cells with respect to the lipid nanoparticle delivery system?

Earlier today, December 15, the Florida Department of Health publicly posted the FDA response authored by CBER director Dr. Peter Marks to Surgeon General Dr. Ladapo dated December 14, 2023. The response failed to address the questions posed by the Surgeon General, instead offering unsubstantiated platitudes such as "safe and effective" combined with redirection to irrelevant and poorly documented information.

Dr. Peter Marks (a hematologist and oncologist), together with the US Government biowarfare specialist Dr. Robert Kadlec, was responsible for initial creation and regulatory management oversight of Operation Warp Speed, is very invested in the success of this program and has proposed that it be expanded to include cancer treatments. Operation Warp Speed exploited the special US Emergency Use Authorization regulatory pathway to bypass many of the regulatory steps and procedures normally required to insure the safety and effectiveness of vaccine products, which typically require up to a decade of development before widespread deployment.

Worldwide administration of the resulting injectable products has been associated with over seventeen million excess deaths (globally), as well as large numbers of cases of heart damage (myocarditis) with a perverse predilection for young people, contradicting the repeated propaganda statement that these products are safe. US Government officials have colluded in a widespread campaign to cover up data concerning myocarditis side effects. There are over 700 peer reviewed academic publications documenting these and many other types of damages and illnesses caused by these products.

In one of the most intensive global propaganda and marketing campaigns ever deployed, it has been widely asserted that these products will enable herd immunity, will prevent infection, replication, and spread of SARS-CoV-2, and will also prevent COVID-19 disease and death. However, it is now widely

recognized that these mod-mRNA provide none of these benefits and are therefore not effective. The messaging used in this propaganda campaign has been supported by over 1,200 peer reviewed academic publications providing propagandists and marketing specialists advice on how to overcome "vaccine hesitancy".

Despite the proven and documented lack of safety and effectiveness, overlapping layers of legal protection (indemnification) prevent both deceived public and damaged individuals from obtaining compensation for this fraud.

In his response to the Surgeon General's questions, Dr. Marks has provided a series of unsupported or misleading statements, combined with circuitous and not scientifically rigorous responses to the specific questions posed. These responses appear to suggest that the FDA has failed to require DNA integration studies to determine the dose limiting toxicity of bacterial plasmid DNA fragments when delivered into animal models using the specific formulations now injected into over a billion human beings. Dr. Marks failed to cite any studies which specifically address DNA fragment integration risks to those receiving these products, instead referring only to studies which can only detect other types of genotoxicity. DNA fragment integration is one of multiple types of genetic damage which such lipid nanoparticle formulations may cause.

In his response to Dr. Ladapo's inquiry, Dr. Marks cites an FDA guidance document which addresses general requirements for assessing DNA contamination of vaccines (such as influenza) which are manufactured using cultured cell lines. This type of manufacturing process often yields vaccine material which is contaminated with large fragments of chromosomal DNA from the animal cells used to grow the vaccine. This contamination is substantially different from that involving the mod-mRNA products, in that we now know that those products are contaminated with small DNA fragments which are more likely to cross into the region of cells which contain the genome, and in contrast to traditional vaccines these mod-mRNA products and their DNA contaminants are assembled into highly active lipid nanoparticle delivery formulations, greatly increasing the risk that such DNA will enter both the cells and the part of the cells which house the genome (the nucleus).

Despite the fact that the risks of DNA contamination with traditional cell-based vaccines are much lower than for the novel mod-mRNA lipid nanoparticle-based products, the cited FDA guidance documents include the following specific warnings concerning DNA contamination:

> Residual DNA might be a risk to your final product because of oncogenic and/or infectivity potential. There are several potential mechanisms by which residual DNA could be oncogenic, including the integration and expression of encoded oncogenes or insertional mutagenesis following DNA integration.

In his response to the Surgeon General, Dr. Marks refers to a specific clause in this guidance to support safety of the levels of DNA fragment contamination, which in turn refers back to a WHO document. What he fails to acknowledge is that this guidance refers to DNA contamination in a directly injected (parenteral) vaccine, not one employing the most highly active DNA and RNA lipid nanoparticle delivery system ever devised by man. This oversight either reveals Dr. Marks' profound ignorance of this significant difference (despite the Surgeon General having pointed this out in his initial letter), or a fraudulent attempt to gaslight and obfuscate the truth of the matter. Either ignorance or intentional cover up, hard to differentiate. Here is the cited clause:

> You should limit residual DNA for continuous non-tumorigenic cells, such as low-passage Vero cells, to less than 10 ng/dose for parenteral inoculation as recommended by WHO (Ref. 31)

Reference 31 refers to a WHO document developed and published in 1998, less than a decade after my initial discoveries relating to large scale mRNA manufacture and delivery and about the same time as Kariko and Weissman's first report of their work with pseudouridine. This outdated WHO statement predates the development of the current generation of mod-mRNA delivery technology by approximately 20 years, and is completely irrelevant.

In additional efforts to cover up the apparent failure of the FDA to require the specific DNA integration toxicology studies both logically needed to rigorously assess patient risk and required for all previous DNA vaccine products prior to human experimental use, Dr. Marks cites the Summary approval document for the Pfizer/BioNTech mod-mRNA product "COMIRNATY" as well as the Summary approval document for the Moderna "SPIKEVAX" product. Specifically, Dr. Marks makes the following assertion:

> studies have been conducted in animals using the modified mRNA and lipid nanoparticle together that constitute the vaccine, including the minute quantities of residual DNA fragments left over after DNAse treatment during manufacturing, and demonstrate no evidence for genotoxicity from the vaccine

The very limited studies performed are incapable of detecting DNA fragment integration. Once again, this statement reflects either intentional gaslighting or incompetence. The COMIRNATY document provides no specific references to genotoxicity or integration studies having been performed prior to human authorization. In contrast, the SPIKEVAX document (SPIKEVAX is not the same product as COMIRNATY) lists the following assays performed:

Other Supportive Toxicology Studies

The safety of SPIKEVAX is further supported by the aggregate rat repeat-dose toxicity profiles observed in six GLP toxicity studies of five vaccines formulated in SM-102 lipid particles containing mRNAs encoding various viral glycoprotein antigens, demonstrating tolerance of repeat doses of these vaccines without any detrimental effects. Three other toxicology studies were also reviewed in support of safety of SPIKEVAX. A study report from an in vitro rat micronucleus assay evaluating the genotoxic potential of (b) (4) mRNA in SM-102 LNP revealed no genotoxic effects of SM-102 LNP. In addition, study reports from a bacterial reverse mutation test and an in vitro mammalian cell micronucleus test of PEG2000-DMG were also reviewed. No genotoxic effects of PEG2000-DMG were observed in these studies.

Under the heading "Other Supportive Toxicology Studies", this regulatory submission demonstrates the gross inadequacy of the testing performed for SPIKEVAX, which despite this inadequacy apparently still exceeds the testing performed for COMIRNATY. The SPIKEVAX documentation refers to an *in vitro* (ergo in a test tube) rat micronucleus assay of the formulated mRNA. No mention is made of any level of DNA fragment contamination in the tested preparation. The in vitro rat micronucleus assay is a method for rapidly testing the activity of a pharmaceutical or radiologic treatment in grossly disrupting chromosomes. It is completely inappropriate and incapable of detecting insertional mutagenesis. PEG2000-DMG is one of many components of the lipid nanoparticle, and these test results are irrelevant to the questions raised by the Surgeon General, as neither mod-mRNA nor DNA fragments

were tested, and once again the tests performed would fail to detect any integration events.

The appropriate testing for DNA fragment integration is covered in the FDA guidance document "Guidance for Industry: Considerations for Plasmid DNA Vaccines for Infectious Disease Indications", which Dr. Marks has failed to cite in his response. Dr. Marks' makes the following assertion in his response to the Surgeon General:

> On first principle, it is quite implausible that the residual small DNA fragments located in the cytosol could find their way into the nucleus through the nuclear membrane present in intact cells and then be incorporated into chromosomal DNA.

Once again, at best this statement reveals Dr. Marks' profound ignorance. The use of this type of lipid nanoparticle technology for delivering both large and small DNA fragments into the nucleus of cultured cells is industry standard, and has been for decades. This statement is also directly contradicted by the guidance cited above, which states the following:

> Theoretical concerns regarding DNA integration include the risk of tumorigenisis if insertion reduces the activity of a tumor suppressor or increases the activity of an oncogene. In addition, DNA integration may result in chromosomal instability through the induction of chromosomal breaks or rearrangements.

In direct contradiction to the poorly cited assertion made by Dr. Marks, Moderna acknowledges these risks in its own patent filings. In the issued US Patent #US2019/0240317 A1 titled "HPIV3 Vaccines", Moderna provides the following text:

> *[0012] Deoxyribonucleic acid (DNA) vaccination is one technique used to stimulate humoral and cellular immune responses to foreign antigens, such as hMPV antigens and/or PIV antigens and/or RSV antigens. The direct injection of genetically engineered DNA (e.g., naked plasmid DNA) into a living host results in a small number of its cells directly producing an antigen, resulting in a protective immunological response. With this technique, however, comes* ***potential problems, including the possibility of insertional mutagenesis, which could lead to the activation of oncogenes or the inhibition of tumor suppressor genes.***

The FDA's own "Guidance for Industry Considerations for Plasmid DNA Vaccines for Infectious Disease Indications" provides clear guidance concerning how the risks of DNA integration risk should be addressed:

> A typical integration study will assess all tissue(s) containing persisting DNA plasmid. We recommend that at least four independent DNA samples be analyzed. Each sample may include DNA pooled from several different donors. Q-PCR is generally used to detect and quantify the amount of plasmid DNA present in each genomic DNA preparation. Unintegrated plasmid DNA may be separated from high molecular weight genomic DNA by gel purification. Concatamer may be eliminated by restriction endonuclease digestion targeting a rare motif present in the DNA plasmid. Specifically designed PCR primers may be used to confirm integration and identify genomic integration sites.

Based on these and many other examples of existing FDA guidance and prior regulatory submissions, there are both well-developed protocols and well-established precedent for performing DNA fragment integration studies. The failure of Dr. Marks to correctly cite FDA guidance, past precedent, or reference any relevant studies performed to assess these risks in the context of either the COMIRNATY or SPIKEVAX regulatory dossiers clearly demonstrates a tragic failure of proper regulatory oversight and diligence.

CONCLUSION

In its response to an appropriate and well-documented inquiry from the Florida Surgeon General, the US FDA has clearly failed to establish that it was aware of the contamination or adulteration of COMIRNATY or SPIKEVAX final drug products with plasmid DNA fragments, and has completely failed to insist on the testing necessary to both establish dose limiting toxicity of DNA fragments when delivered to animals or humans using these highly active lipid nanoparticle formulations. Furthermore, in the written FDA response to the December 6, 2023 inquiry from Dr. Ladapo concerning the risks of this contamination, the FDA has demonstrated a lack of rigor in addressing the questions posed which is combined with a series of statements which can only be interpreted as either ignorant, incompetent or intentionally misleading.

The Surgeon General and citizens of the State of Florida, the US public, and the citizens of the world deserve better than to be mislead and gaslight about the risks of the widely acknowledged DNA fragment contamination present in virtually all batches and lots of COMIRNATY and SPIKEVAX. Based on the FDA's abject failure to address these risks in a serious manner, and its willingness to substitute platitudes, half truths, and outright falsehoods for actual data, the FDA, CBER and Dr. Marks have once again damaged the credibility of the US HHS in the eyes of both the US Public and the world. We all deserve better, but in the interim it must be concluded that the risks associated with DNA plasmid fragment adulteration when delivered with the highly active lipid nanoparticle formulations of COMIRNATY and SPIKEVAX are both real and uncharacterized, and consistent with US Federal statute CFR Title 21, CHAPTER 9, SUBCHAPTER V **§ 351,** the products must be withdrawn from the market until the necessary tests have been performed and safety demonstrated.