

Mission:

To protect, promote and improve the health of all people in Florida through integrated state, county and community efforts.



Ron DeSantis
Governor

Joseph A. Ladapo, MD, PhD
State Surgeon General

Vision: To be the Healthiest State in the Nation

December 6, 2023

Robert M. Califf, MD, MACC
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Springs, MD 20993

CC: Mandy Cohen, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4027

Dear Drs. Califf and Cohen,

Ensuring that pharmaceutical products are both safe and effective for the public is the principal mission of the U.S. Food and Drug Administration (FDA). This function is essential and serves as the foundation for public trust in regulatory agencies and for health officials alike. While accelerated approvals for prescription drugs have been around for over two decades, the opioid crisis and COVID-19 pandemic are just two publicized examples illustrating the risks associated with these accelerated processes for drug approvals. On [November 14, 2023](#), the Florida Public Health Integrity Committee met to discuss this topic and I encourage your team to review the constructive criticism that will further our mission of credible and safe public health.

Related to these regulatory issues, debates over the safety and effectiveness of COVID-19 vaccines have been smeared as “hysteria” since their development – and yet as additional research is conducted, concerns continue to emerge. I have highlighted some of these concerns in a May 10, 2023 [letter](#) sent to you and former Centers for Disease Control and Prevention Director Rochelle Walensky. To date, no response has been received. In addition to my previous letter, I am writing to you to address the recent [discovery](#) of host cell DNA fragments within the Pfizer and Moderna COVID-19 mRNA vaccines.

This raises concerns regarding the presence of nucleic acid contaminants in the approved Pfizer and Moderna COVID-19 mRNA vaccines, particularly in the presence of lipid nanoparticle complexes, and Simian Virus 40 (SV40) promoter/enhancer DNA. Lipid nanoparticles are an efficient vehicle for delivery of the mRNA in the COVID-19 vaccines into human cells, and may therefore be an equally efficient vehicle for delivering contaminant DNA into human cells. The presence of SV40 promoter/enhancer DNA may also pose a unique and heightened risk of DNA integration into host cells.

In 2007, the FDA published guidance on regulatory limits for DNA vaccines in the [Guidance for Industry: Considerations for Plasmid DNA Vaccines for Infectious Disease Indications](#) (Guidance for Industry). This Guidance for Industry highlights important considerations for vaccines that use novel methods of delivery regarding DNA integration:

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- DNA integration could theoretically impact a human's oncogenes – the genes which can transform a healthy cell into a cancerous cell.
- DNA integration may result in chromosomal instability.
- The Guidance for Industry discusses biodistribution of DNA vaccines and how such integration could affect unintended parts of the body including blood, heart, brain, liver, kidney, bone marrow, ovaries/testes, lung, draining lymph nodes, spleen, the site of administration and subcutis at injection site.

Based on this Guidance for Industry, the efficacy of the COVID-19 mRNA vaccine's lipid nanoparticle delivery system, and the presence of DNA fragments in these vaccines, it is essential to human health to assess the risks of contaminant DNA integration into human DNA. With this in mind, I have the following questions for which the public deserves answers:

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?

Considering the urgency of these questions due to the mass administration of these vaccines and currently unavailable data surrounding possible genomic effects, I request that you provide a written response by December 13, 2023, to both my previous letter and the concerns I have outlined above. The American people and the scientific community have a right to have all relevant information pertaining to the COVID-19 vaccines to properly inform individual decision making. I look forward to promptly hearing from you.

Sincerely,



Joseph A. Ladapo, MD, PhD
State Surgeon General