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# COVID Vaccine Shedding Is ‘Real,’ FDA and Pfizer Documents Are Proof: Clinicians

All gene therapy products pose a risk of shedding, according to the FDA.



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By [Marina Zhang](#)

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A A Print

The topic of COVID-19 vaccine shedding has long been controversial, but now, some doctors say it is real.

“Shedding is unfortunately real,” said Dr. Pierre Kory at the Front Line COVID-19 Critical Care Alliance (FLCCC) conference in Phoenix, Arizona, in early February. “The FDA (U.S. Food and Drug Administration) knows that.”

Dr. Kory is a co-founder of the FLCCC, a non-profit advocacy group founded by physicians for the treatment of COVID-19, long COVID, and post-vaccine syndromes. He is also the co-founder of the Leading Edge

Clinic and has treated over a thousand long-COVID and post-vaccine patients.

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Fact-checkers have largely denied shedding on the basis of definition. The commonly cited definition comes from the U.S. Centers for Disease Control and Prevention (CDC) website, which defines shedding as the release of viruses, bacteria, and their components from live vaccines.

While mRNA and adenovirus vaccines are not live vaccines, they function similarly to gene therapy products.

All gene therapy products pose a risk of shedding, according to the FDA.

## FDA Documents

In a [2015 document](#) titled Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products, the FDA defines shedding as “the release of [viral or bacterial gene therapy products] ... from the patient through one or all of the following ways: excreta (feces); secretions (urine, saliva, nasopharyngeal fluids etc.); or through the skin (pustules, sores, wounds).”

In the same document, the FDA also explains what gene therapy products are: “All products that mediate their effects by transcription and/or translation of transferred genetic material.”

The COVID-19 mRNA and adenovirus vaccines [fall into this category](#). They mediate their effects by inducing the body to translate mRNA genetic information into spike proteins.

Some gene therapy products known to shed include an eye treatment branded as Luxturna. Luxturna uses an adenovirus carrier to deliver eye protein DNA to retina cells in patients.



The Luxturna adenovirus and its DNA have been found in patients' tears, according to the product's package insert.

Similarly, mRNA and adenovirus COVID-19 vaccines may cause vaccinated patients to release spike proteins or other vaccine components, Dr. Kory explained.

For example, COVID-19 mRNA has been found in the breast milk of vaccinated mothers, indicating possible exposure of the vaccine to infants. Another study showed that spike protein, the product of COVID-19 vaccination, can last for at least half a year in the blood of vaccinated individuals, indicating prolonged spike protein persistence.

The FDA, however, denied that the 2015 document applies to COVID mRNA vaccines.

"COVID-19 vaccines are not regulated as gene therapy products by the FDA; therefore, the guidance document cited is not applicable to the COVID-19 vaccines," an FDA spokeswoman told The Epoch Times.

## **Pfizer Investigators Told to Report 'Environmental' Vaccine Exposures**

Another piece of evidence resides in Pfizer documents, Dr. Kory added.

In Pfizer's COVID mRNA vaccine protocol, the company instructs investigators to report "environmental exposures" if trial participants expose people around them to the vaccine through inhalation or skin contact.

Examples of such environmental exposures are noted as follows:

- "A male participant who is receiving or has discontinued [vaccine] intervention exposes a female partner prior to or around the time of conception."

- “A female family member or healthcare provider reports that she is pregnant after having been exposed to the [vaccine] intervention through inhalation or skin contact.”

The protocol also goes into what Dr. Kory and his clinic co-founder, Scott Marsland, call “secondary shedding.” This occurs when a person who has had environmental exposure to the vaccine then exposes another person.

“An example of environmental exposure during breastfeeding,” Pfizer writes, “is a female family member or healthcare provider who reports that she is breastfeeding after having been exposed to the study intervention (the vaccine) by inhalation or skin contact.”

## Pfizer’s Documents Showing Indirect Exposures

Pfizer has documented hundreds of adverse events that occurred as a result of indirect exposures or exposure to babies during pregnancy or breastfeeding.

In its Periodic Safety Report submitted to the European Union, Pfizer listed several adverse events it deemed not attributable to the vaccine and that should be excluded from discussion.

The document listed 22 cases of adverse events in babies who had received “indirect exposure” to COVID mRNA boosters, suggesting exposure other than a direct vaccination.

The investigators also monitored several special adverse event cases. Two blood-related adverse events involved babies being exposed through breastfeeding. Ten cases of liver-related adverse events and one adverse event of the vasculature system were reported for the same reason.

Two cases of acute kidney or renal failure and eight respiratory cases also involved babies being exposed during pregnancy or breastfeeding.

## Testimonies From Patients

Patients who may be affected by vaccine exposure tend to be those with a history of sensitivities and chronic diseases, said Dr. Kory and Mr. Marsland. They also tend to have bad experiences with pharmaceuticals and are more likely to be chronically debilitated by COVID-19 or the vaccine.

Dr. Kory said that after compiling over 800 anecdotal reports, they observed a clear pattern in symptoms that they determined to be shedding.

Typically, the manifestation of symptoms is repeatable and predictable, such as when a person repeatedly becomes symptomatic when going into supermarkets or crowded places.

Dr. Kory gave the example of a patient who noticed he could not handle going into grocery stores.

The patient told Dr. Kory that he just couldn’t “go into grocery stores anymore.” Within five minutes of entering a Trader Joe’s grocery store, he “feels so terrible” that he has to leave. He experienced the same aversion upon going to a crowded farmers market.

At the FLCCC event, Mr. Marsland also shared several cases where he believed shedding was involved.

One case involved a 54-year-old male, who previously suffered from symptoms after the COVID-19 vaccine, meeting up with a friend who received a COVID-19 booster.

They sat close to each other, talking and laughing. “Within hours of spending their time together, [the man] had a headache, myalgia, and joint pain, increased fatigue,” Mr. Marsland relayed.

When the patient went to a busy airport, he felt worse.

He returned home and had sexual contact with his spouse, exchanging bodily fluids. Within minutes, the spouse developed severe “nine out of 10” abdominal pain.

The two believed the pain was from shedding, so both took ivermectin, known to bind to and block spike proteins. Within about half an hour, the spouse’s abdominal pain receded.

“It’s the temporal association and the accumulation of symptoms,” Mr. Marsland reasoned.

Other doctors treating long COVID and post-vaccine syndromes, such as Dr. Syed Haider and Dr. Ana Mihalcea, have also reported suspected cases of shedding.

## Some Vaccinologists Disagree

Professors in vaccinology, however, do not acknowledge that mRNA vaccines may induce shedding.

“mRNA leads to the expression of proteins in cells, and this expression is different from shedding, as you would have if you are infected by certain viruses,” associate professor Paulo Verardi of the University of Connecticut told The Epoch Times.

“While SARS-CoV-2 infection leads to virus shedding, and, therefore, transmission of the virus from person to person, shedding of the spike protein does not occur in individuals receiving the COVID-19 mRNA vaccine,” he continued.

While another definition of shedding refers to the release of live viruses in people infected or vaccinated with live vaccines, Dr. Kory reiterated that the shedding discussed in the case of COVID-19 vaccines is different from the shedding of live viruses.

Professor Florian Krammer at the Icahn School of Medicine at Mount Sinai also told The Epoch Times that shedding does not exist.

He did not reply when The Epoch Times presented him with information regarding the FDA’s documents on gene therapy and shedding.

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**Marina Zhang**  
Author

Marina Zhang is a health writer for The Epoch Times, based in New York. She mainly covers stories on COVID-19 and the healthcare system and has a bachelors in biomedicine from The University of Melbourne. Contact her at [marina.zhang@epochtimes.com](mailto:marina.zhang@epochtimes.com).

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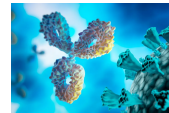
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