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FDA Should Recall 'Adulterated' Pfizer COVID-19 Vaccine: Robert Malone

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Pfizer's vaccine contains a DNA sequence that could cause problems.

Pfizer's COVID-19 vaccine is adulterated due to the undisclosed presence of a DNA sequence, experts say.

That should prompt a recall by the U.S. Food and Drug Administration (FDA), according to Dr. Robert Malone, a vaccine expert whose work has been cited by Pfizer.

"It absolutely should be recalled," Dr. Malone told The Epoch Times.

"Will the FDA do its job?" he added later.

Pfizer's vaccine contains a Simian Virus 40 (SV40) DNA sequence, authorities in Canada confirmed to The Epoch Times. Authorities found the sequence after outside researchers, including Kevin McKernan, discovered the sequence in the shot.

The whole SV40 virus can cause cancer, prompting its removal from polio vaccines in the past. While the primary genetic sequence of the virus associated with cancer is not in Pfizer's

vaccine, there is a portion of the sequence called a promoter-enhancer, which "can get things into the nucleus, so that is a concern," David Wiseman, a former Johnson & Johnson scientist, told The Epoch Times.

Due to the presence of the sequence, some experts say, the FDA should find the product adulterated, which is defined under federal law as having a "strength, quality, or purity differing from the official compendium."

Congress directed the FDA that if tests are run on a drug suspected of being adulterated and the drug fails to meet the standards in the compendium, and there is a health hazard, to direct the manufacturer to issue a recall, Dr. Malone noted in an essay.

If the manufacturer then fails to issue a recall, "seizure should be considered," the law states.

"The general policy is that if there's adulteration and reasonable risk of toxicity, there must be immediate action," Dr. Malone told The Epoch Times. "This is a core mandate to the FDA from Congress to prevent adulteration of drugs, medical devices, and food. And then the next question is, is that adulteration? Is it associated with a reasonable risk of toxicity in humans? And my opinion is, absolutely."

Other experts, such as Dr. Janci Lindsay, also say the sequence presence means the vaccine is adulterated.

Your Health Matters

The FDA declined to comment.

Pfizer has not responded to inquiries.

Sen. Ron Johnson (R-Wis.), ranking member of the Senate Homeland Security and Governmental Affairs' Permanent Subcommittee on Investigations, said that regulators must provide answers.

"I have been researching and consulting experts on the issue of DNA contamination in COVID-19 vaccines since it was exposed," Mr. Johnson told The Epoch Times via email. "The FDA must provide answers to the legitimate questions being raised."

If the FDA does not take action, state attorneys general could move to seize the vaccine due to the adulteration, Dr. Malone said.

The Epoch Times asked several attorneys general if they are considering or would consider such a move, but they did not respond.

'We Do Not Know What Was Disclosed'

Health Canada said sponsors such as Pfizer are expected to identify biologically functional DNA sequences within a plasmid, such as the SV40 sequence, when submitting applications for clearance.

Pfizer did provide the full DNA sequence of the plasmid but "did not specifically identify the SV40 sequence," the health agency said.

After Mr. McKernan and other scientists uncovered the sequence, Health Canada did "confirm the presence of the enhancer," it added.

It's not clear whether the sequence was also not identified for the FDA by Pfizer.

"We don't know what was disclosed to the FDA prior to authorization. If it was disclosed, then its presence is not unexpected. If it was not disclosed, I think there is a case that this is adulteration," Mr. Wiseman said.

The rules under which the vaccine was initially given emergency use authorization (EUA) may provide a defense for the agency, though.

"Could FDA argue that because of the EUA, or because they knew

about it, or some other reason, no action is required on their part, and there is nothing to see here? They may try to argue that. But the totality is that this is completely wrong," Mr. Wiseman said.

Mr. McKernan in June, during an FDA meeting's public comment, presented his findings and showed that Pfizer did not disclose the sequence to the European Medicines Agency (EMA). The FDA does not typically respond during the public comment portion of its meetings, or afterwards to what was presented.

"The really crushing thing here is Pfizer never disclosed the SV40 information to the EMA. They gave them a plasmid map of what the plasmid consisted of, with all of the features labeled, with the exception of the SV40 site," Mr. McKernan told EpochTV's "American Thought Leaders." "They did that because they know the SV40 region is a very controversial base in its history in the vaccine field."

New Paper

In a preprint paper published this month, Mr. Wiseman, Mr. McKernan, and other researchers tested 27 vials of the Moderna and Pfizer COVID-19 vaccines and found the presence of the SV40 sequence in the Pfizer vials, not the Moderna ones.

The testing, along with Health Canada's statement, helps confirm the results of Mr. McKernan's earlier testing, which identified the presence of the sequence.

Dr. Phillip Buckhaults, a cancer genomics expert and a professor at the University of South Carolina, also found pieces of plasmid DNA in the vaccine. He told The Epoch Times that "no one knows if this DNA does anything clinically significant, but it is prudent to

check vaccinated people for any evidence of genome modification."

Dr. Wafik El-Deiry, another cancer expert who serves as director of the Legorreta Cancer Center at Brown University, has said that the findings should spur more research into the impact of the vaccines on different parts of the body, including in the heart and brain.

Matthew Horwood contributed to this report.