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CDC, FDA Respond to Florida Surgeon General's COVID-19 Vaccine Safety Alert

Zachary Stieber, Reporter Mar 14 2023

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U.S. health authorities have responded to the warning from Florida's surgeon general about a spike in reports of adverse events following COVID-19 vaccination.

Drs. Rochelle Walensky and Robert Califf claimed in the response that Dr. Joseph Ladapo, the surgeon general, was misleading the public by focusing on the increase in adverse events reported to the Vaccine Adverse Event Reporting System (VAERS).

“The claim that the increase of VAERS reports of life-threatening conditions reported from Florida and elsewhere represents an increase of risk caused by the COVID-19 vaccines is incorrect, misleading, and could be harmful to the American public,” Walensky and Califf said in [the missive](#).

Walensky heads the U.S. Centers for Disease Control and Prevention (CDC). Califf heads of the U.S. Food and Drug Administration (FDA). The CDC and FDA co-manage VAERS, which accepts reports from anybody but which is primarily used by healthcare workers.

The COVID-19 vaccines were given emergency authorization in

late 2020. Under the emergency authorizations, vaccine companies and healthcare workers are required to report certain adverse events through VAERS, “so more reports should be expected,” Walensky and Califf said.

“Most reports do not represent adverse events caused by the vaccine and instead represent a preexisting condition that preceded vaccination or an underlying medical condition that precipitated the event,” they said.

They did not cite any studies or other research to support the claim.

While anyone can lodge reports with the system, authorities request medical records and other documentation in an effort to verify reports of certain events. Out of 1,826 reports of heart inflammation after Pfizer or Moderna vaccination in adults through May 26, 2022, for instance, the CDC verified 72 percent.

The CDC also [identified hundreds of safety signals](#) for the Moderna and Pfizer COVID-19 vaccines through analyzing VAERS data in 2022, according to records obtained by The Epoch Times. A safety signal is a possible sign of a side effect. Only a handful of adverse events are definitely caused by the vaccines, [according to the CDC](#), including myocarditis, or heart inflammation, and severe allergic shock.

Ladapo [said in February](#) that in Florida, the number of reports to VAERS after the COVID-19 vaccines were authorized spiked by 1,700 percent, while the increase in vaccine administration rose by just 400 percent.

“We have never seen this type of response following previous mass vaccination efforts pushed by the federal government,” Ladapo said in [a letter](#) to Walensky and Califf.

“These findings are unlikely to be related to changes in reporting

given their magnitude, and more likely reflect a pattern of increased risk from mRNA COVID-19 vaccines,” he added, calling for “unbiased research ... to better understand these vaccines’ short- and long-term effects.” The Pfizer and Moderna vaccines both use messenger RNA (mRNA) technology.

Florida officials pointed to [a study that found](#) in the original clinical trials that the vaccinated were more at risk of serious adverse events, as well as [other papers](#) that found an increased risk of adverse events after COVID-19 vaccination.

Florida currently [recommends against](#) COVID-19 vaccination for young, healthy males who have been shown to be at the highest risk of myocarditis. Vaccinating the population “doesn’t make any sense” from a risk-benefit standpoint, Ladapo, appointed by Republican Florida Gov. Ron DeSantis, [told The Epoch Times](#). The heart inflammation causes serious problems and can even lead to death in some cases.



Food and Drug Administration Commissioner Robert Califf speaks to members of Congress in Washington on June 16, 2022. (Joe

Raedle/Getty Images)

Officials Differ

Walensky and Califf, both appointed by Democrat President Joe Biden, told Ladapo that their reference information supports vaccinating virtually all people aged 6 months and older with not only a primary series of the COVID-19 vaccine, but boosters.

“Based on available information for the COVID-19 vaccines that are authorized or approved in the United States, the known and potential benefits of these vaccines clearly outweigh their known and potential risks,” they said. “Multiple well conducted, peer-reviewed, published studies and demonstrate that the risk of death, serious illness and hospitalization is higher for unvaccinated individuals for every age group.”

The officials cited studies [from the CDC](#), including [papers](#) published by the agency’s quasi journal. According to the CDC, some papers published by the journal aren’t peer reviewed. All of the studies are shaped by agency officials to align with its messaging, which during the pandemic has been aggressively pro-vaccination, even as awareness of confirmed and possible side effects has grown.

The messaging was on display in the letter.

“As the leading public health official in state, you are likely aware that seniors in Florida are under-vaccinated, with just 29% of seniors having received an updated bivalent vaccine, compared to the national average of 41% coverage in seniors,” Walensky and Califf said. “It is the job of public health officials around the country to protect the lives of the populations they serve, particularly the vulnerable. Fueling vaccine hesitancy undermines this effort.”

The officials said that they “stand firmly behind the safety and effectiveness of the mRNA COVID-19 vaccines, which are fully

supported by the available scientific data.”

“Staying up to date on vaccination is the best way to reduce the risks of death and serious illness or hospitalization from COVID-19. Misleading people by overstating the risks, or emphasizing the risks without acknowledging the overwhelming benefits, unnecessarily causes vaccine hesitation and puts people at risk of death or serious illness that could have been prevented by timely vaccination,” the officials continued.

The letter came after the CDC’s recent risk-benefit assessment of the new, updated boosters [was criticized](#) by independent medical professionals for downplaying risks and exaggerating benefits.

The officials did not note that the FDA authorized, and the CDC recommended, the new vaccines [absent any clinical trial data](#). More than half a year later, that data has still not been made available, prompting many doctors [to forgo boosters](#). Recent CDC data indicates the vaccines [provide poor protection](#) against infection, that the shielding against severe illness [quickly wanes](#), and that natural immunity [is superior to vaccination](#).



Florida Surgeon General Dr. Joseph Ladapo. (York Du/The Epoch

Times)

Reaction

Walensky's and Califf's response to Ladapo featured citations to flawed studies, Dr. Harvey Risch, professor emeritus of epidemiology at the Yale School of Public Health, told The Epoch Times via email, "The CDC routinely conducts cross-sectional studies and inappropriately analyzes them as if they were case-control studies, which substantially overestimates their reported vaccine efficacy measures.

"In this letter, these doctors cherry pick studies and ignore, for example, reliable Public Health UK data showing the exact opposite of what they claim," Risch said.

"As much as they claim that the VAERS data are not quantitatively useful, these data indeed show a major COVID-19 vaccine rollout-period mortality signal that cannot be ignored or handwaved away by the lack of a population reference. These agencies continuously proclaim their data monitoring of several other information sources, yet they have not been transparent with these data," he added.

Risch noted that insurance data [shows](#) a jump in COVID-19 deaths after the vaccines were authorized and that, according to [a recent survey](#), many Americans know of at least one person who has suffered an adverse event after vaccination.

"FDA and CDC have lost credibility with much of the American public, and accusing Dr. Ladapo of misinformation when they themselves are the official purveyor of misinformation is unconscionable," Risch said.

Nikki Whiting, a spokeswoman for Ladapo, said that the surgeon general would be sending a response letter to the officials.

“The response from the federal government is just another redundant display of the same apathetic talking point of ‘safe and effective.’ Googling their fact sheets would have achieved the same result,” she told The Epoch Times in an email.

“While the Feds gaslight the American public, Florida pushes for the truth. Three inquiries remain unanswered: 1. Access to raw patient-level data to allow for unbiased research. 2. Adequate attention surrounding the risks detected by numerous researchers around the world. 3. Public transparency from the CDC, FDA, and Big Pharma.”