

# FDA and CDC Assertions in Doubling Down on COVID-19 Vaccination

Letter to Florida Surgeon General Tells America to Expect More Tension Over Injuries, Disabilities, and Deaths

By [Dr. Peter McCullough](#)

Global Research, March 13, 2023

[Courageous Discourse](#) 12 March 2023

Region: [USA](#)

Theme: [Law and Justice](#), [Science and Medicine](#)

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*I am frequently asked: why are the government agencies still pushing COVID-19 vaccination after there have been calls in the US Senate and all around the world to pull them off the market for lack of safety and efficacy?*

In a March 10, 2023 letter from FDA Commissioner Robert Califf, MD, and CDC Director Rochelle Walensky, MD, MPH, to Florida Surgeon General Joseph Ladapo, MD, PhD, the agencies give their rationale. While Walensky does not have a compelling academic track record, her FDA counterpart Califf has been considered a staunch advocate of randomized trials and a hawk on safety of cardiovascular drugs over his career which was notable for building the Duke Clinical Research Institute, one of the most impressive academic research organizations in the world.



March 10, 2023

Joseph A. Ladapo, M.D., Ph.D.  
State Surgeon General  
Florida Department of Health  
4052 Bald Cypress Way, Bin A-00  
Tallahassee, FL 32399-1701

*Sent Via Electronic Mail Only*

Dear Dr. Ladapo,

Thank you for your letter regarding COVID-19 vaccine safety. We appreciate this opportunity to address your questions and we would like to correct the associated misinterpretations and misinformation about the data from the [Vaccine Adverse Event Reporting System](#) (VAERS), in the spirit of transparency and supporting and serving the health of our nation.

We 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.

Sincerely,

Robert M. Califf, MD  
Commissioner  
U.S. Food and Drug Administration

Rochelle P. Walensky, MD, MPH  
Director  
Centers for Disease Control and Prevention

Here are 10 assertions that Califf and Walensky make to Ladapo and Americans on why the COVID-19 vaccines should be “pushed.”

1. “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.” They are assuming unproven benefit at the start. The Bradford Hill criteria have been applied to VAERS and causality has been met. Autopsy studies have conclusively demonstrated causality for fatal syndromes. Doctors use the VAERS system when they believe COVID-19 vaccines caused the death, NOT when the death is unrelated to the vaccine in practice.
2. “The FDA-approved and FDA-authorized COVID-19 vaccines have met FDA’s rigorous scientific and regulatory standards for safety and effectiveness and these vaccines continue to be recommended for use by CDC for all people six months of age and older.” The FDA has relied on the false surrogate of antibody

elevations after injection eight times. This is neither rigorous nor valid. Large randomized, double blind placebo controlled trials with hospitalization/death as the primary endpoint are required to prove efficacy in all age groups.

3. "Despite increased reports of these events, when the concern was examined in detail by cardiovascular experts, the risk of stroke and heart attack was actually lower in people who had been vaccinated, not higher." They cite a nonrandomized study with inadequate control for the known determinants of cardiovascular disease. Both selection bias and confounding eliminate any valid claims of benefit. There is no mechanism by which COVID-19 vaccination would reduce cardiovascular events. There are >200 published manuscripts on COVID-19 vaccines mechanistically causing cardiovascular events including myocarditis, accelerated atherosclerotic cardiovascular disease, aortic dissection, hypertensive crisis, etc.
4. "FDA and CDC physicians continuously screen and analyze VAERS data for possible safety concerns related to the COVID-19 vaccines. For signals identified in VAERS, physicians from FDA and CDC screen individual reports, inclusive of comprehensive medical record review. Most reports do not represent adverse events caused by the vaccine and instead represent a pre-existing condition that preceded vaccination or an underlying medical condition that precipitated the event." The agencies have not produced a report giving their analysis of what caused death after vaccination. Since many deaths occur on the day of the shot or in the next few days that follow, the public deserves to see regulatory evidence for cause of death.
5. "In addition to VAERS, FDA and CDC utilize complementary active surveillance systems to monitor the safety of COVID-19 vaccines." CDC V-safe is one of the active systems mentioned. The CDC refused to release to the public until ordered by the courts, demonstrated an unacceptable 7-8% rate of hospitalization, emergency care, or urgent office visit caused by vaccine side effects. So agency use of systems demonstrate lack of safety and are not reassuring to the public.
6. "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. Additionally, not only is there no evidence of increased risk of death following mRNA vaccines, but available data have shown quite the opposite: that being up to date on vaccinations saves lives compared to individuals who did not get vaccinated." There are no randomized placebo controlled trials demonstrating hospitalization/death are reduced as primary endpoints. Thus the agencies cannot make an efficacy claim from a regulatory perspective. Nonrandomized studies have the following threats to validity: 1) selection bias—healthier more health conscious people take vaccines, 2) vaccinated are more likely to seek early treatment which reduces hospitalization/death, 3) no control over prior COVID-19 infection which greatly influences risk of hospitalization/death, 4) no adjudication of COVID-19 endpoints.
7. "Another study using mathematical modeling estimated that the vaccines saved an estimated 14 million lives from COVID-19 in 185 countries and territories between December 8, 2020, and December 8, 2021." Modeling studies start with the unproven assertion that vaccination reduces death which has not been demonstrated in proper randomized trials, hence extrapolations to large populations are invalid.

8. "The most recent estimate is that those who are up to date on their vaccination status have a 9.8 fold lower risk of dying from COVID-19 than those who are unvaccinated and 2.4 fold lower risk of dying from Covid-19 than those who were vaccinated but had not received the updated, bivalent vaccine. Roughly 90% of deaths from COVID-19, as carefully classified by the CDC, in recent months have occurred among those who were not up to date on their vaccines." This estimate did not account for the two known determinants of COVID-19 mortality: early treatment and natural immunity.
9. "Over the course of the pandemic, FDA and CDC have held numerous public meetings to discuss the safety and effectiveness of the COVID-19 vaccines where detailed safety data are shared with outside experts and public comment is encouraged. Further, FDA publishes the full regulatory action package containing hundreds of pages summarizing clinical studies and review for each COVID-19 approval on FDA's website (see "COVID-19 Vaccines Authorized for Emergency Use or FDA Approved") and CDC publishes an extensive amount of information on their clinical use in Interim Clinical Considerations. Complete information about both benefits and risks helps health care providers better care for their patients." The FDA/CDC have never reviewed or commented on the Pfizer 90-day post-marketing data which reported 1223 deaths shortly after the shot. The FDA attempted to block these data to the public for 55 years. The agencies have never conducted a symposium to review the >1000 peer-reviewed published papers on serious adverse events and death after COVID-19 vaccination.
10. "Unfortunately, the misinformation about COVID-19 vaccine safety has caused some Americans to avoid getting the vaccines they need to be up to date." The Rasmussen Report indicates 28% of Americans know someone who has died after the vaccine. Nothing in that report suggested "misinformation" was leading to hesitancy, moreover it was word of mouth on the horrifying outcomes Americans are witnessing among their family and friends that is leading to refusal rates of boosters.

There are easily another ten invalid assertions made by the agency that could be handled by experienced clinical investigators. Take a look at the letter yourself. Keep in mind the FDA/CDC deceived America by asserting that SARS-CoV-2 did not come out of the Wuhan Laboratory and just a few days ago the US House of Representatives voted to declassify our documents from the laboratory after multiple agencies and witnessed capitulated on the lab origin. This casts doubts on truthfulness of any agency public health assertions during the crisis.

The important message to Americans is that our agencies have no intention of carefully considering vaccine safety or changing course on their relentless pursuit of frequent, mass, indiscriminate COVID-19 vaccination down to 6-month old babies. It will be up to you to protect yourself and your family.

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## Sources

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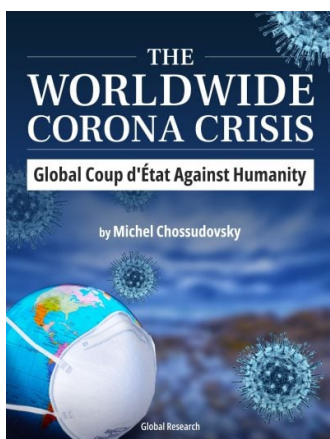
[McCullough PA. Good News on Omicron Outcomes from Prison](#)

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[Kaplan R. House votes 419-0 to declassify intelligence on COVID-19 origins, sending bill to Biden's desk Mar 10 2023](#)

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