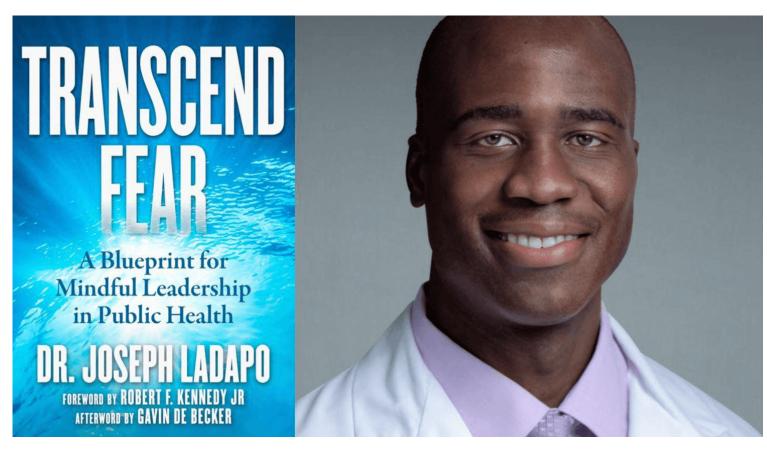
Viewpoint: Florida's Surgeon General is a menace to public health

lorida has many things to recommend, but the state's top public health official isn't one of them. Surgeon General Joseph Ladapo has failed at every turn in managing the COVID crisis.

He has long questioned the safety of COVID vaccines, and early in the pandemic joined a petition opposing the FDA's rapid Emergency Use Authorizations of the Pfizer and Moderna mRNA vaccines. He justifies his position by claiming his views are "part of God's plan." This is inappropriate as the basis for Florida's public health policy.



Ladapo demonstrates a profound lack of understanding about vaccines in general and the COVID vaccines in particular. On September 13, during a roundtable convened by Florida Gov. Ron DeSantis, he <u>said</u> repeatedly, and misleadingly, that there is "not a drop of clinical trial data" to support the new round of COVID vaccines, and he warned healthy adults under the age of 65 against taking them.

On October 3, during an interview on <u>Fox News</u>, he condemned the public health establishment, saying that in the absence of evidence, "they're pushing [the new round of mRNA vaccines] on human beings. That is an anti-human approach ... an anti-human policy." He said he would not recommend the vaccines "to any living being on this planet."

Apparently God told him to say that, but it directly contradicts the CDC and FDA and their respective advisory committees, which recommended the new round of vaccines, now widely available around the

U.S., for everyone over the age of six months. Such recommendations were completely consistent with how the new versions of existing vaccines are developed. Let me explain.

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The original COVID vaccines were tested at the height of the pandemic in clinical trials of more than 30,000 subjects each. There were huge numbers of infections occurring throughout the country, so it was not difficult to demonstrate a statistically significant difference in infection rate, hospitalizations and deaths between the vaccinated and placebo-controlled groups. I read the lengthy summaries of the clinical trials FDA prepared for the Vaccines and Related Biological Products Advisory Committee's consideration, and there was overwhelming evidence of safety and efficacy.

The latest vaccines differ only by the substitution of a new spike protein in order to elicit an immune response to new, circulating variants. But now, with the number of cases lower and some urgency about making available the new round of vaccines, there isn't time to mount huge trials to demonstrate prevention of infection and/or serious disease.

So, instead, the vaccines are tested in animal models – vaccinated and unvaccinated animals challenged with virus — and on a small number of human subjects (without a virus challenge) to show that they develop antibodies and other signs of an immune response, and that there are no obvious safety signals. This is not a process concocted just for COVID vaccines. In fact, it is how seasonal flu vaccines – which are small tweaks of previously validated platforms — are routinely formulated each year.

Ladapo's opposition to the vaccines is dangerous at a time when <u>COVID hospitalizations and deaths have</u> been trending up for the past three months, protection from previous vaccinations is waning, COVID precautions have largely been abandoned, and a winter surge might be approaching.

Ladapo's delusions about COVID vaccines are consistent with his previous pronouncements. In February, he sent a <u>letter</u> to FDA Commissioner Robert Califf and then-CDC Director Rochelle Walensky that was filled with baseless claims about supposed dangers of the mRNA vaccines.

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Some of the data in the letter appeared to be completely fabricated – that is, inconsistent with safety data found elsewhere. It was also clear that Ladapo fails to understand the purpose and mode of reporting of vaccine side effects, or "adverse events," to the federal Vaccine Adverse Event Reporting System (VAERS). He cited numbers of adverse effects from the vaccines reported to VAERS, but as spelled out clearly on the CDC website:

VAERS is the nation's early warning system that monitors the safety of vaccines after they are authorized or licensed for use by the U.S. Food and Drug Administration (FDA). VAERS is part of the larger vaccine safety system in the United States that helps make sure vaccines are safe. The system is co-managed by CDC and FDA.

VAERS accepts and analyzes reports of possible health problems — also called "adverse events" — after vaccination. As an early warning system, VAERS cannot prove that a vaccine caused a problem. Specifically, a **report to VAERS does not mean that a vaccine caused an adverse event** (emphasis in original).

And yet, Ladapo's condemnation of the mRNA vaccines was based almost entirely on reports to VAERS.

The FDA's Califf and CDC's Walensky did not allow Ladapo's misrepresentations to go unchallenged. They sent him a scathing <u>four-page letter</u>, condemning his assertion that COVID-19 vaccines are "harmful." Leaving no doubt as to their irritation, these are some excerpts, all of which are verbatim and retain the emphasis in the original:

- 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.
- Reports of adverse events to VAERS following vaccination do not mean that a vaccine caused the event.
- Adverse events must be compared to background rates in the population.
- In addition to VAERS, FDA and CDC utilize complementary active surveillance systems to monitor the safety of COVID-19 vaccines.
- 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.
- 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.

The nation's top public health officials should not have to explain the vaccine facts of life to a state's surgeon general.

Finally, Califf and Walensky admonished Ladapo directly:

- As the leading public health official in [the] 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. 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. (Emphasis in original.)
- Unfortunately, the misinformation about COVID-19 vaccine safety has caused some Americans to avoid getting the vaccines they need to be up to date. (Emphasis in original.)

Their letter concluded:

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.

Even if Ladapo doesn't trust federal officials, there are other reliable sources he could find reliable information. Numerous studies from academia, some of which were <u>summarized by Yale Medicine</u>, confirm the efficacy of the original vaccines and the subsequent boosters, and an analysis by <u>The Commonwealth Fund</u>, a nonprofit that conducts independent health care research, estimated that COVID-19 vaccination in the U.S. prevented more than 3 million additional deaths, 18.5 million additional

hospitalizations, and 120 million more cases from December 2020 through November 2022. screenshot pm

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But there's more. Ladapo's announcement in October 2022 that young men should not get the COVID-19 vaccine, which was <u>based on a state analysis</u> that purportedly showed that the risk of cardiac-related deaths increased significantly for some age groups after receiving a vaccine, runs counter to medical advice issued by the CDC.

There is also <u>evidence</u> that Ladapo himself improperly manipulated the Florida data that he cited: Early drafts of the analysis showed that a COVID infection could increase the risk of a cardiac-related death more than vaccination, but that information was omitted from the final version published by the Florida Department of Health.

Ladapo's recommendation and the state's analysis have been excoriated by experts, <u>including professors and epidemiologists</u> at the University of Florida, where he is a professor. Dr. Matt Hitchings, an infectious disease epidemiologist and professor of biostatistics university, said it seems that sections of the analysis were omitted simply because they did not fit the narrative the surgeon general was pushing. He added, "This is a grave violation of research integrity."

Others in the scientific community agree. H. Holden Thorp, the editor-in-chief of the prestigious journal *Science*, condemned Ladapo for his blatant misrepresentations that likely cost the lives of thousands of patients.

Florida, the third most populous state in the U.S., is woefully under-vaccinated – unquestionably, in large part because of Ladapo's anti-vaccine advocacy. That makes him responsible for many of the roughly 90,000 COVID deaths in Florida during the pandemic thus far.

As FDA Commissioner Califf and then-CDC Director Walensky said in their letter, "It is the job of public health officials around the country to protect the lives of the populations they serve."

Ladapo is doing exactly the opposite. He is scientifically illiterate and clueless about the danger of infectious respiratory diseases such as COVID-19, how they're spread, and how they can be prevented. As if that wasn't enough, he's dishonest.

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