March 10, 2023

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State Surgeon General
Florida Department of Health
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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.

The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) continue to diligently monitor a variety of data sources to identify any potential risks of the vaccines and to ensure that information is available to the public. That said, focusing on adverse events in the absence of causal association and without the perspective of countervailing benefits is a great disservice to both individuals and public health. Like every other medical intervention, there are adverse effects from vaccination. Serious adverse events from COVID-19 vaccines are rare and are far outweighed by the benefits of these vaccines for every age group.

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. 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. Both FDA and CDC have continued to collect outcome data from multiple sources that demonstrate the clear benefit of COVID-19 vaccines in preventing death, serious illness, and hospitalization from SARS-CoV-2 infection, along with indicating a modest benefit in the prevention of infection and transmission that wanes over time, even as new variants have emerged. Additional benefits include a reduced risk of known complications from SARS-CoV-2 infection, including post-COVID conditions, COVID-19-associated stroke and heart disease, and COVID-19-induced venous thromboembolism.

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Reports of adverse events to VAERS following vaccination do not mean that a vaccine caused the event. Since December 2020, almost 270 million people have received more than 670 million doses of COVID-19 vaccines in the U.S., with over 50 million people having received the updated bivalent vaccine. **The Emergency Use Authorizations (EUAs) for the COVID-19 Vaccines require sponsors and vaccine providers to report certain adverse events through VAERS, so more reports should be expected**. Recent concerns about increased reports of cardiovascular events provide an instructive example of the need to do further analysis when increased reporting of an event occurs. 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.

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.

Adverse events must be compared to background rates in the population. This VAERS review methodology allows for successful identification of rare adverse reactions related to specific COVID-19 vaccines (e.g., Guillain-Barré Syndrome, thrombosis with thrombocytopenia syndrome , and immune thrombocytopenia following use of the Janssen COVID-19 Vaccine or myocarditis, pericarditis and anaphylaxis following use of the Pfizer-BioNTech and Moderna COVID-19 vaccines). Information about these adverse reactions is included in the fact sheets for healthcare providers administering vaccine and vaccine recipients and caregivers. FDA and CDC also continue to post summaries of the key safety monitoring findings and present the data publicly at regularly scheduled advisory committee meetings.

In addition to VAERS, FDA and CDC utilize complementary active surveillance systems to monitor the safety of COVID-19 vaccines. Active surveillance involves proactively obtaining and rapidly analyzing information occurring in millions of individuals recorded in large healthcare data systems to verify safety signals identified through passive surveillance or to detect additional safety signals that may not have been reported as adverse events to passive surveillance systems. FDA is conducting active surveillance using the Sentinel BEST (Biologics Effectiveness and Safety) System and collaborating with the Center for Medicare and Medicaid Services (CMS) and Department of Veterans Affairs (VA). These efforts complement those of CDC's Vaccine Safety Datalink (VSD) and the v-safe text-based monitoring system for conducting surveillance of adverse events, as well as the Clinical Immunization Safety Assessment (CISA) Project. FDA and CDC are also collaborating with other non-federal partners, including state and local health departments.

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. Multiple well conducted, peer-reviewed, published studies here and here demonstrate that the risk of death, serious illness and hospitalization is higher for unvaccinated individuals for every age group. Because we are not the only country in the world using COVID-19 vaccines, we also benefit from the experience of other countries. More than 13 billion doses of COVID-19 vaccines have been given around the world, including hundreds of millions of doses of mRNA vaccines and hundreds of millions of doses to children. Consistent with our data, these multiple international partners have robust monitoring for both safety and effectiveness. They find little evidence of widespread adverse events, also detect rare events as we do, and conclude that the benefits of the vaccines generally far outstrip their risks.

While many studies could be cited, a retrospective cohort study using the CDC's Vaccine Safety Datalink found no increased risk of death for the mRNA and Janssen vaccines across age, sex, and race/ethnicity groups. They found that crude non-COVID-19 mortality rates among COVID-19 vaccine recipients were lower than those among unvaccinated comparators. 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. Vaccination is also associated with a reduction of post-acute sequelae of COVID-19. The data supporting the benefits of the COVID-19 vaccines have been critically reviewed and accepted by the medical and public health community, including state and local public health agencies and academic and professional organizations.

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. Furthermore, as stated above, emerging reports indicate a possible reduction in the risk of post-COVID conditions in vaccinated people who survive an infection.

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. **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.**

We agree that communication between patients and their health care providers is critical, and fully support clear, accurate communication about the benefits and risks of medical products. It is inaccurate to suggest that the federal government will "retaliate" against any health care provider for communicating with their patients about the benefits and risks of a particular medical product.

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.

Unfortunately, the misinformation about COVID-19 vaccine safety has caused some Americans to avoid getting the vaccines they need to be up to date. This has led to unnecessary death, severe illness and hospitalization. These tragic outcomes not only have a devastating effect on individuals and their families, but they also create a tremendous strain on our healthcare systems and clinicians, potentially compromising care for other patients.

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