May 10, 2023

Robert M. Califf, MD, MACC
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
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Rochelle P. Walensky, MD, MPH
Director
Centers for Disease Control and Prevention
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Drs. Califf and Walensky,

Your ongoing decision to ignore many of the risks associated with mRNA COVID-19 vaccines, alongside your efforts to manipulate the public into thinking they are harmless, have resulted in deep distrust in the American health care system. Beginning with Operation Warp Speed, and possibly to be continued with an additional $5 billion investment in Project NextGen, the federal government has relentlessly forced a premature vaccine into the arms of the American people with little to no concern for the serious adverse ramifications.

It is critical to acknowledge and address the negative global impact caused by the emergence of COVID-19. Nonetheless, after two years, your collective decisions to deny that natural immunity confers comparable or superior protection to COVID-19 vaccination, push mRNA COVID-19 boosters for the young and healthy, and delay acknowledging the risks of vaccine-induced myocarditis have only sowed doubt between the American people and the public health community.

Data are unequivocal: After the COVID-19 vaccine rollout, the Vaccine Adverse Events Reporting System (VAERS) reporting increased by 1,700%, including a 4,400% increase in life-threatening conditions. We are not the first to observe such a trend. Dismissing this pronounced increase as being solely due to reporting trends is a callous denial of corroborating scientific evidence also pointing to increased risk and a poor safety profile. It also fails to explain the disproportionate increase in life-threatening adverse events for the mRNA vaccines compared to all adverse events.

Based on the Centers for Disease Control and Prevention's (CDC) own data, rates of incapacitation after mRNA vaccination far surpass other vaccines. This is illustrated in a recent Lancet publication, Rosenblum H et al, *Lancet.* 2022, that reports up to one third of individuals being "unable to perform normal daily activities, unable to work, or [receiving] care from a medical professional" in the days following mRNA vaccination.

The study, Fraiman J et al, *Vaccine*. 2022, also found an excess risk of serious adverse events of special interest for 1 in 550 after mRNA vaccination. As you are aware, this is extraordinarily high for a vaccine. In comparison, the risk of serious adverse events after influenza vaccination is much lower (Lusigan S, *Lancet Regional Health - Europe*, 2021). For you to claim that serious adverse events such as these are "rare" when Pfizer and Moderna's clinical trial data indicate they are not, is a startling exercise in disinformation.

I want to reemphasize that these questions could have been answered if you had required vaccine manufacturers to perform and report adequate clinical trials. Although Project NextGen has been launched under another administration, I anticipate with regret, that you will repeat past mistakes and prematurely promote new therapies to Americans without accurately and truthfully weighing data on risks and benefits.

In light of your stated commitment to transparency and the communication of the risks and benefits associated with these therapies, I am asking that you publicly:

1. Report why randomized clinical trials were not required prior to the approval of mRNA COVID-19 boosters, including the new bivalent booster.
2. Explain why adverse events first detected in the Food and Drug Administration's (FDA) safety surveillance system in 2021 were not published in scientific literature until December of 2022. (Hui-Lee Wong et al, *Vaccine*. 2023)
3. Report the FDA and CDC's interpretations of the study performed in Thailand, which showed a 3% incidence of myocardial injury in young boys, and the Swiss study, which also showed a 3% incidence of myocardial injury in adults after receiving the bivalent booster. (Mansanguan S, *Tropical Medicine and Infectious Disease*. 2022; NCT05438472)
4. Explain why the Pfizer deadline for reporting their subclinical myocarditis study was delayed until December of 2022, despite the CDC promoting vaccination to millions of young people, and then postponed again until June of 2023.
5. Report the results of the VAERS proportionality analyses that you performed.
6. Explain why 26 of the 31 published studies using the V-Safe system only report symptoms within the first seven days of vaccination when it is recognized that most serious events occur after this time.
7. Disclose the rates of adverse events in V-Safe that vaccine recipients believe are related to their COVID-19 vaccine at 12 month follow up.
8. Explain why the patient reporting fields provided for adverse events in V-Safe are limited to those considered "non-serious" by the CDC and why there is an absence of reporting fields for serious adverse events, such as stroke, myocarditis, shingles, etc.

9. Report the number of adolescents that have died within days of receiving a second dose or booster of the mRNA COVID-19 vaccine. (Gill J et al, *Archives Pathology and Laboratory Medicine*. 2022)
10. Explain why you have not publicly reported on the studies indicating a likely increased risk of COVID-19 infection after four to six months from receiving mRNA COVID-19 vaccines. (Chemaitelly H, *Lancet Infectious Disease*. 2023; Altarawneh HN, *New England Journal of Medicine.* 2022; Lin DY, *New England Journal of Medicine.* 2022).
11. Explain why you have not required Pfizer to report results of its randomized trial in pregnant women (NCT04754594), which was completed in July of 2022.
12. Comment on studies illustrating an increased risk of dysautonomia and postural orthostatic tachycardia syndrome after mRNA COVID-19 vaccination. (Kwan AC et al, *Nature Cardiovascular Research*. 2022).

Your organizations are the main entities promoting vaccine hesitancy – Florida promotes the truth. It is our duty to provide all information within our power to individuals so they can make their own informed health care decisions. A lack of transparency only harms Americans' faith in science.

I, Floridians, and people around the world await your response.

Sincerely,

Joseph A. Ladapo, MD, PhD
State Surgeon General