June 20, 2025

RE: Docket NO. CDC-2025-0024

Dear Advisory Committee on Immunization Practices (ACIP),

I am writing to you today, as a mother, wife, and someone who likely could have died if I wasn't vaccinated for COVID-19. The proposal on the agenda today, threatens to remove the recommendation for me to receive the COVID-19 vaccine. It scares me in ways I can never express on paper. Before I got COVID-19, I was healthy and therefore didn't have any of the high risk factors noted by the CDC in the FDA's NEJM paper published on May 20, 2025. However, starting on June 5, 2022, I developed both recurrent pleurisy and pericarditis due to COVID-19, as confirmed by my Internist, requiring multiple rounds of steroids for five months. While I had pericarditis, I was home alone when I developed an heart arrythmia. Thankfully my cat noticed the change in my heart rhythm and took action just seconds before I started to develop pre-syncope symptoms. At the time, I was standing in a corner between a cast iron baseboard heater and a kitchen counter. If it was not for my cat's quick thinking to get me down on the ground, I would have passed out and hit my head likely causing a concussion. I was home alone, and if I did faint it would have been a few hours before my husband came home, found me and called for an ambulance. While it was a very difficult five months, my entire medical team and I all knew it would have been far worse had I not been vaccinated. If I was not vaccinated, I would have required hospitalization and highly likely placed on a ventilator with the possibility of death. Because I got the COVID-19 vaccine is why I survived, never requiring hospitalization, and could continue to be an ever present and loving wife and mother. All that could change based on the decision of the ACIP during your meeting on June 25-26, 2025.

My review of the publicly available and relevant information provided by HHS, FDA and CDC prior to this ACIP meeting has found serious concerns in the scientific evidence and rationale used to justify changes to the COVID-19 vaccine schedule for 2025-2026 and gaps in your analysis. Below are my findings:

1. Concerns were mentioned previously by HHS Secretary RFK, Jr. regarding American's lack of trust in vaccines. If concerns are warranted, given the vaccine compliance data, then is now the appropriate moment to change the vaccine schedule for any vaccines? Have you considered that changing the vaccine schedule right now only promotes uncertainty and lack of confidence in the previous scientific approach to considering and approving a vaccine schedule for any vaccine? Back in May 2025, Americans have already seen a very public display

of contradiction between the FDA and the HHS Secretary RFK, Jr. in whether or not healthy pregnant women should continue to remain on the COVID-19 vaccine schedule. Specifically on May 20, 2025, FDA's Dr. Vinay Prasad and Dr. Martin A. Makary published an article in the New England Journal of Medicine (NEJM) entitled "An Evidence-Based Approach to COVID-19 Vaccination". In it they lay out recommendations for the upcoming COVID-19 vaccine schedule to only include people over the age of 65 and those who are "at high risk for severe COVID-19 outcomes" as outlined in Figure 2 "CDC 2025 List of Underlying Medical Conditions That Increase a Person's Risk of Severe COVID-19", including pregnancy and recent pregnancy. Seven days later, on Tuesday, May 27, 2025, Health and Human Services (HHS) Secretary RFK, Jr.'s announced removal of healthy children and healthy pregnant women from the COVID-19 vaccine schedule, despite "pregnancy and recent pregnancy" identified as a COVID-19 high risk factor in the FDA's NEJM article and supported by your esteemed colleagues at the CDC based on their scientific evaluation. Additionally, HHS Secretary RFK, Jr. appears to assert that healthy adults below the age of 65 should remain on the COVID-19 vaccine schedule where the FDA's NEJM article recommends their removal. The clear contradiction between government agencies under HHS on the topic of the COVID-19 vaccine schedule is deeply concerning. The public demands a strong, united, and unwavering front from the collective HHS Agencies when it comes to our public health and patient safety. Without it, it sows the seeds of distrust in this great institution. I, for one, am among those who are completely confused and uncertain as to where HHS may be headed if it can't effectively communicate and collaborate with the other government agencies under its umbrella. On June 25-26, 2025, the ACIP is tasked with the challenge of review of a number of vaccine's on the agenda, including COVID-19. You need to be the voice of scientific reason in this chaos for the good of us all. Changing the COVID-19 vaccine schedule right now will only lean into the chaos of their indecision on what is best for the American people when it comes to the administration of COVID-19 vaccine and thereby promote public distrust in the CDC and in vaccines. In contrast, promoting the public's faith and trust that the CDC will remain steadfast and on-course as it has in previous years, despite what is happening at other federal agencies, will help stabilize and/or increase vaccine compliance numbers.

What would directly solve the HHS Secretary RFK, Jr.'s concerns of decreasing vaccine compliance is a two-prong approach of 1) education on the benefits of vaccines in providing herd immunity to newborn babies and others who medically or religiously can't get vaccinated and its ability to eradicate the virus and 2) an

understanding of the potential medical costs of not complying to vaccine recommendations. People tend to be more concerned about the minutia of side effects, which exist for every vaccine, medicinal treatment, and medical procedure. You will not find a single medical avenue devoid of risk. However, you will not find in recent years reinforcement of the broader goal of vaccines, herd immunity to protect newborns and others who can't get vaccinated due to religious or medical reasons and the longterm goal of eradication of the virus. A great example is the elimination of the Polio vaccine because Polio was eradicated in the US. There are many Americans who still remember receiving the Polio vaccine. The potential to eradicate COVID-19 is the ultimate dream. For some viruses, this dream is achievable. That should be one of the focuses in increasing the health literacy of the American people. Further, eliminating entire groups of people from the COVID-19 vaccine schedule won't help us realize the potential for eradication of COVID-19 and in certain communities that lack a normal distribution of age groups in their population this could negatively impact herd immunity and jeopardize the health of the entire community. Regarding the second prong, medical costs, Americans have continued to feel the pinch with the inflation of grocery prices and now the rise in fuel costs. Road trips are costing more. The classic summer entertainment of concerts and sporting events have cost twice as much as years past. Cost is very much on the minds of Americans right now. The messaging of the potential medical costs for not remaining vaccine compliant, including the thousands of dollars for hospitalization, at this time given personal finance concerns would pose a better pro-vaccine argument than changing the vaccine schedule. Our Healthcare GDP has been astronomically high. Preventable hospitalizations will only add to it. We can't continue to afford to indirectly solve identified problems in vaccine compliance. We need a strategic, very targeted approach. Increasing healthy literacy is that targeted approach. Changing the vaccine schedule falls very short of accomplishing the goal of increasing vaccine compliance.

2. Vaccines like medicinal treatments all come with adverse reactions and some with severe adverse events. We should not remove certain groups from the vaccine schedule because side effects exist. We should remove certain groups because the scientific evidence overwhelmingly concluded the risks outweighs the benefits in receiving the vaccine for the entire identified group. This data typically originates from post-market surveillance data. Post-market surveillance is commonly known as the fourth clinical trial for its larger exposed group population including groups of individuals who are often not typically represented in Clinical Trial Phases 1-3. The HHS document "COVID Recommendation FAQ" which was sent to members of

Congress to highlight the rationale for the proposed changes to the COVID vaccine schedule. The document cited a single source for review of post-market surveillance data, a study conducted by Rose, et al. published in 2024 in the Therapeutic Advances in Drug Safety entitled "Determinants of COVID-19 Vaccine-Induced Myocarditis". The study using data from the VAERS concluded in their abstract "COVID-19 vaccination is strongly associated with a serious adverse safety signal of myocarditis, particularly in children and young adults resulting in hospitalization and death." The HHS document mischaracterized the study's conclusion as establishing causality between the COVID-19 vaccine and myocarditis. An association warranting further investigation and a causal link are two completely different things. According to the VAERS's disclaimer on the HHS's website (https://vaers.hhs.gov/data.html) "While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. Vaccine providers are encouraged to report any clinically significant health problem following vaccination to VAERS even if they are not sure if the vaccine was the cause. In some situations, reporting to VAERS is required of healthcare providers and vaccine manufacturers. VAERS reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Reports to VAERS can also be biased. As a result, there are limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind." The HHS document issued to justify modification of the COVID-19 vaccine schedule to remove healthy children and pregnant women failed to heed this disclaimer on their own website and knowingly used patient biased data to support changes to the COVID-19 vaccine schedule. The mischaracterizing of a study's conclusion and the use of biased data is not Gold Standard Science. Have you obtained and reviewed causal study data to support your claim that the risks outweigh the benefits of healthy children and pregnant women receiving the COVID-19 vaccine? Did you obtain and review the post-market surveillance data for the COVID-19 vaccine after its been through a thorough review to determine if the reported compliant is truly from receiving the vaccine versus other? If so, can you provide that evidence right now to support your claim that the risks outweigh the benefits in providing the COVID-19 vaccine to healthy children and pregnant women along with your rationale for public comment? Has this data for pregnant women been compared to pregnancy outcomes among the unvaccinated group?

3. As a scientist, researcher and member of the public, I find the credentials of the entire current body of the ACIP severely lacking and question their ability to critically

analyze and review published, peer-reviewed scientific articles and highly technical data in comparison to their predecessors as evident by this previous noted finding. This sows public's mistrust in the current ACIP's ability to determine what is in the best interest of public health and patient safety for Americans.

4. The HHS document "COVID Recommendation FAQ", seems to show that regardless of the final COVID-19 vaccine schedule for 2025-2026, a patient can talk to their physician and be granted permission to obtain the COVID-19 vaccine. I agree that patients should be encouraged to have these conversations with their physician. That said, the COVID-19 vaccine is not administered in the Physician's office. Rather, it is provided by a Community Pharmacist. Is there a mechanism in place to ensure individuals who are not recommended by the CDC to obtain the COVID-19 vaccine but has received authorization by their physician can still access the COVID-19 vaccine at their Community Pharmacy? Also, frequently when the CDC or medical organizations no longer recommend certain vaccines or treatments, the medical insurance will deny coverage causing the patient to pay out of pocket. This presents a significant financial barrier for patients complying with their physician's order to get vaccinated for COVID-19. If they can't afford to pay for the vaccine, and therefore can't get vaccinated they run a significant risk of hospitalization and possibly death due to COVID-19. This series of events would have been triggered not because of the patient's unwillingness to get vaccinated, but because the ACIP said it was not recommended. This goes back to the issue HHS Secretary RFK, Jr. has brought up about vaccine compliance. If you are seeking to increase the numbers of individuals who are vaccinated, adding cost barriers will only further increase the numbers of vaccine noncompliant individuals.

5. The HHS document "COVID Recommendation FAQ" fails to address why contrary to the inclusion of pregnancy and recent pregnancy in Figure 2 "CDC 2025 List of Underlying Medical Conditions That Increase a Person's Risk of Severe Covid-19" of Dr. Vinay Prasad and Dr. Martin A.Makary's published May 20, 2025 NEJM article you are concerned the risks outweigh the benefits for pregnant women to receive the COVID-19 Vaccine. Between the 7 day period from May 20, 2025 when the FDA published their NEJM article and the public announcement on May 27, 2025 by HHS Secretary RFK, Jr. to remove pregnant women from the COVID-19 vaccine schedule, what peer reviewed, unbiased research article(s) was published that supported the decision to remove pregnant women from the COVID-19 vaccine schedule?

6. Was the length of time of COVID-19 immunity considered between the exposed group versus the vaccinated group in pregnant women?

It is crystal clear to me in my review of the information publicly provided by HHS, FDA and CDC prior to the ACIP meeting, no solid justification exists for modification of the COVID-19 vaccine schedule. Current Gold Standard Research doesn't support such changes. My recommendation is to continue the previous 2024-2025 COVID-19 vaccine schedule instituted by the ACIP in 2024 into the 2025-2026 COVID-19 vaccine schedule, leaving the COVID-19 vaccine schedule unchanged. The COVID-19 vaccine should continue to be available to all people across the life spectrum at least at an annual frequency, with the only exception being babies under 6 months of age. Any exceptions of clinical concern should continue to be a conversation between physician and patient. This would eliminate any confusion about vaccine eligibility at a time of lower vaccine compliance, enable access to the COVID-19 vaccine for all people, ensure insurance coverage and affordability of the COVID-19 vaccine to promote continued vaccine compliance among the compliant group, and encourage conversations between patient and physician regarding specific medical conditions and COVID-19 vaccine risk.

The proposal to modify the COVID-19 vaccine schedule to eliminate the previous recommendation for at least the healthy children and healthy pregnant women lacked solid Gold Standard Science to back up such claims that the risks would outweigh benefits. In fact, changes to the COVID-19 vaccine schedule would cause panic among individuals no longer recommended to receive the vaccine who also found as I did that the vaccine saved their life, present a cost barrier to obtaining vaccines thereby causing a significant drop in vaccine compliance, likely increase the Healthcare GDP, and sow public distrust in the CDC's ability to provide vaccine recommendations based on scientific evidence. Instituting an unchanged 2025-2026 COVID-19 vaccine schedule from the previous ACIP approved 2024-2025 COVID-19 vaccine schedule along with the two-prong approach I provided 1) education on the benefits of vaccines in providing herd immunity to newborn babies and others who medically or religiously can't get vaccinated and its ability to eradicate the virus and 2) an understanding of the potential medical costs of not complying to vaccine recommendations will better accomplish the broader goals HHS Secretary RFK, Jr. has laid out.

Thank you ACIP for your time and consideration in this matter.

Sincerely,

Anonymous

Note: This public comment was purposely deidentified for the disclosure of medically relevant information I felt was critical to the argument for securing access to the COVID-19 vaccine for all people above 6 months of age now and in the future. For the good of us all.