

Attachment—Additional Questions for the Record

Subcommittee on Health Hearing on “Booster Shot: Enhancing Public Health through Vaccine Legislation” June 15, 2021

Yvonne Maldonado, M.D.,
Chair, Committee on Infectious Disease, American Academy of Pediatrics,
Professor of Pediatrics and of Epidemiology and Public Health, Stanford University, Center for
Academic Medicine, Pediatric Infectious Diseases

The Honorable Robin Kelly (D-IL)

1. Dr. Maldonado, some women are reluctant about these vaccines for safety concerns.
 - a. As a physician, can you speak to the safety, and the importance, of maternal vaccination, specifically the inclusion of pregnant people in vaccine research?

The AAP strongly encourages all eligible individuals to get vaccinated, including pregnant and breastfeeding people. The available COVID-19 vaccines have undergone extensive and rigorous safety trials and protocols, and research has shown them to be remarkably effective and safe, including for pregnant and breastfeeding people. As noted in guidance and studies from the Centers for Disease Control and Prevention (CDC), pregnant people face higher risk of severe illness and death from COVID-19. Additionally, COVID-19 presents an increased risk for adverse pregnancy and neonatal outcomes, including preterm birth and NICU admission. Maternal vaccination is critically important for the protection of both the parent and the child. In addition to protecting women from COVID-19 infection, recent research has indicated that pregnant women vaccinated in the third trimester may pass antibodies to their babies.ⁱ Studies have also shown that women who get vaccinated against COVID-19 while breastfeeding pass antibodies to their children through their milk.ⁱⁱ

While pregnant people were not included in the initial vaccine clinical trials, follow-up data from vaccine safety monitoring systems have demonstrated its safety for pregnant people. Data compiled by the CDC from 35,692 pregnant women from the v-safe monitoring system found the most common side effects to be the same as non-pregnant women. Frequency of severe adverse events also was similar between the groups. Research has also found there is no increased risk of miscarriage for pregnant women who receive a COVID-19 vaccine.ⁱⁱⁱ This demonstrates the importance of ensuring that pregnant people are included in vaccine clinical trials and follow-up research to assess safety and efficacy. It is important that pregnant people get vaccinated to protect themselves, their children, and the communities around them.

The Honorable Michael C. Burgess, M.D. (R-TX)

1. Vaccines are one of the most effective and safest ways to prevent and even eradicate diseases. One of the biggest barriers to vaccinations in the United States is hesitancy. What have we learned about vaccine hesitancy over the past several months, since the COVID-19 vaccines received Emergency Use Authorization and were made available to the public?

Vaccine hesitancy, which was on the rise in the years leading up to the pandemic, has unfortunately become even more prominent over the last year and a half, hampering a robust uptake of a COVID-19 vaccine. We have seen an alarming degree of misinformation and disinformation about the COVID-19 vaccines being spread rapidly by a vocal subset across social media platforms over the last several months. While the anti-vaccine sentiments being spread online are held by a very small minority, we know that many other individuals still retain some hesitancy regarding COVID-19 vaccination due to concerns such as the speed of its development or long-term side effects. According to the Kaiser Family Foundation's COVID-19 Vaccine Monitor Dashboard, as of September, 21 percent of parents surveyed say they will "definitely not" vaccinate their 12 – 17 year old child and 24 percent say they will "definitely not" vaccinate their 5 – 11 year old child.^{iv} However, the percentage of parents who responded that they would "wait and see" how the vaccine is working before vaccinating their child dropped from July to September for both age groups, down from 23 to 15 percent for parents of 12 – 17 year olds and 40 to 33 percent for parents of 5 – 11 year olds. This demonstrates how vaccine hesitancy can be overcome with the widespread dissemination of accurate, evidence-based information from trusted sources, such as pediatricians, to address the concerns of parents and patients.

2. In response to the measles epidemic that surfaced in 2019, Dr. Schrier and I worked on the VACCINES Act together. I am grateful this bill was signed into law, as it provides the CDC with important resources to understand the driving force behind vaccine hesitancy and barriers to immunization. How can we work to better educate our communities on the safety and importance of vaccinations, and do you think legislation like the VACCINES Act will help address hesitancy?

As mentioned in my testimony, the Academy was extremely grateful that Congress passed the *VACCINES Act* last year and yes, I believe legislation like this will play an important role in bolstering vaccine confidence and addressing vaccine hesitancy in communities across the country.

The *VACCINES Act*, which aims to increase vaccination rates across all ages, authorized a national, evidence-based public education campaign at the CDC to increase awareness and knowledge of the safety and effectiveness of vaccines and combat vaccine misinformation. It also authorized surveillance and data collection to assess factors contributing to underutilization of vaccines and identify communities at high risk of vaccine-preventable disease outbreaks. Additionally, it authorized grants for activities to

address vaccine-preventable diseases, such as partnering with community organizations and health care providers to improve vaccination rates and reducing barriers to access vaccines and evidence-based information. These types of activities seek to understand the root causes of vaccine hesitancy, which often differ across communities and demographic groups, and address them in a meaningful way to educate individuals on the safety and importance of vaccines. It is important to not only address vaccine misinformation, but also recognize the variety of reasons why vaccine hesitancy may persist among certain populations.

The Honorable Neal P. Dunn, M.D. (R-FL)

1. Over the past several months, multi-specialty medical groups and integrated delivery systems have expressed frustration around their lack of inclusion in initial vaccine distribution discussions. Multispecialty medical groups and integrated delivery systems (IDSs) are an untapped resource in the national vaccine administration strategy. These organizations play a critical role in the delivery of healthcare in this country and have long standing relationship with their patients and the communities they serve. They also have tools, such as electronic health records to identify patients at higher risk which allows for prioritization for vaccinations and testing. How can we ensure we leverage the expertise and experience multispecialty medical groups have with vaccine administration in any national vaccine distribution strategy and continue to work together on this current pandemic?

Utilizing the existing vaccine delivery system for the distribution of COVID-19 vaccines is of paramount importance. Multispecialty medical groups and integrated delivery systems that administer vaccines can definitely play a role and should be part of a national COVID-19 distribution plan. In addition, it is crucial that primary care providers, including pediatricians, family physicians, nurse practitioners and others, are made a top priority in COVID-19 vaccine distribution. It is critical to ensure that clinics that want to administer the COVID-19 vaccine can receive it in a timely fashion. This is particularly true for clinicians who serve children and youth with special health care needs, as well as those that are located in underserved areas.

We know that health care providers remain one of the most trusted messengers across populations when it comes to information about vaccinations. A survey conducted by the African American Research Collaborative and The Commonwealth Fund in June found that, among those surveyed, 60 percent said that their personal doctor/primary care physician was the most effective messenger to encourage them to get a shot. Another 53 percent of those surveyed said they preferred to be vaccinated against COVID-19 vaccine in their doctor's office.^v These findings underscore the critical role physicians play in efforts to better educate communities on the safety and importance of vaccinations and increase vaccination rates across all ages. Parents and patients trust health care providers such as pediatricians. To better educate and address hesitancy, we need to listen to a patient or parent's questions, take the information and provide clear, consistent

information. We should state what we know and what we do not know.

2. There is a long-standing vaccine distribution process in place involving medical groups and pharmacies. The Influenza vaccine, for example traditionally reaches 45-50% of the US population. What do you think about defaulting to this tried and true process for COVID-19 going forward? This allows the providers who already have vaccine systems in place to best put shots in arms rapidly, instead of sending half the population to non-healthcare locations, and having medical groups competing with other non-providers who received initial batches of COVID shots.

The Academy definitely supports utilizing the existing vaccine delivery system for administering COVID-19 vaccines. While many adults and some adolescents received COVID-19 vaccines at pharmacies and community vaccination sites, for the upcoming roll out of COVID-19 vaccines to the 5-11 age group, we strongly urge that primary care offices be prioritized in the distribution plan.

Decades of experience show that a pediatric medical home is the best place for children to receive vaccines, where children and their caregivers can have their questions and concerns addressed by a trusted physician. This will be particularly important with younger children as the parents and caregivers of these children will likely have more questions to discuss compared to older children. In addition, with the ability to co-administer COVID-19 and other vaccines, distributing COVID-19 vaccine to pediatric offices will greatly enhance the efforts to vaccinate children against both COVID-19 and the flu, as well as catch children up on routine vaccines they may have missed during the pandemic.

3. There is rapidly mounting evidence about the important role of T cells in COVID-19. In fact, a recent study showed that T-cell responses to certain vaccines remain unaffected by common variants, while neutralizing antibodies are significantly diminished. Given the complementary information T-cell testing can provide, should the FDA require T-cell information from vaccine developers when assessing immunogenicity or when determining how frequently booster shots may be needed in different populations? Do you agree it is important for researchers and vaccine developers to incorporate measures of T-cell response when assessing vaccine response and duration and give physicians the tools they need to make appropriate clinical decisions in treating patients?

T cells and other effectors in our immune response are important for COVID-19, as they are for essentially all infectious diseases. We encourage those who design vaccine studies to incorporate into their protocols the evaluation of multiple arms of the immune response, to the extent possible. Typically, a single immunologic endpoint is chosen as the “primary outcome” based on current knowledge and the other immunologic endpoints are chosen as secondary or exploratory outcomes. That is what has been typically done for COVID-19 vaccine trials in the US, to date. Neutralizing antibodies to the spike protein are certainly an important part of the immune response and remain a reasonable primary immunologic endpoint. Cellular immune responses, including but not limited to T-cell responses, are also important, especially for long term immunologic memory and

for reducing risk of severe disease and should be evaluated as part of the vaccine development program. The FDA need not require that all persons enrolled in all studies of all COVID-19 vaccines have cellular immune responses evaluated, but it is certainly important to understand both humoral and cellular responses and the FDA should (and typically does) encourage sponsors to evaluate immune responses to their investigational vaccines that go beyond only antibody concentrations. The FDA should, and typically does, work with sponsors on developing complete clinical investigational plans that include evaluation of both short term and longer-term protection. In the plans for longer term protection, the consideration of boosters is one of the important details to be entertained.

4. How can the National Institutes of Health (NIH) support additional research to build on existing evidence on the use of T Cell testing for COVID-19? To assess the long-term effects of COVID infection? To examine the cellular immune response as it studies vaccine efficacy and duration? For other known diseases? To prevent or mitigate future pandemics?

The NIH should provide funding to researchers to discover the crucial immune responses to vaccines, including vaccines directed against COVID-19. It is a very well-known fact, among vaccinologists and immunologists, that study of the relevant immune responses to vaccines is crucial to understanding how and when they protect. Although T cell responses are often important, so too are memory cells, B cells, NK cells, and others, in some instances. The NIH should encourage investigators to propose the science that is most relevant to the disease and vaccine under evaluation, since the crucial outcome measures may differ by pathogen or vaccine. Regarding COVID-19 vaccines, much work has been done on T cell responses and should be continued as we learn more about human responses to the various COVID-19 vaccines and vaccine platforms. We would also support research on the long-term effects of COVID-19 infection in both children and adults.

ⁱ <https://www.aappublications.org/news/2021/04/21/covid-vaccine-pregnancy-safety-042121>

ⁱⁱ <https://www.aappublications.org/news/2021/08/18/covid-antibodies-breast-milk-vaccine-081821>

ⁱⁱⁱ <https://www.researchsquare.com/article/rs-798175/v1>

^{iv} Kaiser Family Foundation, COVID-19 Vaccine Monitor Dashboard, September 2021. Accessed at: <https://www.kff.org/coronavirus-covid-19/dashboard/kff-covid-19-vaccine-monitor-dashboard/>.

^v American COVID-19 Poll. The African American Research Collaborative and the Commonwealth Fund. June 2021.