American Academy of Pediatrics
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Arnold Monto, MD
Acting Chair
Vaccines and Related Biological Products
Advisory Committee
U.S. Food and Drug Administration
Silver Spring, MD 20993

Prabhakara Atreya, PhD.
Acting Designated Federal Officer
Vaccines and Related Biological Products
Advisory Committee
U.S. Food and Drug Administration
Silver Spring, MD 20993

Docket No. FDA-2020-N-2242 for "Vaccines and Related Biological Products; Notice of Meeting; Establishment of a Public Docket; Request for Comments."

Dear Dr. Monto and Dr. Atreya:

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of more than 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of all infants, children, adolescents, and young adults, I write to provide comments as the Vaccines and Related Biological Products Advisory Committee discusses the Moderna, Inc., COVID-19 Vaccine for the prevention of COVID-19 in individuals 18 years and older

With this second meeting in a week on a COVID-19 vaccine held by this committee, I would like to take this opportunity to highlight the urgent need for manufacturers to include children in COVID-19 vaccine trials so that our children can benefit from them, including the Moderna vaccine that has been discussed here today, the Pfizer vaccine examined last weekend and other vaccines that are still being developed and will come before the FDA in the future. As we saw with last week's discussion regarding data on 16- and 17-year-old recipients of the Pfizer vaccine, there is a great need to gather more information on this age group and to continue to move forward with including younger children in trials as well.

While some studies have shown that children under the age of 10 may be less likely to become infected and less likely to spread the virus to others, more recent data suggest children older than 10 years may spread SARS-CoV-2 as efficiently as adults. While the likelihood of spreading the disease may vary among different aged children, we know that children can and do spread the virus to household members, grandparents, teachers, and other children.

In fact, as of December 10, more than 1.6 million children have been infected with the virus since the start of the pandemic, representing 12.2 percent of all cases. Among the children who have acquired COVID-19, 162 have died from the virus. More than two-thirds of these deaths occurred in Black and Latinx children.

Beyond the direct impact of the infection, children have been greatly affected by the pandemic, with large disruptions to in-person school and early learning, limited social interactions with peers and relatives, and curtailed access to playgrounds, sports activities, and other activity that helps develop social and emotional well-being. We know that lengthy time away from school and associated interruption of supportive services often results in social isolation, making it difficult for schools to identify and address important learning deficits as well as child and adolescent physical or sexual abuse, substance use, depression, and suicidal ideation.

As such, it is counter to the ethical principle of distributive justice to allow children to take on great burdens during this pandemic but not have the opportunity to benefit from a vaccine, or to delay that benefit for an extended period of time, because they have not been included in vaccine trials. Children must be included so we can best understand any potential unique immune responses and unique safety concerns. Questions about unknown safety concerns will not be answered by posing questions, but only through carefully designed trials which include children.

We also know this research takes time. The longer manufacturers hold off on including children in their clinical trials, the less likely a vaccine will be available for children before the next school year. We know that children can be infected with COVID-19 and can transmit it to others. To reduce the spread of this virus and control the pandemic as well as for their own safety, it is crucial that children be included in the national vaccination program and that vaccines are made available to children as soon as possible.

We applaud Moderna for recently announcing a plan to begin testing its COVID-19 vaccine in children ages 12 through 17, joining Pfizer in studying that age group. We strongly encourage other COVID-19 manufacturers to do the same, and then for all manufacturers to expand these trials to include younger children.

In addition to children, the AAP encourages evaluating COVID-19 vaccines in pregnant women. Women who are pregnant and their newborns are particularly vulnerable to infections and should also benefit from the protection provided by immunization. For example, the Centers for Disease Control and Prevention (CDC) reported 27,566 illnesses from COVID-19 in pregnant women with 44 deaths from January 22 to October 20, 2020. In addition, women who test positive for COVID-19 during pregnancy also appear to experience more adverse birth outcomes, such as preterm birth and neonatal intensive care unit admission. Further, priority groups set to receive early administration of a COVID-19 vaccine such as health care providers, first responders, and non-medical essential workers include many women of child-bearing age, some of whom may unknowingly be pregnant when they receive a vaccine. Because of this, we need to know what the effects of this vaccine are on pregnant women and including them in vaccine research can help answer this question.

Finally, it is vitally important that vaccine trials continue to reflect the racial and ethnic diversity of the U.S. population and not exclude populations at risk that may greatly benefit from vaccinations, including those with underlying comorbidities. These populations must be included in COVID-19 vaccine trials and data regarding safety, immunogenicity, and efficacy must be made available for approved vaccines in these populations. Many Americans, particularly those living in communities of

color, have a hard time trusting the U.S. healthcare system based on its history of discriminatory treatment, unethical research, and unequal access to quality care. Including these populations in clinical trials, and publishing the safety and efficacy data, will help people in these communities decide to receive a vaccine and can help ensure an equitable distribution and uptake of a vaccine.

In short, children are not little adults. We must include children in the COVID-19 vaccine trials as soon as it is safe to do so. In order for parents to be comfortable giving these vaccines to their children, we must have studies showing they are safe and effective in children as well. We also need to include pregnant women, Americans of color and those with underlying comorbidities in clinical trials.

The Academy appreciates the opportunity to provide this feedback as the FDA and VRBPAC consider the Moderna COVID-19 vaccine. We applaud Moderna for announcing that they will begin to include children in their vaccine trials, and we encourage other manufacturers to do the same. If you have any questions on our comments, please contact Patrick Johnson in our Washington, DC office at 202/347-8600 or pjohnson@aap.org.

Sincerely,

Sara H. Goza, MD, FAAP
President

SHG/pmj