

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®



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February 25, 2021

Jeffrey Zients

Coordinator

COVID-19 Response Team

Executive Office of the President

The White House

1600 Pennsylvania Avenue, N.W.

Washington, DC 20500

Anthony Fauci, MD

Chief Medical Advisor

COVID-19 Response Team

Director, National Institute of Allergy

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31 Center Drive

Bethesda, MD 20814

David Kessler, MD, FAAP

Chief Science Officer

COVID-19 Response

Department of Health and Human Services

200 Independence Avenue, S.W.

Washington, DC 20201

Janet Woodcock, MD

Acting Commissioner

U.S. Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20933

Dear Mr. Zients, Dr. Kessler, Dr. Fauci and Dr. Woodcock:

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 urge the administration to use every measure available to achieve authorization of COVID-19 vaccines in children as soon as can be done safely. The administration must increase its efforts to speed the enrollment of children of all ages in clinical trials for these critical vaccines.

There is an urgent need for manufacturers to include children in COVID-19 vaccine trials so that our nation's youngest citizens can benefit from the vaccine as adults have. The same focus and effort from the administration and manufacturers that was expended to enroll adults in COVID-19 vaccine trials must be replicated to enroll adolescents and younger children as soon as possible. Recent predictions from the administration that data for children under age 12 may not be available until early 2022 highlights the need to redouble our efforts to enroll younger children in COVID-19 clinical trials.

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, but data also 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, children can and do spread the virus to household members, grandparents, teachers, and other children.

In fact, as of February 18, over 3.1 million children have been infected with the virus since the start of the pandemic, representing 13 percent of all cases, an increase of over two percentage points since November. Among the children who have acquired COVID-19, 247 have died from the virus, with more than two-thirds of these deaths occurring in Black and Latinx children.

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. 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. While the Pfizer vaccine has been authorized for teens aged 16 and 17 years of age—and both Pfizer and Moderna are conducting trials in adolescents 12 years of age and above—trials for younger children must be initiated soon so we can best understand any potential unique immune responses and unique safety concerns.

We know this research takes time. The longer manufacturers delay including younger children in their clinical trials, the less likely a vaccine will be available for them before the next school year. We also know that children of all ages need to be vaccinated in order for the United States to achieve herd immunity against COVID-19. It is estimated that 70 to 90 percent of the population will need to be immunized to reach herd immunity, and children 18 years of age and under make up approximately 22 percent of the population. There are also many adults who may not be vaccinated due to medical reasons, and others will simply refuse the vaccine. Having a COVID-19 vaccine available for children is essential for this nation to control and end the pandemic.

It is also vitally important that vaccine trials in children reflect the racial and ethnic diversity of the U.S. population, which is becoming more diverse each year, and not exclude populations at risk that may greatly benefit from vaccinations, particularly Black and Latinx children. We urge the administration to assist the manufacturers in promoting trial enrollment for children in these populations.

The Academy appreciates all the work that the federal government has done to ensure that safe and effective COVID-19 vaccines are being made available to the American public. The speed and thoroughness of the adult trials have been extraordinary. The Academy urges the administration to help ensure that COVID-19 vaccine trials in children can be conducted as swiftly as possible so that children of all ages can benefit from a COVID-19 vaccine. If you have any questions on or would like to discuss further, please contact Patrick Johnson in our Washington, DC office at 202/347-8600 or pjohnson@aap.org.

Sincerely,

A handwritten signature in dark ink, consisting of a stylized 'L' followed by a long, sweeping horizontal stroke that curves slightly upwards at the end.

Lee Savio Beers, MD, FAAP
President

LSB/pmj