American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

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August 5, 2021

Janet Woodcock, MD
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear 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 Food and Drug Administration (FDA) to continue working aggressively towards authorizing safe and effective COVID-19 vaccines for children under age 12 as soon as possible.

Pediatricians and the families they care for have been anxiously awaiting a vaccine that can be used in children 11 years of age and younger, and especially so now given the rise of the hyper infectious Delta variant. The Delta variant is surging at extremely alarming rates in every region of America. This surge is seriously impacting all populations, including children. The AAP and the Children's Hospital Association have been tracking COVID cases in children since the start of the pandemic. **Last week saw the largest week-over-week percentage increase in pediatric COVID-19 cases since the start of the pandemic.** The data show 71,726 COVID cases in children reported last week, almost double the 38,654 reported in the previous week. Simply stated, the Delta variant has created a new and pressing risk to children and adolescents across this country, as it has also done for unvaccinated adults.

As the numbers of children infected with the Delta variant have increased, not surprisingly the proportion of COVID-19 cases occurring in the United States among children is also increasing, in large part due the current ineligibility of children under 12 years of age to receive COVID vaccines. Since the pandemic began, children have represented 14.3% of total cumulated cases. However, for the week ending July 29, children were 19.0% of reported weekly COVID-19 cases. The higher proportion of cases in this population means this age group could be contributing in driving continued spread of COVID-19. Sadly, over 350 children have died of COVID since the start of pandemic and millions of children have been negatively impacted by missed schooling, social isolation, and in too many cases, the death of parents and other caregivers.

We understand that the FDA has recently worked with Pfizer and Moderna to double the number of children ages 5-11 years included in clinical trials of their COVID-19 vaccines. While we appreciate this prudent step to gather more safety data, we urge FDA to carefully consider the impact of this decision on the timeline for authorizing a vaccine for this age group. In our view, the rise of the Delta variant changes the risk-benefit analysis for authorizing vaccines in

children. The FDA should strongly consider authorizing these vaccines for children ages 5-11 years based on data from the initial enrolled cohort, which are already available, while continuing to follow safety data from the expanded cohort in the post-market setting. This approach would not slow down the time to authorization of these critically needed vaccines in the 5–11-year age group.

In addition, as FDA continues to evaluate clinical trial requirements for children under 5 years, we similarly urge FDA to carefully consider the impact of its regulatory decisions on further delays in the availability of vaccines for this age group. Based on scientific data currently available on COVID-19 vaccines, as well as on 70 years of vaccinology knowledge in the pediatric population, the Academy believes that clinical trials in these children can be safely conducted with a 2-month safety follow-up for participants. Assuming that the 2-month safety data does not raise any new safety concerns and that immunogenicity data are supportive of use, we believe that this is sufficient for authorization in this and any other age group. Waiting on a 6-month follow-up will significantly hinder the ability to reduce the spread of the hyper infectious COVID-19 Delta variant among this age group, since it would add 4 additional months before an authorization decision can be considered. Based on the evidence from the over 340 million doses of COVID-19 doses administered to adults and adolescents aged 12-17,as well as among adults 18 and older, there is no biological plausibility for serious adverse immunological or inflammatory events to occur more than two months after COVID-19 vaccine administration.

While there is justifiable concern about reported cases of myocarditis in younger adults and adolescents receiving a mRNA COVID-19 vaccine, these events are extremely rare, and, if they were to occur, they would most likely happen within four weeks of receiving the vaccine. In even rarer cases this might present at six weeks, but not longer. In addition, data on the severity of reinfections of COVID-19 do not seem to prime a more adverse immunological response, which lessens the concern that there would be a late negative adverse effect of COVID vaccination.

The Academy appreciates all the work that the FDA has done to ensure that safe and effective COVID-19 vaccines are available to the American public. We urge your continued dedication to help ensure that COVID-19 vaccines for children can be authorized as swiftly as possible so that children of all ages can benefit from them.

Sincerely,

Lee Savio Beers, MD, FAAP
President

LSB/pmj