



Association of Medical School Pediatric Department Chairs

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September 7, 2021

A Message from Pediatric Department Chairs

As the Association of Medical School Pediatric Department Chairs, we lead departments of pediatrics at academic medical centers throughout North America whose missions are to advance and protect child health. Thus, we are alarmed by the sharp rise in case numbers of Severe Acute Respiratory Syndrome-Coronavirus- 2 (SARS-CoV-2) infection and Coronavirus disease 2019 (COVID-19) hospitalizations in children in recent weeks, caused by a confluence of the circulation of the more transmissible SARS-CoV-2 delta variant and schools reopening with COVID vaccines only approved for use in those over 12 years of age. Hospitalization of children for COVID have increased over 4-fold in the month of August, to an average of over 350 hospitalizations daily. The known risk of not having a vaccine available to children has become undeniable. Moreover, we continue to struggle to address the epidemic of children's mental health and learning concerns that emerged during the interruption of in-person school during this pandemic, which further increase the risks of not having a vaccine available to reduce virus transmission in classrooms. Thus, the status quo of this pandemic having a minimal effect on children compared to adults has shifted dramatically in the last month and calls for additional action towards making a vaccine available to all children.

With this change in the risk profile for children at this inflection point in the SARS-CoV-2 pandemic, we are urging the Food and Drug Administration to perform a rapid review of the known and potential benefits and risks for emergency use approval of the SARS-CoV-2 mRNA vaccine for children upon submission of the 2 month follow-up safety, dose-ranging, and immunogenicity data in the originally-designed vaccine trials in 5-11 yr olds, projected to be available from Pfizer in September 2021, followed by rapid review for recommended use by the Advisory Committee on Immunization Practices of the Center for Disease Control. While we agree that studying additional children in these trials will be useful, even doubling or tripling the number in the trials of children under 12 will still be too small to detect rare adverse events, such as myocarditis. Thus, the request for increased trial participant numbers should not hold up emergency use authorization. Moreover, the adverse events attributable to vaccines have universally occurred within a few weeks after vaccination, and thus 2 month follow up data should adequately address the safety concerns. Yet, close follow up of the safety outcomes in both the trial participants and, eventually, real world-vaccinees should be ongoing.

We call upon leaders of federal regulatory agencies reviewing vaccine approvals and recommendation for use to rapidly review the SARS-CoV-2 vaccine data for school age children for authorization and recommended use with the same speed and urgency as was given to the adult and adolescent vaccine authorizations and recommendations. Moreover, we advocate for similar urgent action in the review of vaccines for children younger than 5 years as data become available. Pediatricians and pediatric vaccinologists need to have an important role in assessing the safety and immunogenicity of the COVID vaccines and in making decisions

regarding their use.

With such a powerful tool to safely and effectively prevent disease at our fingertips, we must avoid further delay of its use for the youngest members of our society, whose lives remain disrupted and whose health remains at risk due to this pandemic virus. Together, we can safely bring these remarkable disease-preventing vaccine innovations to children.

On behalf of,

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