

United States Senate

WASHINGTON, DC 20510

September 27, 2021

Janet Woodcock M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Acting Commissioner Woodcock,

We write to urge the Food and Drug Administration (FDA) to work as quickly and aggressively as possible to authorize safe and effective COVID-19 vaccines for children under the age of 12.

Parents, teachers, and caregivers have been eagerly awaiting a vaccine for children 11 years of age and younger. It is needed even more now with the rise of the Delta variant.¹ Surging at alarming rates in every region of America, the Delta variant has created a new and pressing risk to children and adolescents across the country. This is a risk that requires immediate attention.

The American Academy of Pediatrics and the Children's Hospital Association have been tracking COVID-19 cases in children since the start of the pandemic. In the last few weeks, they reported the largest increase in pediatric COVID-19 cases since the start of the pandemic.² The data shows 243,373 cases for the week of September 2 to September 9, 2021.³ That's 3.4 times higher than four weeks earlier, during the week of July 29 to August 5, 2021.⁴ Similarly, while children had represented 14.3% of total cumulated COVID-19 cases over the course of the pandemic, they represented 28.9% of cases during the week ending on September 9. That's almost a 10% increase from four weeks earlier, during the week of July 29.⁵

Tragically, over 460 children have died of COVID-19 since the start of pandemic. Millions more children have been negatively impacted by missed schooling, social isolation, and, in too many cases, death of their parent or caregiver.⁶ We should be giving children the opportunity to grow in a safe and healthy environment. The rise of COVID-19 among children has taken away too much of that health and safety.

¹ <https://www.fda.gov/news-events/press-announcements/fda-will-follow-science-covid-19-vaccines-young-children>

² <https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-state-level-data-report/>

³ Ibid.

⁴ Ibid.

⁵ Ibid.

⁶ Ibid.

More than 5.2 million children have tested positive for COVID-19 in the United States since the pandemic began.⁷ We are particularly concerned about the prevalence of Long COVID in children after initial infection. A study conducted in Israel showed that 11% of children reported symptoms of Long COVID after contracting the virus.⁸ The chances of Long COVID were much higher among children that had COVID-19 symptoms, versus those that were asymptomatic.⁹ The prevalence of Long COVID among children is of particular concern for the long-term impacts on their success and health.

We understand that the FDA has recently worked with Pfizer¹⁰ and Moderna and is awaiting data from their clinical trials in order to begin reviewing for Emergency Use Authorizations (EUAs) for ages 5-11. We strongly encourage you to review the data as quickly and safely as the science allows. We appreciate 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 younger children can be authorized as swiftly as possible.

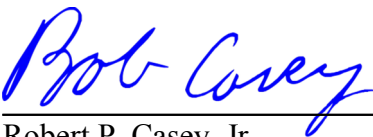
Sincerely,



Martin Heinrich
United States Senator



Christopher S. Murphy
United States Senator



Robert P. Casey, Jr.
United States Senator



Alex Padilla
United States Senator

⁷ <https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/post-covid-19-conditions-in-children-and-adolescents/>

⁸ <https://www.gov.il/en/departments/news/13092021-01>

⁹ Ibid.

¹⁰ <https://thehill.com/policy/healthcare/572385-pfizer-plans-to-seek-covid-vaccine-authorization-in-november-for-kids-under>