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By Electronic Submission

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**Re: Docket No. CDC-2022-0079
Comment to ACIP Notice of Meeting June 17-18, 2022**

To Whom it May Concern:

On behalf of the American College of Clinical Pharmacy (ACCP) and Pediatric Pharmacy Association (PPA), we respectfully submit this comment to the Centers for Disease Control and Prevention, in response to the Notice of Meeting of the Advisory Committee for Immunization Practices on June 17 and 18, 2022. We applaud the CDC and ACIP committee for recommending both Moderna and Pfizer-BioNTech vaccines for children of ages 6 months and up. We encourage the CDC to develop and disseminate resources to aid health professionals in their engagement with concerned parents and caregivers. Members of ACCP and PPA have a particular interest in pediatric COVID vaccines and preventative medicine. We have provided clinical services to the infants, children, and adolescents who developed COVID disease - those who recovered, those who have lingering symptoms, and those who died. As pediatric pharmacy practitioners, our members have administered COVID vaccines since December 2020 to adults and adolescents and will continue to administer the vaccine to the pediatric population during the pandemic.

The American College of Clinical Pharmacy (ACCP) is a professional and scientific society that provides leadership, education, advocacy, and resources for clinical pharmacists to achieve excellence in practice, research, and education. ACCP's membership is composed of about 18,000 clinical pharmacists, residents, fellows, students, scientists, educators, and others who are committed to excellence in clinical pharmacy practice and evidence-based pharmacotherapy. ACCP's members practice in a variety of team-based settings, including ambulatory care environments, hospitals, colleges of pharmacy and medicine, the pharmaceutical industry, government and long-term care facilities, and managed care organizations. The College's 28 Practice and Research Networks comprise clinical pharmacists who practice and pursue research in specialized fields of interest, including pediatrics, ambulatory care, infectious diseases, global health, health outcomes, health equity, and community-based practice. The ACCP Pediatric Practice and Research Network (PRN) provides a

forum within ACCP for professional interaction and networking of 651 pediatric pharmacist members that leads to opportunities for collaborative research, problem solving, and professional discussion of issues relevant to pediatric practice. The PRN supports the development and promotion of excellent and innovative pediatric clinical pharmacy practice, research, and education that will positively influence the total pharmaceutical care of the patient.

The Pediatric Pharmacy Association (PPA) is a professional pharmacy association that advances pediatric pharmacy practice, supports the health and wellbeing of children, and promotes safe and effective medication use in children through collaboration, advocacy, research, and education. There are more than 1,800 members of PPA within the US and internationally who practice in inpatient and outpatient pediatric areas with many focused in subspecialties such as infectious disease, critical care, general pediatrics, hematology/oncology, etc.

At the beginning of the pandemic, it was thought that children may not be as affected or at-risk from the COVID-19 viral infection; yet, over time, we saw firsthand the impact this virus can have on the pediatric population. Vaccine administration can prevent hospitalization, complications, and severe illness from COVID. In children ages 5 to 11 years, there were more than 8,300 hospitalizations and almost 100 deaths related to COVID-19, making it the 4th leading cause of death for children 5 - 14 years of age in January 2022. Children, like adults, can also have short-term and long-term complications after being infected with the virus. Between April 2020 and October 2021, more than 2,300 children who were 5 to 11 years of age reported having multisystem inflammatory syndrome (MIS-C).¹ The Pfizer COVID-19 vaccination of teenagers resulted in a 91% effectiveness (95% CI 78-97) in preventing MIS-C disease. Additionally, pediatric patients diagnosed with COVID are up to 2.5 times more likely to be newly diagnosed with diabetes 30 days or more post-infection.²

Long COVID has been associated with a multitude of symptoms and conditions, but limitations in study design have made it difficult to evaluate the data. A recent study reviewed data from 18 pediatric clinics from 8 regions of Italy from Oct 2020-July 2021. Children hospitalized with COVID had a 58% incidence of long COVID, while 47% of those with symptomatic infection and 11.5% of those with asymptomatic infection developed long COVID.³ Importantly, this study did not demonstrate significance in the incidence of long COVID in children with or without prior conditions.

A 2022 study of the COVID-19–Associated Hospitalization Surveillance Network found that of 2,293 pediatric hospitalizations, 745 (32.5%) were infants and children less than 2 years of age.⁴ Among this age group, patients with chronic lung disease, neurologic disorders, cardiovascular disease, prematurity, and airway abnormalities were associated with severe COVID-19 disease. Severe disease was also associated with hospitalized pediatric patients 2 to 17 years of age who had feeding tube dependence, diabetes mellitus, or obesity. Other at-risk populations include children with sickle cell

¹ CDC. Myths and Facts about COVID-19 Vaccines for Children. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/children-facts.html> Updated Nov 22, 2021. Accessed Dec 1, 2021.

² Barrett CE, Koyama AK, Alvarez P, et al. Risk for Newly Diagnosed Diabetes >30 Days After SARS-CoV-2 Infection Among Persons Aged <18 years ? United States, March 1, 2020-June 28, 2021. *MMWR Morb Mortal Wkly Rep.* ePub: 7 January 2022. DOI: <http://dx.doi.org/10.15585/mmwr.mm7102e2>.

³ Trapani, G., Verlato, G., Bertino, E. et al. Long COVID-19 in children: an Italian cohort study. *Ital J Pediatr* 48, 83 (2022). <https://doi.org/10.1186/s13052-022-01282-x>

⁴ Woodruff RC, Campbell AP, Taylor CA, et al. Risk Factors for Severe COVID-19 in Children. *Pediatrics.* 2022;149(1):e2021053418

disease or those being treated for cancer. A global review found higher rates of severe or critical infection and death from COVID-19 infection in children with cancer than in the general public. Of 1319 patients, 50 (3.8%) died due to COVID-19, a disproportionate amount compared to the general pediatric population. More than 55% of patients required modifications to their cancer-directed therapy. These data illustrate the need for a vaccine for our most vulnerable patients.⁵

Safety should always be considered in COVID vaccine recommendations. Both the Moderna and Pfizer-BioNTech COVID vaccines studied in children ages 6 months to 5 years had primarily mild to moderate side effects consistent with vaccine administration and response. Although myocarditis and anaphylaxis were not seen in the younger study population, this is likely due to the rare occurrence of these adverse events. In the adolescent male population myocarditis occurred in approximately 1 out of every 20,000 patients after COVID vaccination. In contrast, myocarditis was 16 times more common in those with natural COVID infection.

Pharmacists are essential and trusted health professionals, providing education to parents and COVID-19 vaccinations to children. The PREP Act authorized pharmacists to provide COVID-19 vaccines to patients as young as 3 years old. The broadening of this authorization on a federal level was important during the initial 11 week launch of vaccination for children 5 to 11 years of age, as the CDC reports that pharmacists provided almost 50% of the initial doses of these vaccines. Clinical pharmacists are key members of the care team engaging with patients and caregivers for optimal medication use and disease prevention. By partnering with other clinicians on the care team, clinical pharmacists collaborate with pediatric and family practice physicians to improve pediatric vaccination rates, including but not limited to COVID vaccination.

In summary, we appreciate the opportunity to provide comments regarding the recommendation of pediatric COVID vaccination in children of age 6 months to 5 years. We applaud the commitment of the CDC and ACIP committee to advancing protective and preventive public health measures for young children. We encourage the CDC to provide resources to help clinicians engage with parents and caregivers to address their concerns. The ACCP Pediatric Practice and Research Network and Pediatric Pharmacy Association have both clinical experience and expertise in vaccine advocacy, and we look forward to future opportunities to remain engaged in our nation's efforts to build vaccine confidence for young children.

Respectfully submitted,



⁵ Mukkada S, Bhakta N, Chantada GL, et al.. Global characteristics and outcomes of SARS-CoV-2 infection in children and adolescents with cancer (GRCCC): a cohort study. *The Lancet Oncology*. 2021;22(10):1416-1426