



Association of Medical School Pediatric Department Chairs

Executive Office: 6728 Old McLean Village Drive • McLean, VA 22101-3906
Phone (703) 556-9222 • Fax (703) 556-8729 • www.amspdc.org • info@amspdc.org

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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,

The Pediatric Department Chairs of North America

Ann Reed, MD

Duke University School of Medicine

D. Wade Clapp, MD

Indiana University School of Medicine

Joseph St. Geme, III, MD

University of Pennsylvania School of Medicine

Sallie Permar, MD, PhD

Weill Cornell Medicine

Sherin Devaskar, MD

University of California, Los Angeles David Geffen School of Medicine

Alexander G. Bassuk, MD, PhD

University of Iowa Stead Family Department of Pediatrics, University of Iowa Stead Family Children's Hospital

Angelo P Giardino, MD, PhD

University of Utah Department of Pediatrics

Arnold W. Strauss, MD

Cincinnati Children's Hospital Medical Center

Barbara E. Ostrov, MD

Albany Medical College

Robert Vinci, MD

Boston University

Bruce K Rubin, MD

Children's Hospital of Richmond

C. Joan Richardson, MD

University of Texas Medical Branch, Galveston

C.W. Gowen, Jr., MD

Children's Hospital of the King's Daughters/Eastern Virginia Medical School

Catherine S. Manno, MD

NYU Grossman School of Medicine

Charles J. Mullett, MD, PhD

West Virginia University

Charles Schleien, MD

Cohen Children's Medical Center/Northwell Health

Charlotte Boney, MD

UMMS – Baystate

Cynthia L. Emory, MD, MBA

Atrium Health, Wake Forest Baptist

David A. Margolis, MD

Medical College of Wisconsin/Children's Wisconsin

David Deutsch, MD

University of Illinois College of Medicine Rockford

David Gozal, MD, MBA

University of Missouri

Dawn S. Tuell, MD

East Tennessee State University

Desmond Schatz, MD

University of Florida

Dilipkumar R. Patel, MD, MBA, MPH

WMU Homer Stryker MD School of Medicine

Douglas Carlson, MD

Southern Illinois University

Evelyn Montalvo Stanton, MD, FAAP, FCCP

Kirk Kerkorian School of Medicine at UNLV

Gary A. Silverman, MD, PhD

Washington University School of Medicine and St. Louis Children's Hospital

Glenn Flores, MD

University of Miami Miller School of Medicine and Holtz and Children's Hospital

Glenn J. Fennelly, MD, MPH

Texas Tech University Health Sciences Center El Paso, Paul L. Foster School of Medicine

Gordan E. Schutz, MD

Baylor College of Medicine

Harpreet Pall, MD, MBA, CPE

Hackensack Meridian School of Medicine

Jeanne James, MD, MBA, FAAP

Children's Mercy Kansas City and the University of Missouri-Kansas City and University of Kansas Schools of Medicine

Jeffrey M. Devries, MD, MPH

Oakland University William Beaumont School of Medicine/Beaumont Health

John C. Duby, MD, FAAP, CPE

Wright State University Boonshoft School of Medicine

John M. Cunningham, MD

University of Chicago

Jordan Orange, MD, PhD

Columbia University

Joseph P. Neglia, MD, MPH

University of Minnesota Medical School

Joseph Zenel, MD, MPH

University of South Dakota Sanford School of Medicine

Karen D. Hendricks-Muñoz, MD, MPH
Children's Hospital of Richmond at VCU

Kari Simonsen, MD, MBA
University of Nebraska Medical Center

Kimberly Boland, MD, FAAP
University of Louisville School of Medicine

Leslie Walker-Harding, MD
University of Washington/Seattle Children's Hospital

Lewis First, MD
University of Vermont Larner College of Medicine

Lisa Satlin, MD
Mount Sinai Kravis Children's Hospital

Margaret R. Moon, MD, MPH
Johns Hopkins Children's Center

Mark L Hudak, MD
University of Florida College of Medicine – Jacksonville

Marlene R. Miller, MD, MSc
UH Rainbow Babies and Children's

Mary B. Taylor, MD
Children's of Mississippi University of MS Medical Center

Mary C. Ottolini, MD
The Barbara Bush Children's Hospital at Maine Medical Center

Mary Leonard, MD
Stanford University School of Medicine

Melvin Bonilla-Felix, MD
University of Puerto Rico – Medical Sciences Campus

Meredith Irwin, MD
Hospital for Sick Children, University of Toronto

Michael Cabana, MD, MPH

Albert Einstein College of Medicine/Children's Hospital at Montefiore

Michael Donnelly, MD

Georgetown University School of Medicine

Mitchell B. Cohen, MD

University of Alabama at Birmingham

Onajovwe Fofah, MD

Rutgers New Jersey Medical School

Orlando A. Torres, MD

Ponce Health Sciences University School of Medicine

Phyllis A. Dennery, MD

Brown University

Raphael Hirsch, MD

University of California San Francisco

Raymond G. Watts, MD

Louisiana State University Health – New Orleans

Renee Turchi, MD, MPH

St. Christopher's Hospital for Children

Richard Jacobs, MD

University of Arkansas Medical Sciences

Sally Radovick, MD

Rutgers Robert Wood Johnson Medical School

Satyan Lakshminrusimha, MD, FAAP

UC Davis Children's Hospital

Shonola S. DaSilva, MD, MBA

University of Toledo College of Medicine and Life Sciences

Stephanie Davis, MD

University of North Carolina at Chapel Hill

Stephen Aronoff, MD

Lewis Katz School of Medicine at Temple University

Stephen Daniels, MD, PhD

University of Colorado and Children's Hospital Colorado

Steven E. Lipshultz, MD

University of Buffalo Jacobs School of Medicine and Biomedical Sciences

Steven Seidner, MD

The University of Texas Health Science Center at San Antonio

Stewart Goldman, MD

Phoenix Children's Hospital University of Arizona College of Medicine – Phoenix

Terence S. Dermody, MD

University of Pittsburgh School of Medicine

Tina Cheng, MD

Cincinnati Children's Hospital, University of Cincinnati

Z Leah Harris, MD

Dell Medical School at the University of Texas at Austin