ELECTRONIC SUBMISSION

February 17, 2023

Grace M. Lee, MD, MPH
Chair, Advisory Committee on Immunization Practices
1600 Clifton Road, N.E., Mailstop H24-8
Atlanta, GA 30329-4027

RE: Centers for Disease Control and Prevention, Docket No. CDC-2023-0007

Dear Dr. Lee:

The National Minority Quality Forum (NMQF) is a 501(c)(3) not-for-profit research and advocacy organization based in Washington, DC. The mission of NMQF is to reduce patient risk by assuring optimal care for all. Our vision is an American health services research, delivery and financing system whose operating principle is to reduce patient risk for amenable morbidity and mortality while improving quality of life.

NMQF is submitting this public comment to urge the Advisory Committee on Immunization Practices (ACIP) to help ensure that all infants have equitable access to technologies that prevent Respiratory Syncytial Virus (RSV). We request that ACIP initiate action to include new RSV immunization technologies such as monoclonal antibodies in the Vaccines for Children (VFC) Program.

NMQF believes that our request is consistent with President Biden's Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government issued on January 20, 2021.[1] As stated by President Biden:

> *Our Nation deserves an ambitious whole-of-government equity agenda that matches the scale of the opportunities and challenges that we face…It is therefore the policy of my Administration that the Federal Government should pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. Affirmatively advancing equity, civil rights, racial justice, and equal opportunity is the responsibility of the whole of our government. Because advancing equity requires a systematic approach to embedding fairness in decision making processes, executive departments and agencies (agencies) must recognize and work to redress inequities in their policies and programs that serve as barriers to equal opportunity.*

Further, this request falls within the purview of ACIP as stated on the CDC website:

> *The Advisory Committee on Immunization Practices (ACIP) comprises medical and public*

[1] https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support for-underserved-communities-through-the-federal-government/

health experts who develop recommendations on the use of vaccines in the civilian population of the United States. The recommendations stand as public health guidance for safe use of vaccines and related biological products.[2]

Discussion

Respiratory Syncytial Virus (RSV) is a common, highly contagious virus which circulates every autumn and winter in the US. RSV is widespread, infecting 2 out of 3 infants by the age of 12 months.[3] RSV is the most common cause of lower respiratory tract infections, such as bronchiolitis and pneumonia[4], and the leading cause of hospitalizations in infants under 12 months, regardless of gestational age or month of birth.[5] The impact of RSV on infants has been under-estimated as historically this virus was thought to be only a danger to premature infants or those with an underlying medical condition. It is now recognized that 72% of RSV-related hospitalizations are in healthy, full-term infants.[6] While RSV cases can often be mild, they can also be quite serious, and can lead to severe illness and hospitalization. The virus is the most common cause of complications like bronchiolitis (an inflammation of the small airways in the lung) and pneumonia (an infection of the lungs), especially in children under the age of one.

Socioeconomic disparities in RSV hospitalizations are prevalent in North America. Medicaid infants have a 2x higher RSV hospitalization rate compared to non-Medicaid infants (1999-2003).[7] Alaska Native infants from the Yukon-Kuskokwim Delta (YKD) experienced RSV hospitalization rates 5 times higher and an RSV season twice as long as the general US infant population.[8] One in 10 Native American babies in the southwest United States will be hospitalized with RSV each year.

The following alert is currently highlighted on the CDC website:[9]

CDC surveillance has shown an increase in RSV detections and RSV-associated emergency department visits and hospitalizations in multiple U.S. regions, with some regions nearing seasonal peak levels. Clinicians and public health professionals should be aware of increases in respiratory viruses, including RSV.

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2 https://www.cdc.gov/vaccines/acip/committee/index.html (Note: The ACIP was established under Section 222 of the Public Health Service Act (42 U.S.C. §2l7a), as amended. The Committee is governed by the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App 2). The ACIP has been given statutory roles under subsections 1928(c)(2)(B)(i) and 1928(e) of the Social Security Act (42 U.S.C. § 1396s(c)(2)(B)(i) and 1396s(e)) and subsection 2713(a)(2) of the Public Health Service Act (42 U.S.C. § 300gg-13(a)(2)).

3 Centers for Disease Control and Prevention. RSV in infants and young children. https://www.cdc.gov/rsv/high-risk/infants-young-children.html. Accessed December 7, 2021.

4 Leader S, Kohlhase K. Recent trends in severe respiratory syncytial virus (RSV) among US infants, 1997 to 2000. J Pediatr. 2003; Nov; 143(5 Suppl): S127-S132. doi:10.1067/s0022-3476(03)00510-9 PMID: 14615711.

5 Zhou H, Thompson WW, Viboud CG, et al. Hospitalizations associated with influenza and respiratory syncytial virus in the United States, 1993-2008. Clin Infect Dis. 2012;54(10):1427-1436. 5

6 Arriola CS, Kim L, Langley G, et al. 2014-15. J Pediatric Infect Dis Soc. 2020;9(5):587-595.

7 Mina Suh, Naimisha Movva, Xiaohui Jiang, Heidi Reichert, Lauren C Bylsma, Jon P Fryzek, and Christopher B Nelson. Respiratory Syncytial Virus Burden and Healthcare Utilization in United States Infants <1 Year of Age: Study of Nationally Representative Databases, 2011–2019. J Infect Dis. 2022 Aug 15; 226(Suppl 2): S184–S194. Published online 2022 Aug 15. doi: 10.1093/infdis/jiac155; PMCID: PMC9377028; PMID: 35968879

8 Bruden DJ, Singleton R, Hawk CS, Bulkow LR, Bentley S, Anderson LJ, Hermann L, Chikoyak L, Hennessy TW. Eighteen Years of Respiratory Syncytial Virus Surveillance: Changes in Seasonality and Hospitalization Rates in Southwestern Alaska Native Children. Pediatr Infect Dis J. 2015 Sep;34(9):945-50. doi: 10.1097/INF.0000000000000772. PMID: 26065863; PMCID: PMC6931377.

9 https://www.cdc.gov/rsv/. Accessed 02/17/2023.

Newborns and young infants are ineligible for traditional vaccines as their immune systems are not yet fully developed. Therefore, increased awareness of and access to new preventative immunizations such as monoclonal antibodies, is essential to reducing the risk of infection and the related consequences. Given the impact of RSV in all infants, it is essential that ACIP assure that new preventative immunizations approved by the FDA receive broad coverage that increases access and eliminates financial barriers that may serve to compromise access for low income and underserved urban and rural communities.

As with any public health response strategy, preparedness is essential.

The Vaccines for Children (VFC) Program (as noted on their website) helps provide vaccines to children whose parents or guardians may not be able to afford them. This helps ensure that all children have a better chance of getting their recommended vaccinations on schedule. Vaccines available through the VFC Program are those recommended by the Advisory Committee on Immunization Practices (ACIP). These vaccines protect babies, young children, and adolescents from 16 diseases, including Respiratory Syncytial Virus. Funding for the VFC program is approved by the Office of Management and Budget (OMB) and allocated through the Centers for Medicare & Medicaid Services (CMS) to the Centers for Disease Control and Prevention (CDC). CDC buys vaccines at a discount and distributes them to grantees (i.e., state health departments and certain local and territorial public health agencies) which in turn distribute them at no charge to those private physicians' offices and public health clinics registered as VFC providers.[10]

In Closing

The Vaccines for Children (VFC) program is an established safety net for childhood immunizations and was enacted by Congress in 1993 to protect children by ensuring equitable access to immunization services. Approximately half of America's children under age 19 receive VFC-supported vaccines. As noted in an analysis completed in 2014, at a cost savings to society of $1.38 trillion the VFC program resulted in nearly 90% vaccine coverage rates for older vaccines, such as polio and other related vaccines; prevention of approximately 322 million illnesses, 21 million hospitalizations, and 732,000 premature deaths among children born from 1994-2013.[11]

Statutory language authorizes the ACIP to recommend new vaccines to the Vaccines for Children Program and the Routine Childhood Immunization Schedule.[12,13] Given the impact of RSV in all infants, it is essential that new preventative immunizations approved by the FDA be included in the Vaccines for Children Program to enable access regardless of income or geographic location. Therefore, the National Minority Quality Forum encourages ACIP to maximize the potential of the Vaccines for Children Program to prevent RSV infections and related comorbidities.

We would be pleased to discuss this with you. If you have any questions, please contact

[10] https://www.cdc.gov/vaccines/programs/vfc/about/index.html
[11] Centers for Disease Control and Prevention. Benefits from immunization during the vaccines for children program era – United States, 1994-2013. MMWR, Morb Mortal Wkly Rep. 2014;63(16):352-355.
[12] Centers for Disease Control and Prevention. Benefits from immunization during the vaccines for children program era – United States, 1994-2013. MMWR, Morb Mortal Wkly Rep. 2014;63(16):352-355.
[13] Legal Information Institute, Cornell Law School. 42 U.S. Code § 1396s – program for distribution of pediatric vaccines. https://www.law.cornell.edu/uscode/text/42/1396s. Accessed June 29, 2022.

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Sincerely,

Gary A. Puckrein, PhD
President and Chief Executive Officer
National Minority Quality Forum

CC: Chiquita Brooks-LaSure, MPP, Administrator, Centers for Medicare & Medicaid Services
Rochelle P. Walensky, MD, MPH, Director, Centers for Disease Control and Prevention