CYSTIC FIBROSIS FOUNDATION®

January 27, 2021

José Romero, MD
Chair, Advisory Committee on Immunization Practices (ACIP)
1600 Clifton Road, NE
Mailstop A27
Atlanta, GA 30329

Re: CDC-2021-0002, Advisory Committee on Immunization Practices (ACIP), January 27

Filed electronically at regulations.gov.

Dear Dr. Romero:

On behalf of the Cystic Fibrosis Foundation, thank you for this opportunity to provide comments for the Advisory Committee on Immunization Practices (ACIP) meeting on January 27th. We are aware of how challenging it has been for the ACIP and other decisionmakers to balance competing ethical principles and public health priorities, as well as the urgency of improving health equity in vaccine distribution plans, and we thank committee members for the many thoughtful discussions regarding COVID-19 vaccine allocation.

Our comments below call on the committee to ensure that allocation recommendations clearly reflect the need for early vaccine access for high-risk rare disease populations, including those with CF. We look forward to working with the committee as efforts continue related to COVID-19 vaccine development, distribution, and allocation planning.

***Background on cystic fibrosis and COVID-19***

The Cystic Fibrosis Foundation is a national organization actively engaged in the research and development of new therapies for cystic fibrosis – a rare, life-threatening genetic disease that affects more than 30,000 people in the United States. The buildup of thick, sticky mucus in the lungs characteristic of the disease makes people with CF particularly prone to intractable bacterial infections. These chronic airway infections are punctuated by pulmonary exacerbations, events that are a risk factor for an irreversible decline of lung function and associated with morbidity and mortality. A significant proportion of pulmonary exacerbations are triggered by respiratory viral infections as well. With continued progress of the disease, some individuals with CF and advanced lung disease pursue lung transplantation.

The absent or malfunctioning protein that causes CF is also associated with a wide range of disease manifestations beyond the lungs, including pancreatic insufficiency that can lead to malnutrition, gastrointestinal issues, biliary cirrhosis, and diabetes mellitus.

While we have seen incredible progress in recent decades for those living with cystic fibrosis, COVID-19 represents a serious threat for this population. The strongest evidence to date on the threat COVID-19

poses to people with CF may come from a published global analysis of 181 COVID-19 cases among people with CF made possible through an international collaboration of 19 countries including the US.[1] From that analysis, it appears CF patients with advanced lung disease, those that are post-lung transplantation, and those with diabetes mellitus may be at risk of severe outcomes including death.

Due to the risks posed by viral infections described above and multi-system manifestations of the disease, people with CF may be at increased risk of poor outcomes from COVID-19 infection. However, despite being identified by the Centers for Disease Control and Prevention (CDC) as a condition that might put individuals at increased risk for worse outcomes,[2] not all states are prioritizing people with CF for COVID-19 vaccines.

***Clear guidance on allocation recommendations is needed to support high-risk rare disease patients***

We urge the ACIP to provide clarifying language and guidance on phase 1c allocation recommendations for rare diseases that might be at increased risk for serious complications from COVID-19 infection to ensure high-risk patients like those with CF are able to gain early access to COVID-19 vaccines alongside others with high-risk conditions.

We are seeing a wide range of interpretations of ACIP's recommendations among states and localities, which is resulting in confusion and concern within patient communities like ours. Unfortunately, some states have not included people with CF and other rare diseases on their list of prioritized populations. Some states also established allocation plans that limit vaccine access to the CDC's list of conditions known to increase risk of worse outcomes with no allowance for physician discretion. In these instances, people with CF are denied the ability to access COVID-19 vaccines alongside others with high-risk conditions despite ACIP guidance.

We were pleased that the ACIP included persons aged 16 to 64 years with high-risk medical conditions in final recommendations for phase 1c. Additionally, we appreciate that the committee's recommendations are accompanied by language from the CDC about using individual clinical judgement to identify patients whose risks factors warrant priority vaccine access and new language on the CDC's website recognizing the limitations of available evidence on COVID-19's impact for many disease groups, including rare diseases like CF. This language is important for ensuring people with CF and other rare disease populations at increased risk for worse outcomes with COVID-19 are not excluded from prioritized vaccine access.

We urge the ACIP to build on the CDC's language about clinical discretion in identifying high-risk patients and lack of evidence for rare disease populations and provide clarifying language on phase 1c recommendations. It is critical that ACIP allocation recommendations clearly reflect the needs of both diseases with large populations capable of generating clear evidence of risk of severe COVID-19 illness and other rare disease populations too small to generate similar evidence. We ask ACIP to clarify the need for a broad definition of high-risk medical conditions based on the CDC's list and allow for clinician

[1] Cosgriff, Rebecca et al. "The global impact of SARS-CoV-2 in 181 people with cystic fibrosis." Journal of Cystic Fibrosis (2020), in press

[2] https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

discretion in identifying additional high-risk individuals so vulnerable patient populations are able to access COVID-19 vaccines as early as is feasible.

***Further guidance is needed to support early vaccine access for rare disease pediatric patient caregivers***
We urge the ACIP to provide guidance on how parents and other caregivers of children with high-risk rare diseases may get early access to COVID-19 vaccines before the general public while we wait for approved vaccine use for pediatric populations.

While the risks for most children are thought to be minimal, COVID-19 may pose a more substantial risk to some children with underlying conditions such as CF. Data on the impacts of COVID-19 on children with CF is limited. However, a recently published global study on the impact of COVID-19 on children with CF demonstrated that those with lower baseline lung function and body mass index were more likely to be hospitalized.[3] The best protection we can provide for these children, who are not yet eligible for vaccines themselves, is to surround them with adults who are vaccinated. Recommending prioritized access for parents and caregivers of high-risk children will help protect vulnerable pediatric populations within the CF community as well as other rare disease groups.

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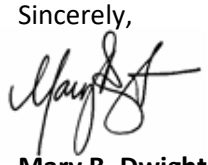
Once again, we thank you for your attention and consideration of people with cystic fibrosis as you tackle these difficult issues. These are important opportunities for collaboration and discussion regarding the ACIP's work to support public access to safe and effective COVID-19 vaccines, and we stand ready to work alongside the committee in this endeavor.

Sincerely,



**Mary B. Dwight**
Chief Policy and Advocacy Officer
Senior Vice President of Policy and Advocacy
Cystic Fibrosis Foundation

[3] Cosgriff, Rebecca et al. "Clinical characteristics of SARS-CoV-2 infection in children with cystic fibrosis: an international observational study." Journal of Cystic Fibrosis (2020), in press