



August 26, 2020

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

Re: CDC-2020-0083-0001, Advisory Committee on Immunization Practices (ACIP) - August 26 2020

Filed electronically at <http://www.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 taking place on August 26<sup>th</sup>. Our comments below call on the committee to ensure: any COVID-19 vaccine allocation framework prioritizes high-risk populations for early access, including those with CF; clear communication to the public on the risks and benefits of different COVID-19 vaccines; transparency of pre-clinical and clinical trial data to help inform clinicians and patients; and affordability of COVID-19 vaccines for all. We hope the committee will consider our comments as work continues related to COVID-19 vaccine development, distribution, and allocation planning.

**Background on Cystic Fibrosis and the CF Foundation**

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 cystic fibrosis particularly prone to viral and bacterial infections, which can lead to dramatic losses in lung function. Some individuals with CF may also suffer from CF-related diabetes or be transplant recipients taking immunosuppression medications – both of which increase the risk of poor outcomes when battling infectious diseases such as COVID-19.

We have seen incredible progress over the last decade for those living with cystic fibrosis. When the CF Foundation was formed in 1955, no CF-specific drugs existed. Today, there are 14 therapeutic products available in the United States to treat people with cystic fibrosis, four of which treat the underlying cause of the disease. Additionally, the highly specialized care that patients with CF receive at their CF Foundation accredited care centers is helping those living with the disease lead longer, more productive lives. In fact, we have seen dramatic improvements in life expectancy for people with CF; from 2004 to 2019, the predicted median survival has risen from 34.1 to 46.2 years of age.<sup>1,2</sup>

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<sup>1</sup> <https://www.cff.org/Research/Researcher-Resources/Patient-Registry/2018-Patient-Registry-Annual-Data-Report.pdf>

<sup>2</sup> <https://www.cff.org/Research/Researcher-Resources/Patient-Registry/Cystic-Fibrosis-Foundation-Patient-Registry-Highlights.pdf>

Despite the progress we have seen, we know that infections will continue to pose a serious threat to the health of people with cystic fibrosis. In recognition of the urgency of providing both immediate and long-term solutions for the chronic and intractable respiratory infections that are a hallmark of cystic fibrosis, the CF Foundation has dedicated \$100 million over five years to our Infection Research Initiative. This initiative, which supports a number of research projects aimed at improving detection, diagnosis, prevention, and treatment of infections related to CF, will also be leveraged to build data and evidence on the direct impacts of COVID-19 on people with CF. The Foundation recently released a request for grant applications to fund research into COVID-19 pathogenesis in cystic fibrosis.<sup>3</sup> We hope this work will help shed light on whether there are underlying biological differences in the way that people with CF may be infected by or respond to coronavirus infection leading to COVID-19 compared with the general population.

### **High-Risk Populations Must Be Prioritized for Access to COVID-19 Vaccines**

As discussions on equitable vaccine allocation progress, we urge the ACIP to prioritize people considered at high-risk of severe illness from COVID-19, including those living with cystic fibrosis, for access to COVID-19 vaccines. Due to the heightened life-long risk of infections described above, the Centers for Disease Control and Prevention (CDC) has included cystic fibrosis on the list of conditions that may cause people to be at increased risk for severe illness from COVID-19.<sup>4</sup> We recommend that the allocation framework take into account the work of the CDC in identifying those at increased risk of COVID-19.

Like many other small, rare disease populations, we have struggled to get a clear picture over the last six months on the direct impacts of COVID-19 for people living with cystic fibrosis. However, we do know that the indirect impacts have been devastating for people with CF and their families. In the absence of robust data on the impacts of COVID-19 for those living with CF, many patients and families are forced to make choices that can have significant consequences for their health, education, and livelihood. Specifically, we know that many families of people with cystic fibrosis have struggled throughout the pandemic to balance the need for maintaining their source of income and health insurance while keeping vulnerable members of their family safe during this time. Job loss can be particularly hard for those living with CF, as many in the community rely on employer-sponsored insurance to cover the high health care costs associated with caring for a chronic illness; the high costs of CF care can be exceptionally burdensome on families struggling to make ends meet. Earlier access to an effective COVID-19 vaccine would potentially allow people with CF and their families to continue to or return to work, thereby keeping critical health insurance and generating income to pay for essential needs of the family.

A number of patients and families in our community have shared their experience with balancing employment and the need to protect their health or their loved one's health during this time. One such individual with CF living in Tennessee, who has run out of options with her employer, shared that she faces a difficult decision to either lose her position as a nurse practitioner or return to in-person work at great risk to her health. We have also heard from families who are forced to live apart to protect vulnerable members in their household. To protect his daughter with CF, one father who is an essential worker has been staying in his family's camper to avoid exposing his family to COVID-19.

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<sup>3</sup> <https://www.cff.org/Research/Researcher-Resources/Awards-and-Grants/Research-Awards/SARS-CoV-2-and-Cystic-Fibrosis-Research-Award/>

<sup>4</sup> <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

One such story, shared here, demonstrates the difficult choices families in our community are being forced to make in an effort to protect vulnerable individuals with underlying conditions:

*“For eleven years my wife and I have spent hours every day taking care of our daughter with cystic fibrosis. She engages in physical therapy at home that often takes two to four hours a day. She takes, without exaggeration, thousands of pills each year to maintain her health. My wife and I are both teachers, and while no one knows what the future holds, we have been able to keep our child alive, healthy, and safe for the eleven years she has been alive. All of that work is threatened now as schools work at reopening this fall. Our child will attend school safely online, but my wife and I are subject to the decisions of our school district. We either choose to stay home to keep our child safe and lose the jobs we both love so deeply, or we return to the classroom knowing we could bring home COVID-19 germs that could potentially kill her. Because we do not have the option of taking leave until there is a vaccine, our high-risk daughter may pay the price with her life. No economic success or weakness matters to people who are dead. We need to help those who are most vulnerable to survive.”*

Importantly, prioritized access to a vaccine, if appropriate, means that those living with serious chronic conditions like cystic fibrosis will be able to regain some sense of normalcy and return to society. While the experiences of the CF community are not unique among those living with a number of underlying conditions, the threat of respiratory infections looms over the everyday lives of those with CF and their loved ones, and the pandemic has only worsened this fear. Without vaccine access, those living with CF and their loved ones continue to face significant challenges in participating in necessary activities of daily living. Until we know more about the direct impacts of COVID on those living with CF, early access to COVID-19 vaccines deemed safe and effective by the FDA could help keep individuals with CF and their loved ones safe.

#### **Allocation Frameworks Should Be Responsive to and Communicate the Unique Vaccine Safety Issues and Benefits**

While we urge the ACIP to prioritize high-risk populations for access to COVID-19 vaccines, it is critical that vaccine allocation frameworks used during this time be responsive and adaptable to the unique characteristics of any given COVID-19 vaccine made available to the public. We also ask that the ACIP consider and clearly communicate to the public any relevant safety and effectiveness information on individual COVID-19 vaccines as part of allocation recommendations.

Given that we do not yet know the characteristics of COVID-19 vaccines that will be made available to the public, it is critical that vaccine allocation frameworks are not created with a one-size-fits-all approach. We understand that not every COVID-19 vaccine will have the same benefits and risks, and that certain vaccines may be more or less optimal for certain subsets of the population. In particular, we encourage the ACIP to carefully consider the needs of and impacts on vulnerable patient populations, including rare disease populations and those with chronic lung diseases, when evaluating and making determinations on allocation recommendations. COVID-19 vaccine allocation frameworks ultimately should be responsive to safety issues and benefits of a given COVID-19 vaccine in order to best protect and serve vulnerable populations during the ongoing pandemic.

#### **All Vaccine Development Data Should be Transparent and Accessible**

In order to best serve vulnerable populations and the public at-large, transparent and accessible data on safety and efficacy must be made available for any COVID-19 vaccine candidate so health care providers

can understand the risks and benefits for their patients. Clinical experts and trusted public health sources will be expected to communicate information on available COVID-19 vaccines and make recommendations to unique patient communities on appropriate use and risks. For clinicians to understand and communicate the full scope of benefits and risks associated with any early COVID-19 vaccine candidate, data from pre-clinical and clinical testing must be made available to the public in a timely manner. It is also important to note that peer review can help ensure data quality and increase public confidence in COVID-19 vaccine candidates. The federal government must do everything in its power to ensure a transparent vaccine development process, and we urge the ACIP to facilitate this process.

**COVID-19 Vaccines Must Be Affordable for All**

Finally, we strongly believe that any COVID-19 vaccine must be made available at little or no cost to patients. Ensuring access to COVID-19 vaccines will be critical for encouraging vaccine uptake and ultimately halting the COVID-19 pandemic. As we continue to press forward with development of multiple vaccine candidates, it is essential we ensure current health plans and federal programs provide access to any approved COVID-19 vaccine.

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Mary B. Dwight', with a stylized, cursive script.

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