



**Statement for the Record
House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
Comments Regarding Biden Administration Actions to Increase COVID-19 Vaccinations
March 12, 2021**

On behalf of the more than 30,000 people with cystic fibrosis in the United States, the Cystic Fibrosis Foundation thanks the House Energy and Commerce Subcommittee on Oversight and Investigations for convening this important hearing on the national COVID-19 vaccination effort.

As the committee looks for ways to support COVID-19 vaccination, we urge you to consider people living with cystic fibrosis, who need a vaccine distribution strategy that is both aggressive and predictable. We are concerned that COVID-19 vaccination efforts to date have left patient communities like ours confused and frustrated as they attempt to navigate state and local COVID-19 vaccine eligibility and processes. Urgent steps should be taken to ensure that the process for vaccine distribution prioritizes those most at risk, that this process is clearly communicated to and easily navigated by eligible patients, and that all vaccination efforts keep in mind the needs of those considered at high-risk for worse outcomes with COVID-19 such as people with CF.

We share these and other comments below, and we look forward to working with the committee as efforts continue related to COVID-19 vaccine development, distribution, and administration.

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 characterized by the buildup of thick, sticky mucus in the lungs. People with cystic fibrosis are 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. Continued progression of the disease can result in advanced lung disease so severe that lung transplantation may be the only life extending option.

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 comes 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

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.

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 known risks posed by viral infections and multi-system manifestations of the disease, people with CF should be considered at increased risk of poor outcomes from COVID-19 infection.² 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, not all states are choosing to prioritize people with CF for COVID-19 vaccines.

The Biden Administration should ensure states follow CDC Advisory Committee on Immunization Practices (ACIP) recommendations on vaccine allocation

We are seeing a wide range of interpretations of CDC's Advisory Committee on Immunization Practices (ACIP) COVID-19 vaccine allocation 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. In these instances, people with CF are denied the ability to access COVID-19 vaccines alongside others with high-risk conditions despite CDC guidance. Further guidance from the Administration is needed to ensure states uphold allocation recommendations put forth by the ACIP, which calls for prioritizing individuals with high-risk conditions, such as those with CF, for early vaccine access.

We are also deeply concerned by the emerging trend of age-based vaccine distribution plans in states across the US, which deprioritize younger individuals with high-risk conditions such as CF. In 2019, the median age at death for those living with CF was 32 years of age. Over 260 people with CF received a solid organ transplant that same year, and 77 percent of those receiving a transplant were under the age of 40.³ Using age-based distribution alone to define prioritized populations will result in people with CF who are vulnerable to worse outcomes from COVID-19 getting vaccinated after older, healthier adults simply because those with CF have a shorter life expectancy.

These allocation schemes abandon the carefully crafted recommendations finalized by the ACIP in December. The ACIP recommendations are the result of months of thoughtful deliberation by vaccine and public health experts with input from thousands of stakeholders. The ACIP and other decisionmakers have worked diligently to balance competing ethical principles and public health priorities, as well as the urgency of improving health equity in vaccine distribution plans. Importantly, the committee's process has included meaningful public engagement and transparency on how the committee weighed different considerations related to prioritized populations.

The ACIP recommendations are accompanied by important CDC guidance on the limitations of available evidence on COVID-19's impact for many disease groups, including rare diseases like CF. This CDC guidance recommends using clinical judgement in identifying patients whose individual risks factors warrant priority vaccine access but whose condition may not be on the CDC's list of high-risk conditions. Together, these recommendations support prioritized vaccine access for people with CF and other rare disease populations that, due to small population size, are unable to generate the same level of evidence on the risk of severe illness from COVID-19 as substantially larger disease populations.

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

³ <https://www.cff.org/Research/Researcher-Resources/Patient-Registry/2019-Patient-Registry-Annual-Data-Report.pdf>

The Administration must signal the importance of upholding the committee's existing interim vaccine allocation recommendations to states, which balance important objectives such as minimizing harm to those most at risk for worse outcomes, increasing access to disadvantaged populations, and ensuring a transparent process—and reaffirm the need to prioritize high-risk rare disease populations. We recognize that states are contending with overwhelming demand for vaccine access in the absence of adequate resources and support to carry out efficient mass vaccination efforts. However, the desire for simplicity must not come at the expense of those who are most vulnerable to the consequences of COVID-19 infection.

Clear communication on the vaccination process is needed to support high-risk patients

The national COVID-19 vaccine rollout has been hampered in part by a lack of clear communication on how and when members of priority groups will receive information about vaccine eligibility and appointments. People with underlying conditions, such as those with CF, remain confused as to whether they qualify for prioritized access to COVID-19 vaccines, how they will be notified when they become eligible, how they will be expected to demonstrate eligibility at the time of vaccination, and where they will need to go to get vaccinated. These challenges have been exacerbated by significant differences between state vaccination efforts, leaving our community frustrated by the lack of information needed to navigate and understand this process.

The Administration can accelerate safe and timely access to COVID-19 vaccination for millions of Americans, including those with high-risk conditions, by sharing best practices with states on how to inform different populations about when they become eligible and how to make appointments. Additionally, the appointment registration process itself, which has been plagued with technical challenges and overwhelming demand, should be improved to ensure eligible patients are able to access vaccination appointments. The Administration should provide the support necessary to ensure a smooth registration process, such as providing a registration model to states and technical support.

This pandemic has been enormously taxing on many in the CF community, and for those living with CF and their families, prioritized access to a vaccine means regaining some sense of safety, normalcy, and ultimately a return to society. Instead of seeing a light at the end of the tunnel now that vaccines are publicly available, many in our community feel anxious and frustrated by ongoing confusion about vaccine access. States need guidance on how best to bring increased transparency around vaccine eligibility and access so patients with high-risk conditions like CF can understand how and when they may receive a vaccine.

Mass vaccination efforts should protect vulnerable patient populations

We are encouraged by the Administration's plans to increase vaccination sites and to make sites accessible for hard to reach populations. It is critical that patients have access to COVID-19 vaccines in their community, and that we do not rely solely on large health care systems or pharmacy chains.

As decisionmakers consider ways to increase the number of vaccination sites, it is important that the needs of vulnerable populations like those with CF are kept in mind. As mentioned above, people with CF are particularly vulnerable to respiratory infections. In order to protect those with high-risk conditions like CF, it is critical that any vaccination site uphold public health measures such as social distancing. Decisionmakers should ensure that all vaccination sites are selected and operate with the most vulnerable patients in mind.

Once again, we thank the House Energy and Commerce Subcommittee on Oversight and Investigations for convening this important hearing on national COVID-19 vaccination efforts. We urge the committee to keep in mind the needs of people with cystic fibrosis as you tackle critical issues related to COVID-19 vaccine distribution and vaccination. The CF Foundation stands ready to work alongside Congress and the Administration on these challenges and more.