



January 21, 2021

The Honorable Joseph R. Biden, Jr.  
President of the United States  
The White House  
1600 Pennsylvania Avenue NW  
Washington, DC 20500

Dear President Biden:

On behalf of the more than 30,000 people with cystic fibrosis in the United States, the Cystic Fibrosis Foundation thanks you for your commitment to accelerating the distribution of COVID-19 vaccines and supporting necessary public health measures to help end the pandemic. We are encouraged by your leadership on health care issues throughout your public life and look forward to working with your new administration.

As you develop and implement your approach to the COVID-19 pandemic, we urge you to take into consideration people living with CF and their families who need a vaccine distribution strategy that is both aggressive and predictable. We are concerned that vaccination efforts to date have left patient communities like ours confused and frustrated as they attempt to navigate COVID-19 vaccine eligibility and processes. We ask that your administration take urgent steps to ensure that the process for vaccine distribution and vaccination 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 administration as efforts continue related to COVID-19 vaccine development, distribution, and vaccination.

**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. 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.<sup>1</sup> 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.<sup>2</sup> 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. Additionally, people with CF are facing further barriers to vaccination due to distribution challenges at the state level.

**National and state vaccine allocation schemes should follow those issued by the CDC Advisory Committee on Immunization Practices (ACIP)**

We appreciate your commitment to ensuring an equitable national vaccine allocation scheme that provides prioritized access to the most vulnerable populations. However, we urge you not to override the allocation recommendations put forth by the CDC's Advisory Committee on Immunization Practices (ACIP).

The recommendations released by the ACIP are the result of months of careful deliberation by vaccine and public health experts and input from thousands of stakeholders. The ACIP and other decisionmakers sought 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 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.

We appreciate the ACIP's rigorous process and the CDC guidance to help states and other decisionmakers identify patients in need of prioritized access. We encourage the administration to work closely with states to ensure vaccine distribution plans build on ACIP and CDC's work to ensure that all people at high-risk are able to access vaccines at the earliest point rather than issuing new national allocation recommendations.

**Support and resources for state vaccination efforts will be key to speeding the national vaccine rollout**

We thank you for your commitment to provide states with additional resources and support as they carry out vaccine campaigns at the local level. Much work remains to be done to ensure a successful national vaccination effort, and states need adequate support to address vaccine hesitancy and to tackle immense challenges related to vaccine distribution and logistics. Monetary resources, technical

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

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

assistance, and guidance will be key to ensuring state and local vaccine programs are both equitable and efficient. We appreciate your recognition that states need significantly more resources and applaud your decision to make this a top priority in the early days of your new administration.

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

To date, the national COVID-19 vaccine rollout has been hampered in part by a lack of clear process on how members of priority groups will receive a vaccine and communication to the public on that process. 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.

We ask that your administration 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.

We further ask the administration to provide guidance to states on how eligible patients with high-risk conditions demonstrate eligibility. If patients are expected to demonstrate they have an eligible condition at the time an appointment is made or when the patient shows up at a vaccination site to receive their vaccine, the types of documentation that will be accepted must be clearly described. Patients should be able to easily access information on documentation requirements, which should be flexible enough to avoid excessive barriers for those with limited access to health care.

We ask the administration to work closely with states to clarify their processes for distributing COVID-19 vaccines and communicate this information to the public. 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. We urge you to work with states 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 you consider ways to increase the number of vaccination sites, we urge you to keep in mind the needs of vulnerable populations like those with CF. 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. The

administration should ensure that all vaccination sites are selected and operate with the most vulnerable patients in mind.

***COVID-19 vaccines must be affordable for all***

Finally, we applaud you for your commitment to ensuring that COVID-19 vaccines are available free of charge and without any cost-sharing. 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 that decisionmakers engage with payers early and often to ensure costs do not serve as a barrier to COVID-19 vaccination efforts. We stand ready to work with you to ensure that all health plans and public programs provide access to approved COVID-19 vaccines without cost to patients.

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Once again, we thank you for your leadership and commitment to speeding up national COVID-19 vaccination efforts. We urge you to keep in mind the needs of people with cystic fibrosis as you tackle critical issues related to COVID-19 vaccine distribution and vaccination, and the CF Foundation stands ready to work alongside the administration on these challenges and more.

Sincerely



**Mary B. Dwight**

Chief Policy and Advocacy Officer  
Senior Vice President of Policy and Advocacy  
Cystic Fibrosis Foundation