



December 7, 2020

The Honorable Joseph R. Biden, Jr.
President-Elect

Dear President Elect-Biden:

On behalf of more than 30,000 people with cystic fibrosis, the Cystic Fibrosis Foundation congratulates you on your election victory. We are excited and encouraged by your leadership on health care issues throughout your public life and look forward to working with your new administration. As you develop your policy priorities for the upcoming year, particularly when addressing issues surrounding COVID-19, we urge you to take into consideration individuals living with cystic fibrosis and their families. This virus represents a serious threat for people with CF due to the risks posed by viral infections and multi-system manifestations of the disease. The CF Foundation has a unique voice when addressing issues related to COVID-19 and we stand ready to work with your administration to protect the CF community and the American people.

The CF Foundation is a national organization actively engaged in the research and development of new therapies for CF – a rare, life-threatening genetic disease. The buildup of thick, sticky mucus in the lungs characteristic of the disease makes people with CF particularly prone to viral and 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. Cystic fibrosis also affects multiple systems in the body and people living with the disease often suffer from chronic pancreatic insufficiency, malnutrition, diabetes mellitus, liver disease, bone disease, and other comorbidities. With continued progress of the disease, some individuals with CF and advanced lung disease must pursue lung transplantation.

As the CF Foundation looks towards the future of CF care during the time of this public health emergency and beyond, our priorities include (more details can be found in the appendix):

COVID-19 Vaccines

- Support early vaccine access for individuals at higher risk for severe morbidity and mortality due to COVID-19, including those with CF
- Assist states with vaccine distribution and education efforts to combat COVID-19 vaccine hesitancy
- Track and disseminate COVID-19 vaccine information for specific disease groups so patients and clinicians have the most accurate picture possible about the relative safety and efficacy of a COVID-19 vaccine
- Ensure all COVID-19 vaccines and related administration are available without cost-sharing for all Americans

Telehealth

- Individuals with CF are particularly conscientious about potential exposure to the COVID-19 virus and therefore rely heavily on access to telehealth services during this pandemic. We urge your administration to work with Congress to do the following:
 - Permanently remove the originating site and geographic restrictions to ensure a patient's home can serve as the site of care
 - Continue expanding access to audio-only telehealth visits

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- Enable temporary licensing reciprocity for all licensed and certified practitioners in all states for all types of services for the duration of the COVID-19 pandemic

Paid Family & Medical Leave

- It is essential people with CF and working members of their household have the opportunity to remain in self-isolation for the duration of the COVID-19 pandemic to ensure their health and safety. We urge your administration to:
 - Expand the paid family and medical leave program to include individuals who have been advised by their physicians to remain at home during this time because of a serious health condition
 - Expand paid family and medical coverage to include household members of someone who has been advised by a physician to remain home
 - Remove existing time limit placed on paid leave to ensure that individuals can remain home as long as the COVID-19 pandemic remains a serious threat

Increasing Access to Affordable Care

- In order to access high quality, specialized care, people with CF need adequate, affordable insurance. We support policies in your campaign platform to increase affordability of coverage, including:
 - Eliminating the eligibility cap for premium subsidies at 400% of the federal poverty level
 - Lowering the affordability threshold so families can purchase subsidized marketplace coverage instead of employer-sponsored coverage

Antimicrobial Resistance

- Improve reimbursement for antibiotics and invest in innovative payment models that incentivize novel antibiotic development

While we have seen incredible progress in the development of effective treatments over the past decade for those living with CF, we are still losing people who are much too young, and COVID-19 represents a serious threat for our community. Due to the risks posed by viral infections described above and multi-system manifestations of the disease, people with CF should be considered at increased risk of serious complications and poor outcomes from COVID-19 infection.

Thank you for your leadership and focus on improving America's health care system. The CF Foundation looks forward to working with you on the issues you have championed, as well as additional issues we have raised for your consideration. To begin the conversation, I have submitted a formal request and would welcome the opportunity to meet with a member of the transition team to talk about the CF Foundation's policy priorities in more detail. For more information and to discuss further, please contact me at mdwight@cff.org or 301-841-2639.

Sincerely,

Mary B. Dwight



Senior Vice President
Chief Policy & Advocacy Officer
Cystic Fibrosis Foundation

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APPENDIX

COVID-19 Vaccines

Individuals with Cystic Fibrosis Should Be Prioritized for Access to COVID-19 Vaccines

A number of stakeholders at the national level, including the National Academy of Medicine and the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP), have identified those at higher risk for severe morbidity and mortality due to COVID-19 as needing prioritized access to COVID-19 vaccines. We were pleased to see that the most recent iteration of the ACIP's interim vaccine allocation proposal includes individuals with high-risk medical conditions such as those with CF, among other prioritized populations. Due to the heightened life-long risk of infections described above, the CDC has included cystic fibrosis on the list of conditions that may cause people to be at increased risk for severe illness from COVID-19.¹ Additionally, certain patients with CF, such as those living with advanced disease or who are post-transplant, may be especially vulnerable to worse outcomes due to COVID-19.²

Support States as They Implement Vaccine Campaigns

While we are encouraged by ACIP's proposal, which would allow patients with high-risk conditions to take advantage of early COVID-19 vaccine access, much work remains to be done to have a successful national vaccination campaign. Specifically, states need support to address widespread vaccine hesitancy and tackle immense challenges related to vaccine distribution and logistics. We urge the new Administration to ensure states and other stakeholders have the resources and guidance they need to successfully vaccinate all eligible Americans.

COVID-19 Vaccine Development Data Collection and Transparency

Ongoing data collection and public communication on safety and efficacy will be critical for COVID-19 vaccination efforts, including data collection for specific disease populations. It is unlikely there will be data on the specific risks or benefits for people with rare diseases like CF at the time of a vaccine authorization or approval. Therefore, it is critical that public health agencies conduct ongoing monitoring and regular external communication about adverse events and efficacy so clinicians and patients can understand the risks and benefits of a vaccine for different populations. We urge the new Administration to track and disseminate this information for specific disease groups, including rare diseases, so patients have the most accurate picture possible about the relative safety and efficacy of a COVID-19 vaccine for people with their condition.

COVID-19 Vaccines Must be Affordable for All

Finally, it is essential that decisionmakers ensure health plans and public programs provide access to approved COVID-19 vaccines without cost-sharing 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 the 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.

Telehealth

People with CF are particularly conscientious about potential exposure to the COVID-19 virus and therefore rely heavily on access to telehealth services. Recognizing the need for strict adherence to social distancing guidelines and taking into account special considerations for their patient population, CF care teams have responded rapidly to changes in care delivery and are embracing telehealth in their clinics. Today, nearly all of the 130 CF Foundation-accredited care centers in the U.S. are providing some form of telehealth services to their patients.

¹ https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fneed-extra-precautions%2Fgroups-at-higher-risk.html

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

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Permanently Remove Originating Site and Geographic Restrictions

It is imperative that telehealth remains available to people with CF for as long as they need to follow social distancing guidelines and in the event of another serious public health emergency. To ensure telehealth is accessible for people with CF, we urge your administration to work with Congress to permanently remove the originating site and geographic restrictions to ensure a patient's home can serve as the site of care. This enables infected patients to receive care without spreading the virus and allows other patients—including those with underlying conditions like CF—to receive care without putting themselves at increased risk of COVID-19 infection.

Continue Expanded Access to Audio-Only Telehealth Visits

Additionally, coverage for telehealth visits conducted via devices like smartphones and for certain services using audio-only platforms has been critical for ensuring widespread access to telehealth. We urge the Administration to continue to allow patients to access care via these technologies. During the public health emergency, the Centers for Medicare and Medicaid Services (CMS) have expanded coverage of audio-only services, ensuring patients without access to the internet, a computer, or smartphone are still able to receive needed care. This flexibility is especially critical for providers that serve rural or low-income populations; for instance, a CF clinician from Tucson, Arizona said that most of her patients do not have access to the internet and many are relying on audio-only telehealth visits with their care team during the pandemic. Your new Administration should work to ensure coverage for telehealth visits conducted via audio-only platforms, as well as expanded audio/visual devices, for as long as COVID-19 remains a threat to people with CF and establish mechanisms to provide these flexibilities during future public health emergencies

Practitioner Licensing Reciprocity During Public Health Emergencies

Licensure requirements for clinicians can create barriers to telehealth for individuals with CF who travel across state lines for their CF care. Allowing temporary reciprocity across the country for health care providers in good standing and with a valid license to practice medicine would ensure individuals with CF are able to access remote care from their regular care team. While many states have adjusted their licensure requirements to enable greater flexibility for patients who live in a different state from their providers, the variability from state-to-state results in some individuals with CF still struggling to see their established care team remotely.

For those who rely on out-of-state care centers to help manage their CF, licensure reciprocity is an important tool to make care more accessible. We urge the administration to work with Congress to enable temporary licensing reciprocity for all licensed and certified practitioners in all states for all types of services for the duration of the COVID-19 pandemic and future public health emergencies.

Paid Family Leave

Given the increased risk of complications from COVID-19, it is essential people with CF and working members of their household have the opportunity to remain in self-isolation for the duration of the COVID-19 pandemic to ensure their health and safety. Currently, paid family medical leave provides support only to those with children or adults with disabilities whose local school district or usual care providers are closed due to the pandemic. This policy does not meet the needs of the many Americans who are at increased risk of complications due to COVID-19, including those living with CF. The lack of viable paid leave options for individuals who live with significant health conditions forces these individuals to face a devastating choice: place their health or their loved one's health at risk by going back to work or lose their job and likely their health insurance.

A number of patients and families in our community have shared their experiences 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.³ Ultimately, she lost her job. We have also heard from families who are forced to

³ <https://fox17.com/news/local/at-risk-workers-left-without-protections>

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. These American stories illustrate just a few examples of how inadequate protections are forcing vulnerable workers and their families to choose between their livelihood and their safety.

As your administration develops proposals to better respond to COVID-19, we urge you to prioritize expanding the paid family and medical leave program created by the Families First Coronavirus Response Act (FFRCA) to include individuals who have been advised by their physician to remain at home during this time because of a serious health condition. Additionally, those who have been advised by a physician to remain home because there is a member of their household with underlying conditions must also be covered by this policy. Finally, the existing time limit placed on paid leave must be removed to ensure that these individuals can remain home as long as the COVID-19 pandemic poses a serious risk to their health and wellbeing, and this program must apply to employers of all sizes and types to prevent arbitrary gaps in eligibility.

Increasing Access to Affordable Care

In order to access high quality, specialized care, people with CF need adequate, affordable insurance. Although nearly everyone with CF has public or private health insurance, most individuals and families rely on multiple sources of coverage to address their care needs and the cost burden associated with the disease. Often this is because health insurance plans are unaffordable or have gaps in coverage for CF care and treatments.

The CF Foundation is encouraged by your campaign platform to build upon the Affordable Care Act (ACA) and is excited to work with this administration on increasing access to affordable care. The ACA has led to a historic decrease in the uninsured rate and provided critical protections for people with serious health conditions. However, there is room for improvement to increase affordability, such as eliminating the eligibility cap for premium subsidies at 400% of the federal poverty level and lowering the affordability threshold at which point families can purchase subsidized marketplace coverage instead of employer-sponsored coverage. This will increase affordable coverage options for individuals with CF and their families, ensuring they can access the care they need.

Antimicrobial Resistance

Addressing growing infectious disease threats – both viral and bacterial – will be crucial for preventing or mitigating the impacts of public health crises in the future. Unfortunately, too many people with CF find themselves battling difficult-to-treat infections for which existing antibiotics are not effective. These experiences are not limited to the CF community; each year, 2.8 million Americans acquire serious infections caused by antibiotic-resistant bacteria, and 35,000 of them die as a result.

Current drug reimbursement methods fail to incentivize novel antibiotic development. However, payment methods, such as the one proposed in the Pioneering Antimicrobial Subscriptions to End Up Surging Resistance (PASTEUR) Act, that de-link sales volume from revenue can help. Other reimbursement changes – for example, the one proposed in the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act – that increase payments for newer antibiotics may provide more immediate relief while improving market outlook.

Products in the antibiotics pipeline would ideally be supported by a robust ecosystem of incentives to combat the low market, high societal value of novel antibiotics. The CF Foundation is committed to combating antimicrobial resistance and has made significant investments in the development of new antibiotics that would benefit not only people with CF, but all Americans—including dedicating \$100 million over five years to our Infection Research Initiative. However, investment in antibiotics still lags other therapies. Current successful practices and programs that assist sponsors during early product development, such as CARB-X and other efforts by the Biomedical Research and Development Authority could be expanded to cover additional sponsors or additional phases of clinical development. We urge this administration to work with Congress to improve reimbursement for antibiotics and invest in innovative solutions ensuring access to antibiotics that work both now and in the future.

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