1012 14th Street, NW
Washington, DC 20005

February 17, 2021

Mr. Jeffrey Zients
Whitehouse COVID-19 Response Coordinator

Dr. Rochelle Walensky
Director
Centers for Disease Control and Prevention

Dear Mr. Zients and Dr. Walensky,

On behalf of the EveryLife Foundation for Rare Diseases and the more than 30 million Americans living with a rare disease or disorder, we are writing to highlight the ongoing challenges the rare disease community is facing as they seek to obtain COVID-19 vaccines.

EveryLife's policy priorities are informed by the needs of our community and our shared mission of advancing the equitable development of and access to lifesaving diagnoses, treatments and cures. To inform our policy work, we convene the Community Congress, a forum for collaboration across stakeholders, representing over 200 individual rare disease patient advocacy organizations in addition to over 90 other healthcare and biotechnology organizations. Since March, 2020, the Ad Hoc COVID-19 Response Working Group has met regularly to share community experiences, inform policy needs and coordinate efforts.

Background

The rare disease community includes more than 7,000 rare diseases with varied causes, symptoms, progression, and prognosis. We commend the swift action of the COVID-19 response team in implementing the National Strategy for the COVID-19 Response outlined by President Biden on January 21, 2021. As part of your ongoing efforts to protect the public's health we urge you to continue to protect rare disease patients and their caregivers who are particularly vulnerable to the devastating effects of COVID-19.

Many with rare diseases are considered significantly immunocompromised and others have severe heart, lung, kidney or liver damage due to their rare disease. Patients and their families have largely put their lives on hold, making all possible sacrifices to reduce the likelihood that they would contract COVID-19 due to their pre-existing health challenges. Our community's hope for resuming activities of daily living rest on the ability to obtain a safe and effective vaccine—and on the implementation of guidelines and practices that will enable a safe return to the community.

While state and local governments play a critical role in vaccine prioritization, communication and distribution, federal guidance in these targeted areas can

facilitate more widespread adoption and faster implementation. In this regard, we request the COVID-19 Response Team provide the following guidance to states:

- Reinforce to states that the list of conditions used as examples of individuals with underlying medical conditions was NOT intended to be used to strictly limit the people eligible for vaccine in Phase 1c AND encourage states to follow ACIP recommendations that high-risk adults be included in phase 1c.
- Prioritize unpaid family caregivers, including adult siblings in the household, as healthcare workers under COVID-19 vaccine allocation guidelines;
- Ensure accessible and safe vaccine administration sites, taking into consideration the needs of the blind, disabled, cognitively impaired, and elderly; and,
- Facilitate better communication to the public by drafting templates for state and local health departments to customize and use in their outreach to communicate vaccine prioritization phases, vaccination sites, resources to schedule vaccinations, required documentation, and related information.

We share more details about each of these priorities below.

Reinforce to states that the list of conditions used as examples of individuals with underlying medical conditions was NOT intended to be used to strictly limit the people eligible for vaccine in Phase 1c AND encourage states to follow ACIP recommendations that high-risk adults be included in phase 1c.
On December 22, 2020, the Centers for Disease Control and Prevention (CDC) issued updated recommendations for allocation of the COVID-19 vaccine that placed individuals aged 16-64 with medical conditions that increase the risk of severe COVID-19 in Phase 1c.

In earlier comments submitted to the National Academy of Sciences' Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine, we urged the Committee and subsequently CDC to clearly state that Phase 1c include vulnerable rare disease patients[1]. The small populations and extreme level of sacrifice that has occurred in the rare disease community mean that individual rare diseases are not likely to be captured in the data sources used to create the list of diseases provided as examples in the NAS Framework and the CDC recommendations. However, it is important to note that the conditions identified in the CDC ACIP evidence table[2] supporting current recommendations have many parallels in pathophysiology and symptomology to rare diseases, thus it is reasonable to assume these individuals are also at higher risk of severe outcomes. Additionally, the very nature of living with many rare diseases and the frequent healthcare services they need, results in these individuals having increased risks of exposure to COVID-19 in the home and in healthcare settings.

While we were disappointed that the CDC recommendations did not list individuals with rare diseases among the conditions that should be prioritized, we appreciate CDC's acknowledgement that the "list of underlying medical conditions is not exhaustive and only includes conditions with sufficient evidence to draw conclusions."[3]

Unfortunately, since the initiation of COVID-19 vaccine programs, rare disease patients have faced two roadblocks related to state's vaccine prioritization plans.

- States have diverged from ACIP's recommendations and placed age-based populations ahead of adults with underlying medical conditions.

- States have strictly applied the list of underlying medical conditions provided by CDC to their eligibility criteria.

While we are aware of some states that have followed ACIP recommendations and in which rare disease patients have successfully obtained vaccine, there is tremendous confusion and unnecessary delays occurring in most areas. We are aware that the population with underlying medical conditions is larger than available supply will cover in the short-term, however, these individuals should be provided the opportunity to get in line along with others in phase 1c as ACIP recommended, rather than being forced to wait through the long period as a state attempts to vaccinate all individuals 65 and over. We urge you to clarify this stance and to reinforce that the list of underlying medical conditions eligible is not intended to be limited to those appearing on the CDC list so that vulnerable rare disease patients are not left behind.

Prioritize unpaid family caregivers, including adult siblings in the household, as healthcare workers under COVID-19 vaccine allocation guidelines

Individuals with rare diseases rely on a large network of traditional, facility-based and homebased medical and non-medical support services. In addition to skilled health care staff caring for rare disease patients in these settings-of-care, patient's families also play an integral role. During the pandemic, many families have forgone traditional home-based medical and non-medical support services and have stepped in to provide this care to their loved ones to avoid the risk of exposure whenever possible.

In this regard, we request these essential (and often unpaid) caregivers—parents, grandparents, foster parents, legal guardians, siblings—be prioritized for the COVID-19 vaccine as other home healthcare workers have been. While several states have recognized the importance of unpaid caregivers and have prioritized their placement in vaccine allocation, it is not adopted by most states. In this regard, we request the COVID-19 Response Team recommend ACIP revise its prioritization list to include caregivers and/or communicate to states the importance of immunizing this population from COVID-19 in the early phases.

Ensure accessible and safe vaccine administration sites, taking into consideration the needs of the blind, disabled, cognitively impaired, and elderly

Rare disease patients and families have exercised great caution to avoid COVID-19 exposure, and many have unique needs that severely limit mobility, time out of the home and the ability to participate in the standard consenting process. In most states, there have been no efforts made to address the needs of individuals for whom accessing a vaccine clinic is impossible. While we recognize the challenges of distributing the currently approved vaccines to more accessible locations and into the home, we urge you to rapidly identify qualified homecare, primary care, specialist and other trusted community providers that can focus on meeting the needs of these vulnerable groups.

Facilitate better communication to the community by drafting templates for state and local health departments to customize and use in their outreach to communicate vaccine prioritization phases, vaccination sites, resources to schedule vaccinations, required documentation and related information.

There are two distinct communication needs that have resulted in confusion, missed vaccination opportunities and vaccine hesitancy in the rare disease population.

1) As you are aware, states, and in some cases, counties, have established a patchwork of prioritization plans, vaccination sites and documentation requirements. This patchwork has created massive confusion about who is eligible to receive a vaccine and how to obtain an appointment. While we recognize that states will continue to have different eligibility requirements, **simple actions such as standard language and formats for communicating about eligibility** would go a long way towards eliminating unnecessary confusion and anxiety for patients.

   One area where individuals with rare diseases are struggling is the differences in required documentation to prove eligibility under the current phase. This is especially true for those who are or will be eligible based on the presence of underlying medical conditions that make them high-risk for severe COVID-19. We have heard reports from the community that letters from physicians are required and, in some cases, states or individual vaccine sites require different details that must appear in these letters. Already stretched clinicians are going to be faced with increasing demands for documentation that may or may not be sufficient or necessary and patients risk being turned away after finally securing and traveling to a vaccine appointment.

   We urge you to communicate with states and identify one standard method for substantiating eligibility and to provide patients and families with an easy to use format for gathering the required information.

2) Individuals with rare diseases and their families have complex health conditions including many whom are significantly immunocompromised. They may utilize innovative cell and gene therapies, be participating in clinical trials and some are prohibited from receiving traditional recommended vaccines. These are just a few of the issues that are facing rare disease patients as they navigate the decision-making process to ensure a COVID-19 vaccine will be safe for them. In our recent US Rare Disease COVID-19 Vaccine Survey, patients and caregivers reported that safety in clinical trials and in real world evidence were the two most important factors in their decision, closely followed by effectiveness in trials and in real world evidence. We also learned that about 3 out of 4 respondents considered their primary care clinicians and clinical specialists as important information sources to guide their decisions.
   Unfortunately, as the vaccine roll out continues, we are hearing from our community members that not only are they confused about how to get a vaccine, they are not getting the answers they need about whether they should get a vaccine in the first place. Primary care physicians and specialists are not receiving the level of clear information they need in order to provide complex patients with the best guidance about the safety and efficacy of the vaccine in their individual circumstances.

   We urge you to work with the vaccine manufacturers and public health officials to establish robust and consistent communication with professional societies and clinicians across healthcare specialties. Physicians need access to information sources that can help them make the best recommendations for individual patient circumstances. If rare disease patients and families are not confident that the vaccine will be safe and effective given their unique health needs, they are unlikely to proceed, forcing families to make difficult decisions to continue restrictive isolation or risk their lives as society reopens and isolating becomes impossible.

We understand the task of coordinating the allocation and distribution of a new vaccine during this public health emergency is monumental and the road will have twists and bumps along the way. We appreciate the renewed focus on providing clear guidance to the states on how to approach complicated pandemic related initiatives and we urge you to consider the aforementioned requests as you continue this communication with

state leaders. We have listed several examples of states that have addressed some of the issues noted in this letter in the references below to assist in your efforts.

The EveryLife Foundation and the hundreds of partners in the rare disease community stand ready to assist federal and state leaders as you continue to refine the vaccine allocation and administration plans. Please contact Jamie Sullivan, Director of Public Policy, at jsullivan@everylifefoundation.org or by phone at 202-445-4009.

Sincerely,

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Annie Kennedy
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CC:

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Jamie Sullivan, Director of Public Policy, EveryLife Foundation

References

1. https://everylifefoundation.org/wp-content/uploads/2021/01/NAS-Vaccine-Framework Comments.EveryLifeFoundation.9.4.20-002.pdf
2. https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/evidence-table-phase-1b-1c.html
3. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

Examples as Referenced in the Letter

1. Ohio Vaccine Plan: expanded the list of conditions that qualify as high-risk and placed both the high-risk population and those over 65 within the same priority group. https://coronavirus.ohio.gov/wps/portal/gov/covid-19/covid-19-vaccination-program
2. Massachusetts: issued communication clarifying the eligibility of unpaid family caregivers as home healthcare workers: https://curetheprocess.sharepoint.com/:b:/s/EveryLifeFoundation2/EQ24pcVozk1Jg5t30pzAmoEBMO28a-Hs-AudzqzSYY4zZw?e=gVae1m
3. New Jersey: explicitly states essential caregivers are included in the definition of healthcare personnel https://covid19.nj.gov/faqs/nj-information/slowing-the-spread/who-is-eligible-for-vaccination-in-new-jersey-who-is-included-in-the-vaccination-phases
4. Tennessee: includes family caregivers of children under 16 who are medically fragile as eligible in the phase with adults with underlying medical conditions https://www.tn.gov/content/dam/tn/health/documents/cedep/novel-coronavirus/COVID-19_Vaccination_Plan.pdf