February 17, 2021

Dr. Rochelle Walensky, MD, MPH
Director
Centers for Disease Control and Prevention
Mailstop F-80
4770 Buford Highway, NE
Atlanta, GA 30341-3717

Dear Director Walensky:

On behalf of the 25-30 million Americans living with a rare disease, the undersigned organizations appreciate the ongoing efforts by the Centers for Disease Control and Prevention (CDC) to combat the COVID-19 pandemic. However, the patient populations we represent continue to hold widespread concerns about their access to the life-saving vaccines that are now available. Therefore, we urge the CDC to provide additional guidance to states to ensure that rare disease patients, and in some instances, their full-time family caregivers, are able to access COVID-19 vaccines at the appropriate time.

The COVID-19 pandemic has been devasting for everyone, but for the rare disease community, it has had unique impacts. There are over 7,000 known rare diseases (defined in the United States as a disease affecting fewer than 200,000 Americans), and these small patient populations mean that there simply is not enough knowledge or clinical research into how COVID-19 impacts those with a particular rare disease. This has resulted in many rare disease patients being unsure as to whether their condition puts them at elevated risk for severe COVID-19 and confusion as to whether they should be prioritized for COVID-19 vaccination along with other individuals who have conditions demonstrated by clinical research to put them at elevated risk for severe disease.

The CDC's Advisory Committee on Immunization Practices (ACIP) has enumerated phases for suggested vaccine prioritization based on a variety of factors, including whether certain groups are at increased risk of severe COVID-19. "Phase 1c" of the ACIP recommendation provides that the COVID-19 vaccine should be offered to "persons aged 16–64 years with medical conditions that increase the risk for severe COVID-19."[1] When developing their vaccination strategies, many states relied heavily on the CDC's web page, People with Certain Medical Conditions (CDC web page), which is based on available clinical research, to determine which underlying conditions indicate a higher risk of severe COVID-19 and therefore should be included in Phase 1c. The CDC web page recommends that "individuals with any underlying medical condition (including those conditions that are NOT on the current list) should consult with their healthcare providers about personal risk factors

[1] CDC. The Advisory Committee on Immunization Practices' Updated Interim Recommendation for Allocation of COVID-19 Vaccine — United States, December 2020. Accessed 2/3/21. https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e2.htm?s_cid=mm695152e2_w

and circumstances to determine whether extra precautions are warranted."[2] While the explicit mention of those whose conditions are not on the list is appreciated, our organizations are aware there is a wide range of interpretations of high-risk conditions among states and localities, which is resulting in confusion and concern within patient communities like ours and creating additional barriers to timely vaccine access.

Our organizations are concerned that a state's strict adherence to the conditions included on the CDC web page may inadvertently leave many rare disease patients, who indeed "are at an increased risk" or "might be at increased risk" due to the nature of their rare disease, ineligible, simply because of a lack of data. A recent analysis by the Kaiser Family Foundation (KFF) found 37 states were listing or explicitly relying on the CDC's web page for medical conditions that have been shown to increase risk of severe COVID-19 and 25 states were listing or explicitly relying on the CDC's web page for medical conditions that might increase risk for severe COVID-19.[3] Even if jurisdictions are not intentionally excluding individuals with non-listed high-risk conditions, they are unwittingly preventing them from making a vaccine appointment by not allowing for an "other high-risk disease" option to be chosen during the sign-up process.

We applaud the CDC's ongoing efforts to ensure the rare disease community has the information they need about the COVID-19 vaccines. On January 15, NORD, along with the ALS Association, Cystic Fibrosis Foundation, and the Muscular Dystrophy Association, hosted a webinar to educate the rare disease community about the available vaccines. When discussing vaccinating individuals with underlying medical conditions, CDC's Dr. Amanda Cohn, Chief Medical Officer for the Vaccine Task Force and the National Center for Immunization and Respiratory Diseases, stated, "we know that many rare conditions put individuals at increased risk for severe outcomes from COVID-19, so we do want to make sure that all of you know that you are absolutely in that group." Dr. Cohn also referred to the list of conditions on the CDC web page and prioritization groups noting that "people living with rare medical conditions don't see themselves in this group…but that does not mean that we are leaving behind people who are not on that [CDC web page] list." Furthermore, with regard to the sub-prioritization of groups with underlying medical conditions, the January 2021 COVID-19 Vaccination Program Interim Playbook for Jurisdictions Operations Annex (Annex) stated, "[a]s COVID-19 vaccines become more widely available in provider locations and pharmacies, healthcare providers may use clinical judgment to determine an individual patient's priority for vaccination."[4]

While our organizations are grateful for Dr. Cohn's comments and the reference to the use of clinical judgment in the Annex, this perspective is not reflected in many of the current state vaccination strategies. According to KFF, just six states and the District of Columbia currently include provisions to allow for provider discretion in determining conditions to allow for the higher vaccine prioritization.[5] Therefore, it is vital that state health authorities are made aware of this intent by the CDC and are urged to expeditiously vaccinate those within the rare disease community who are

[2] CDC. People with Certain Medical Conditions. Accessed 2/3/21. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
[3] KFF. The Next Phase of Vaccine Distribution: High Risk Medical Conditions. Accessed 2/16/21. https://www.kff.org/policy-watch/the-next-phase-of-vaccine-distribution-high-risk-medical-conditions/
[4] CDC. COVID-19 Vaccination Program Interim Playbook for Jurisdictions Operations Annex. Accessed 2/8/21. https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-vaccination-program-playbook-annex.pdf
[5] KFF. The Next Phase of Vaccine Distribution: High Risk Medical Conditions. Accessed 2/16/21. https://www.kff.org/policy-watch/the-next-phase-of-vaccine-distribution-high-risk-medical-conditions/

deemed to be at higher risk by a health care provider. At minimum, we urge that the language in the Annex regarding the sub-prioritization of groups with underlying conditions be included on the CDC web page "People with Certain Medical Conditions." We ask that you act expediently to provide additional, clear guidance to states on the CDC's intent with respect to vaccine access for rare disease populations to state health authorities and implementation monitored. Also, we ask that the CDC encourage all jurisdictions to include an "other high-risk condition" option on any jurisdiction or vaccine provider webpage to allow those with a non-listed high-risk disease to sign up and make a vaccine appointment.

Finally, our organizations would also be supportive of the CDC providing additional guidance on how family caregivers of those with high-risk conditions should approach vaccination. Our organizations have heard numerous concerns from those who care for their family members with rare diseases, but this particular group does not fall under the definition of healthcare worker as defined by the CDC as their home is not traditionally a "healthcare setting."[6] Clarity as to where these family caregivers fall within the vaccine prioritization guidelines would be a welcome consideration by the rare disease community.

Our organizations fully support the efficient and equitable allocation of vaccines. Not all rare disease patients have conditions that put them at elevated risk. Consequently, we are not advocating that all rare disease patients, or their full-time caregivers, be automatically prioritized for vaccination. However, it is critical that the CDC provide additional guidance to states to ensure proper prioritization and access to vaccines for rare disease patients whose providers do believe they are at elevated risk.

We thank you for your consideration of our concerns and sincerely appreciate the efforts that the CDC has undertaken to combat this pandemic. We look forward to working together to support policies that translate into the responsible vaccination of rare disease patients.

Sincerely,

National Organization for Rare Disorders
The ALS Association
Cystic Fibrosis Foundation
Muscular Dystrophy Association

cc: Advisory Committee on Immunization Practices

[6] CDC. The Importance of COVID-19 Vaccination for Healthcare Personnel. Accessed 2/12/21. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/hcp.html#:~:text=Healthcare%20personnel%20include%20all%20paid,to%20patients%20or%20infectious%20materials.