American Lung Association.

September 4, 2020

The Honorable William H. Foege, M.D., M.P.H.
The Honorable Helene Gayle, M.D., M.P.H.
Committee on Equitable Allocation of Vaccine for the Novel Coronavirus Co-Chairs
National Academies of Sciences, Engineering, and Medicine
500 Fifth St. N.W.
Washington, D.C. 20001

Re: Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine

Dear Dr. Foege and Dr. Gayle:

The American Lung Association is pleased to have the opportunity to provide feedback to the National Academies of Sciences, Engineering and Medicine's Committee on Equitable Allocation of Vaccine for the Novel Coronavirus on its Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine.

The American Lung Association is the oldest voluntary public health association in the United States, representing the millions of Americans living with lung diseases, including chronic obstructive pulmonary disease (COPD), lung cancer, asthma, cystic fibrosis and pulmonary fibrosis. The Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through research, education and advocacy.

The Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine offers a strong first step toward the equitable and efficient allocation of COVID-19 vaccines. The Lung Association greatly appreciates the work of the Committee under a highly accelerated timeframe and strongly supports the underlying goal.

Of particular importance, the Lung Association supports the Committee's emphasis on the need for evidence-based determinations and processes. As the Committee discusses within its draft, achieving equitable and efficient vaccine distribution hinges entirely on the utilization of independent, evidence-driven processes that are free of political interference as well as the perception of such.

Again, the Lung Association enthusiastically supports the Committee's discussion draft and offers the following comments on the proposed framework.

Foundational Principles
The principles selected by the Committee establish a solid foundation from which to launch equitable allocation efforts. The Lung Association is particularly pleased with the inclusion of mitigation of health inequities and evidence-based as principles. As stated above, it is impossible to overstate the importance of this effort being firmly rooted in strong scientific evidence.

In this vein, the Lung Association is also pleased that the Committee has recognized evidence of the outsized impact that the COVID-19 pandemic has had on people of color as a result of systemic racism. The mitigation of health inequities principle and the subsequent allocation criteria aim to capture those individuals through the acknowledgement of the underlying comorbidities and social determinants of health that have elevated the risk for minority racial and ethnic groups. This is absolutely essential to the equitable allocation of a COVID-19 vaccine.

In addition to the fundamental health inequities that are already addressed in this discussion draft, the Lung Association recommends the inclusion of environmental exposure to air pollution, including PM 2.5 and ozone. Emerging research suggests that a small increase in long-term exposure to air pollution is associated with a large increase in the COVID-19 death rate.[1] Given the significant intersectionality between air pollution and other social factors discussed within the discussion draft, it is likely that many of those who are negatively impacted by air pollution are already accounted for, but air pollution ought to receive consideration in its own right.

Further, in finalizing this principle and the framework that stems from it, the Lung Association encourages the Committee to do all that it can to obtain input from communities that have long experienced health disparities as a result of systemic racism. The Lung Association recognizes the Committee's efforts thus far as well as the challenges associated with the expeditated timeline, but input from these communities is vital for equitable allocation as well as utilization.

As for the remaining principles, the Lung Association agrees with the Committee that they, in partnership with the others, provide a strong basis to guide decision-making. The Lung Association does urge the Committee, though, to explicitly include mention of disability status in the discussion of the principle of equal regard. Separate but related efforts around allocation of scarce resources during this pandemic have led to frameworks that devalue the lives of those with a disability.[2] While this discussion draft already emphasizes that no one person be valued over another, given the existence of these alternative approaches, the Lung Association asks that the Committee specifically include disability in the final framework.

COVID-19 Vaccine Allocation Framework

Overall, the Lung Association supports the allocation framework and appreciates that the Committee has included people of all ages with comorbid and underlying conditions that put them at significantly higher risk in the phase 1b category. This group includes patients with many health conditions that, according to the Centers for Disease Control and Prevention (CDC), put them at increased risk for severe illness from COVID-19, including patients with cancer, COPD and who are immunocompromised from a solid organ transplant.[3] The Lung Association urges the Committee to continue to reference this CDC guidance in the final framework so that additional health conditions may be included in this category as the scientific understanding of COVID-19 expands.

Understanding the limited number of doses that will likely be available, the Lung Association also supports prioritizing individuals with two or more of these designated conditions to receive vaccinations within the phase 1b group. As the Committee notes, data from the COVID-19 Associated Hospital Surveillance Network show that as of August 15, about 75% of individuals hospitalized with COVID-19 in the United States had at least two comorbid conditions.[4] However, the Lung Association does urge the

Committee to clarify that even if individuals with two or more designated conditions are prioritized, all individuals with at least one of these designated conditions should still be vaccinated during phase 1b.

The Lung Association also supports including individuals of all ages with comorbid and underlying health conditions that put them at moderately higher risk in phase 2. Again, based on current CDC guidance about individuals who may be at increased risk for severe illness from COVID-19, this group includes patients with moderate to severe asthma, cystic fibrosis and pulmonary fibrosis, as well as individuals who use corticosteroids and individuals who smoke.[5] The Lung Association agrees that based on the current research and evidence, the inclusion of individuals with these conditions at this stage of vaccine allocation should help to reduce the morbidity and mortality of COVID-19.

Ensuring Equity

As discussed earlier, the Lung Association appreciates the Committee's focus on mitigating health inequities throughout the draft report and encourages the Committee to continue to strengthen this focus in the final report. In addition to our recommendations above, we also urge the Committee to address the following topics.

The Lung Association shares the concern that cost will be a barrier to vaccination for certain populations. The Lung Association urges all health plans be required to cover COVID-19 vaccines without cost-sharing and strongly supported the provisions in the Coronavirus Aid, Relief, and Economic Security (CARES) Act that require Medicare to cover COVID-19 vaccinations once licensed by the Food and Drug Administration (FDA) and most private insurance plans to cover COVID-19 vaccinations recommended by CDC's Advisory Committee on Immunization Practices (ACIP) within 15 days. However, critical coverage gaps remain. For example, patients enrolled in private health insurance plans that do not comply with the Affordable Care Act's (ACA) coverage requirements – including grandfathered health plans, short-term plans and farm bureau plans – may not have coverage for a COVID-19 vaccine or be charged significant copays. Additionally, vaccine coverage for adults in the traditional Medicaid population is optional for state Medicaid programs.[6]

The cost of vaccination could particularly be a barrier for individuals who lack health insurance. Millions of Americans have lost employer-sponsored health insurance coverage as a result of the COVID-19 pandemic and its economic impact.[7] Ensuring that the uninsured can access COVID-19 vaccines at no cost will also be critical to addressing disparities, as about half of the 30 million Americans without insurance are people of color.[8] Existing public health systems providing free vaccines to the uninsured will need to be supported and strengthened to ensure that lack of insurance coverage and costs are not barriers. Additionally, the federal government needs to support robust outreach and enrollment assistance to uninsured and underinsured individuals during this year's ACA open enrollment period to ensure that as many people as possible have comprehensive coverage that includes COVID-19 vaccines at no cost. The Lung Association urges the Committee to further highlight these issues and the need for universal coverage of COVID-19 vaccines without cost-sharing in the final report.

Finally, the Lung Association strongly supports the Committee's statement that all individuals should receive vaccination at the appropriate phase of the framework regardless of immigration status. Undocumented workers are disproportionally employed in many essential industries where they have a higher risk of exposure to COVID-19, such as agriculture and home health.[9] Migrant workers also have

high rates of lung diseases, such as asthma, and other health conditions that may put them at greater risk for severe illness from COVID-19.[10] As the Committee acknowledges, if large proportions of certain communities do not receive vaccinations, the risk of COVID-19 outbreaks increases for everyone. The Lung Association urges the Committee to include this recommendation about vaccination regardless of immigration status in its final report.

An Adaptable and Dynamic Framework

This draft framework acknowledges several uncertain factors that may affect vaccine allocation. The Lung Association is pleased with the Committee's call for an adaptable and dynamic framework that can react as more information becomes available about the characteristics of the vaccine, vaccine uptake, epidemic conditions and other key issues. The Lung Association agrees that as scientific and medical knowledge around vaccine safety and efficacy grows, the framework may need to change to reflect that. We echo the Committee's call to continuously monitor vaccine safety and effectiveness among all population subgroups outlined in the framework. We urge the Committee and other decision-makers to continue to analyze the vaccine and to focus allocation on populations and individuals for whom the available vaccine is proven to be safe and effective.

Additionally, the Committee acknowledges that this framework relies on the availability and tracking of key data that include race/ethnicity, age, gender, and social status. Some of this information, including public health surveillance data to identify populations with comorbid and underlying conditions, may be difficult to obtain and track given the limits of our current public health surveillance system. This is a direct result of chronic underfunding of our public health infrastructure. Without clear and consistent nationwide data, it will be difficult to identify and reach individuals who fall into different phases of the allocation plan and ensure that the plan is implemented effectively. The Lung Association continues to advocate for sustained and robust investment in our public health infrastructure, especially at CDC and in each state.

Additional Considerations

The Committee noted that there are additional topics that will be covered in more detail in the final report. The Lung Association offers the following comments on some of these critical areas and encourages the Committee to elaborate in the final report.

Vaccine Administration

While we do not know the characteristics of the vaccine or vaccines that will ultimately be administered, we do know some characteristics of some vaccine candidates that have reached Phase 3 of clinical trials. For example, two of the candidates in Phase 3 are mRNA vaccines and will require storage at extreme cold, and some may have a short shelf life.[11] Those characteristics can impact how the allocation framework is carried out. Extreme cold chain requirements may make it difficult to transport and store the vaccine in certain geographic locations. A state, local, tribal or territorial entity may find that they have doses of vaccine that are due to expire shortly or cannot be stored. They might also struggle to reach certain populations in a given phase. We urge the Committee to consider these important issues and make recommendations to mitigate this challenge.

Vaccine Hesitancy

The Lung Association echoes the Committee's concerns about vaccine hesitancy as it pertains to the COVID-19 vaccine, and we encourage the Committee to include more discussion of vaccine uptake in its final report. As previously mentioned, any perceived political or outside influence on vaccine development, approval and allocation will increase hesitancy around the COVID-19 vaccine. Additionally, culturally competent messaging around the safety and effectiveness of this vaccine will be essential. We urge special consideration for at-risk populations that may be more inclined to distrust the vaccine. A long history of health inequities and systemic racism have made some communities of color particularly distrustful of public health initiatives, including new vaccine campaigns. Additionally, racial and ethnic minorities have been disproportionately impacted by the COVID-19 pandemic because of these very health inequities. The Lung Association encourages the Committee to further elaborate on the special efforts necessary to address issues related to vaccine hesitancy and health inequities.

Global Cooperation

The Committee did not include recommendations about global cooperation in this discussion draft but plans to include more information in its final framework. The Lung Association emphasizes the importance of global cooperation in vaccine allocation. A key component of disease control and surveillance is a global pandemic response and global preparedness. Pathogens do not respect borders, and a COVID-19 outbreak in any country is a threat to the United States. The Lung Association looks forward to reading the Committee's recommendations in this area.

Conclusion

The American Lung Association has moved swiftly to respond to the unique challenges of the COVID-19 pandemic. Many of our patients have lung conditions that put them at moderately to significantly higher risk for severe illness from COVID-19. In response, we have launched the COVID-19 Action Initiative, a robust and comprehensive plan to end COVID-19 and defend against future respiratory virus pandemics. Through this initiative, the Lung Association will work to expand our ongoing respiratory research program, enhance key public health measures through education and advocacy and establish an advanced network to stop future respiratory virus pandemics. We are already working to develop resources to educate patients about COVID-19 vaccines and to reach patients in key population subgroups. When a vaccine is available, the Lung Association will be prepared to focus our efforts on vaccine education and outreach and is eager to partner with the public health community on these efforts.

The Lung Association greatly appreciates the opportunity to submit comments on the Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine. We appreciate the tremendous undertaking that this discussion draft represents, and we thank the Committee for its thoughtful work in developing this framework.

Sincerely,

Harold P. Wimmer
National President and CEO

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