



October 30, 2020

Advisory Committee on Immunization Practices
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS H24-8,
Atlanta, GA 30329-4027

Re: Docket No. CDC-2020-0100: October ACIP Meeting

Dear Members of the Advisory Committee on Immunization Practices,

In service of the over 300,000 Americans living with one of more than 40 neuromuscular diseases (NMDs), the Muscular Dystrophy Association (MDA) thanks the Advisory Committee on Immunization Practices (ACIP) for its continued efforts on guiding COVID-19 vaccination allocation and distribution. We respectfully submit this letter encouraging you to include individuals living with NMDs in Phase 1B of the vaccination administration any FDA-approved or authorized COVID-19 vaccine. As set forth herein, the experiences, comorbidities, and impacts of NMDs should serve as qualifying factors.

MDA is the nation's leading nonprofit organization dedicated to transforming the lives of individuals living with neuromuscular diseases through innovations in science and innovations in care. MDA's advocacy efforts include, but are not limited to, ensuring access to care from day one, accelerating the development of more and better treatments, and fostering empowerment and independence for individuals with NMDs. During the COVID-19 pandemic, MDA has advocated for greater access to telehealth services, flexible insurance coverage of necessary treatments and care, and the adaptation of ongoing clinical trials to ensure that needed progress for the NMD community is not unduly hampered by the pandemic.

Neuromuscular diseases are a wide range of conditions varying in symptom severity and patient experience, but generally implicate the peripheral nervous system resulting in progressive muscle weakness affecting both skeletal muscles and the muscles of internal organs. Consequently, progressive muscle weakness and mobility issues as well as cardiac, pulmonary, and digestive complications are common. Disorders in this category include amyotrophic lateral sclerosis (ALS), muscular dystrophies, and spinal muscular atrophy (SMA) along with many myopathies and mitochondrial diseases, among others.

As governmental and advisory bodies have deliberated on COVID-19 vaccine administration timelines, a common structure has emerged. The National Academies recommended four phases of administration: Phase one will include frontline responder, individuals at a high-risk for severe

COVID-19, and older adults in congregant settings; phase two includes moderately at-risk individuals, teachers, all older adults, critical workers, and others; phase three includes children and young adults as well as workers in fields of high importance; phase four includes everyone who does not fall within one of the first three categories.¹ The ACIP has discussed a similar structure, albeit with three phases rather than four.²

In discussion of who should qualify for Phase 1B access to a vaccine, ACIP thus far has discussed individuals with high-risk medical conditions, namely cancer, chronic kidney disease, chronic obstructive pulmonary disease (COPD), immunocompromised state from solid organ transplant, obesity, a serious heart condition, sickle cell disease, and type 2 diabetes.³ The National Academies have gone further and recommended that individuals must have two of these high-risk comorbidities to qualify for Phase 1B access rather than one.⁴

MDA strongly believes that individuals living with a neuromuscular disease should be included in Phase 1B of vaccination administration due to the complexity of the multi-system impact of NMDs that results in co-morbidities that cause a high risk for adverse COVID outcomes. Consequently, we request ACIP to include those with NMDs in Phase 1B of your official recommendations.

In addition to other organ and system involvement, cardiac complications are common in individuals living with neuromuscular disease as an impact of the disorder. Additional common symptoms in neuromuscular diseases could lead to a higher risk to negative outcomes from COVID-19. For example, NMDs can weaken the pulmonary muscles diaphragm over the progression of the disease, increasing the risk of severe pulmonary infection, and making the outcome of COVID-19 particularly dangerous.⁵ Individuals with NMDs often are prescribed corticosteroids to combat the muscle weakening, and the CDC has listed individuals who take corticosteroids as “might be at an increased risk” for severe COVID-19 due to the associated weakening of the immune system.⁶ Additionally, individuals with certain NMDs, such as myasthenia gravis and Lambert-Eaton myasthenic syndrome (LEMS) require immunosuppressants to treat the disease, leaving them more vulnerable to contracting severe

¹ National Academies of Sciences, Engineering, and Medicine 2020. Framework for Equitable Allocation of COVID-19 Vaccine. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25917>.

² Routh, Janell, (2020, Oct 28-30) *COVID-19 Vaccine Implementation Planning Update*, Meeting Presentation, ACIP October 2020 Meeting

³ Dooling, Kathleen, (2020, Sept. 20) *COVID-19 Phase 1 allocation COVID-19 vaccine: Work Group considerations*, Meeting Presentation, ACIP September 2020 Meeting

⁴ National Academies of Sciences, Engineering, and Medicine 2020. Framework for Equitable Allocation of COVID-19 Vaccine

⁵ Cao, Michelle, et. Al, “Pulmonary Support for Neuromuscular Disease Patients During COVID19 Pandemic, Retrieved From https://www.mda.org/sites/default/files/2020/03/MDA-Guidelines-for-Healthcare-Pros_Pulmonary-Support-Neuromuscular-Disease-Patients-COVID-19.pdf

⁶ Centers for Disease Control and Prevention, (2020, Oct. 16) *People with Certain Medical Conditions*, Retrieved from: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

COVID-19.⁷ CDC also lists neurological conditions as a potential increased risk factor for severe COVID-19.⁸

Finally, since each individual neuromuscular disease is considered rare (fewer than 200,000 individuals in the United States), there is little to no research on the effects of COVID-19 on individuals with an NMD. Consequently, there may be additional risk factors causing an increased susceptibility to severe COVID-19 of which we may be unaware. This may be true for many rare diseases, and we are grateful that the National Academies have recognized this possibility in the final recommendation.⁹

In summary, MDA requests that ACIP include individuals with neuromuscular diseases in Phase 1B of its recommended COVID-19 vaccination administration timeline as the cardiac, pulmonary, neurological, sometimes immunological, and potential additional risk factors put individuals with neuromuscular diseases at higher risk for severe COVID-19. We thank ACIP for the opportunity to comment on these proceedings, and we welcome the opportunity to discuss our request further. For questions on these comments, please contact Paul Melmeyer, Director of Regulatory Affairs, at advocacy@mdausa.org.

Sincerely,



Paul Melmeyer, MPP
Director of Regulatory Affairs

⁷ Jacob, Sujaih, et. Al. Guidance for the management of myasthenia gravis (MG) and Lambert-Eaton myasthenic syndrome (LEMS) during the COVID-19 pandemic: *Journal of the Neurological Sciences*: Volume 412, 116803, May 15, 2020 <https://doi.org/10.1016/j.jns.2020.116803>.

⁸ Centers for Disease Control and Prevention, (2020, Oct. 16) *People with Certain Medical Conditions*

⁹ National Academies of Sciences, Engineering, and Medicine 2020. Framework for Equitable Allocation of COVID-19 Vaccine