

## Statement for the Record

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Neil Thakur, Ph.D., Chief Mission Officer, The ALS Association  
for the

House Energy and Commerce Health Subcommittee Hearing  
entitled

"The Future of Telehealth: How COVID-19 is Changing the Delivery of Virtual  
Care"

March 2, 2021

The ALS Association would like to thank Chairwoman Eshoo, Ranking Member Guthrie, and members of the Energy and Commerce Health Subcommittee for the opportunity to submit this statement for the record for the Subcommittee hearing entitled, "The Future of Telehealth: How COVID-19 is Changing the Delivery of Virtual Care."

The COVID-19 pandemic has been challenging for the more than 20,000 Americans with ALS we represent. People with ALS are at increased risk of death from COVID-19 and require routine monitoring and treatment from health care providers in order to maintain their health. We appreciate that in response to the public health emergency, federal and state agencies provided new, and in some cases time-limited, flexibilities for telehealth services to enable patients to see providers from the safety of their homes in order to reduce disruptions to care.

ALS is an always fatal neurodegenerative disease in which a person's brain loses connection with the muscles. People with ALS lose their ability to walk, talk, eat and eventually breathe. There is no cure, and the average life expectancy following diagnosis is less than 5 years.

### **Telehealth and Multidisciplinary Care**

Multidisciplinary care is clinically proven to increase the quality of life<sup>1</sup> and survival<sup>2</sup> for people with ALS. Since 1998, The ALS Association's nationwide network of Certified Treatment Centers of Excellence has provided evidence-based, multidisciplinary ALS care and services in a supportive atmosphere with an emphasis on hope and quality of life.<sup>3</sup> The ALS Association's Certified Treatment Center of Excellence program provides a national standard of best-practice care in the management of ALS. Certifications are based on established

<sup>1</sup> Van den Berg L, Kalmihn S, Lindeman E, et al. Multidisciplinary ALS care improves quality of life in patient with ALS. *Neurology*. 2005; 65:1264-1267.

<sup>2</sup> Traynor BJ, Alexander M, Corr B, Frost E, Hardiman O. Effect of a multidisciplinary amyotrophic lateral sclerosis (ALS) clinic on ALS survival: a population based study, 1996-2000. *J Neurol Neurosurg Psychiatry*. 2003; 74:1258-1261.

<sup>3</sup> <https://www.als.org/local-support/certified-centers-clinics/more-information-certified-centers-clinics>



OUR VISION: Create a world without ALS.

OUR MISSION: To discover treatments and a cure for ALS, and to serve, advocate for, and empower people affected by ALS to live their lives to the fullest.

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requirements of the program, professionals' skill sets, people living with ALS served, active involvement in ALS-related research, relationships with local chapters, and access to care.

As the disease progresses, people with ALS eventually become unable to leave their homes to attend a multidisciplinary clinic. Counterintuitively, the time-limited flexibilities for telehealth during the COVID-19 pandemic has provided people with ALS increased access to vital multidisciplinary medical care that was out of reach prior to the pandemic. Telehealth has proven an effective tool to allow clinicians more effective care for patients for whom travel to clinic is burdensome, fatiguing, or otherwise impractical.<sup>4</sup> Importantly, many states have suspended or relaxed interstate telehealth physician licensure requirements.<sup>5</sup> This has enabled telehealth infrastructure to improve and provided researchers with new opportunities to advance ALS science through remote clinical trials.

### Remote Clinical Trials

The ALS Association's Certified Treatment Centers of Excellence also offer people with ALS the potential to participate in clinical trials and research. Recognizing the importance of remote trials, the Food and Drug Administration (FDA) published guidance in 2016 with recommendations on the use of electronic systems and processes for obtaining informed consent for both HHS-regulated human subject research and FDA-regulated clinical investigations of medical products, including human drug and biological products, medical devices, and combinations thereof.<sup>6</sup> Following the COVID-19 pandemic, the FDA published additional guidance on the conduct of clinical trials of medical products during the public health emergency.<sup>7</sup> While the challenges to research caused by COVID-19 are unprecedented, desperately needed research for ALS treatments can continue through remote televisits, home safety measures like sending a service to collect labs, medical surveys, and even wearable technologies.<sup>8</sup> Remote clinical trials are accelerating the science to find new treatments and cures

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<sup>4</sup> Andrews JA, Berry JD, Baloh RH, et al. Amyotrophic lateral sclerosis care and research in the United States during the COVID-19 pandemic: Challenges and opportunities. *Muscle & Nerve*. 2020;62:182–186. <https://doi.org/10.1002/mus.26989>

<sup>5</sup> Federation of State Medical Boards. <https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf>. Accessed February 24, 2021.

<sup>6</sup> US Food and Drug Administration. *Use of electronic informed consent: questions and answers, guidance for institutional review boards, investigators and sponsors*. December 2016. <https://www.fda.gov/media/116850/download>. Accessed February 24, 2021.

<sup>7</sup> US Food and Drug Administration. (2020, February). *Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency - Guidance for Industry, Investigators, and Institutional Review Boards*. <https://www.fda.gov/media/136238/download>

<sup>8</sup> Andrews JA, Berry JD, Baloh RH, et al. Amyotrophic lateral sclerosis care and research in the United States during the COVID-19 pandemic: Challenges and opportunities. *Muscle & Nerve*. 2020;62:182–186. <https://doi.org/10.1002/mus.26989>

through increased trial participation and availability that was previously restricted to patients living near a trial site.

### **Conclusion**

The COVID-19 pandemic has catalyzed expansion of telehealth clinical care and research through remote clinical trials. The ALS Association believes that telehealth and remote clinical trials can and should be used to increase ALS patient access to care and clinical trials. We stand ready to work with Congress, the Administration, and state governments to ensure that all patients can continue to safely access appropriate telehealth services during and after the COVID-19 public health emergency. As policymakers begin to shape what telehealth looks like post-pandemic, it is important that the patient perspectives be considered to ensure that policymakers fully account for the needs of all Americans, including patients with rare, orphan diseases like ALS.

Again, thank you for the opportunity to submit this statement for the record. With your support, we can change the course of ALS for thousands of Americans and bring an end to this terrible disease. Please contact Abram Bieliauskas ([abieliauskas@alsa-national.org](mailto:abieliauskas@alsa-national.org) / 202-464-8634) with any questions the Subcommittee may have.

Sincerely,



Neil Thakur, Ph.D.  
Chief Mission Officer  
The ALS Association  
als.org

**Attached:** Andrews JA, Berry JD, Baloh RH, et al. Amyotrophic lateral sclerosis care and research in the United States during the COVID-19 pandemic: Challenges and opportunities. *Muscle & Nerve*. 2020;62:182–186.  
<https://doi.org/10.1002/mus.26989>