Congress of the United States
Washington, DC 20515

January 18, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Lawrence Tabak
Acting Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

The Honorable Walter Koroshetz
Director
National Institute of Neurological Disease and Stroke
9000 Rockville Pike
Bethesda, MD 20892

The Honorable Janet Woodcock
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Secretary Becerra, Acting Director Tabak, Director Koroshetz, and Acting Commissioner Woodcock:

We write to you today on the heels of an historic victory for people living with amyotrophic lateral sclerosis (ALS) and other rare neurodegenerative diseases. Owing in large part to the advocacy of people living with ALS and their families and researchers who have dedicated their careers to finding effective treatments and cures for ALS, Congress passed and President Biden signed into law the *Accelerating Access to Critical Therapies for ALS Act,* or *ACT for ALS* (P.L. 117-79), which we led in our respective chambers. The passage of this momentous legislation represents not just a path forward for finding effective treatments and cures for ALS, but also hope for people living with ALS and their families. It is critical to move quickly to fully implement the Act to transform ALS innovation and accelerate progress toward a cure for people living with ALS and other rare neurodegenerative diseases.

We are deeply grateful for President Biden's support for this bill and for Secretary Becerra for joining the signing ceremony. The President echoed this message of hope when he signed the bill. The Department of Health and Human Services (HHS), including the Food and Drug Administration (FDA) and the National Institutes of Health (NIH), played vital roles in shaping the final version of this Act. This collaboration goes back to early 2020 when a number of our offices worked closely with FDA and NIH to identify existing resources to offer open label extension to patients in a particular trial. The bill that was ultimately passed by both chambers of Congress reflects a collaborative process and a good-faith effort to ensure that the legislation would achieve its goals while assuring the integrity of clinical trials.

As you know, the authorization period for *ACT for ALS* runs from fiscal year (FY) 2022 through FY 2026. As members of the Appropriations Committees in our respective chambers, we urge HHS to immediately implement the law. Congress has demonstrated a strong and consistent commitment to the research infrastructure within HHS and we intend to continue our record of supporting that invaluable work, including the new requirements authorized by *ACT for ALS.*

Section 2 of *ACT for ALS* directs NIH to make grants to clinical trial sites for the purpose of enabling expanded access to promising treatments for ALS. In FY 2021, Congress provided $2,513,393,000 to the National Institute of Neurological Disease and Stroke (NINDS). The House-passed bill for FY 2022 would increase that amount by over $286 million, while the Senate proposed bill would increase it by over $210 million. We urge NINDS to implement this important program immediately and to the greatest scale feasible upon the enactment of appropriations for the Departments of Labor, Health and Human Services, Education, and Related Agencies for FY 2022. We believe it is crucial to begin helping individuals living with ALS who cannot access promising treatments through an existing a clinical trial using this new appropriation for 2022. Making grants now will not only give many people with ALS the chance to slow the disease; it will also begin the collection of new, valuable research data from individuals who are not eligible for clinical trials, contributing to the body of knowledge that can accelerate cures for this and other devastating neurodegenerative diseases.

Section 5 of *ACT for ALS* directs FDA to award grants and contracts to public and private researchers for the purposes of research and development of interventions for rare neurodegenerative diseases, including ALS. It is critical that this Rare Neurodegenerative Disease Grant Program is implemented immediately to begin accelerating FDA-directed high-impact research into rare neurodegenerative diseases. The report accompanying the House bill which provides FY 2022 appropriations for FDA (H. Rept. 117-82) notes the inclusion of an additional $5 million for the Orphan Products Grant Program for the purposes of ALS clinical trials and investments in regulatory science. Should this amount be included in the final FY 2022 bill, we expect it to begin to satisfy the requirements of Section 5 for FY 2022. We will work with HHS and the FDA to assure appropriate funding in future years.

In addition, we look forward to the development of FDA’s ALS and Other Rare Neurodegenerative Disease Action Plan and the HHS Public-Private Partnership for Rare Neurodegenerative Diseases. We look forward to collaborating with HHS on fulfilling the statutory deadlines for the publishing of the Action Plan and the implementation of the Public-Private Partnership by June 23, 2022 and December 23, 2022, respectively.

This bill represents hope for the future for people living with ALS and their families, and we are dedicated to begin realizing that hope. Enhancing access to promising therapies now while strengthening and accelerating research into ALS puts us on a fast track to truly effective treatments and, one day, a cure.

Thank you for your partnership as we fight to end ALS. *ACT for ALS* is a major milestone in the effort to find treatments and cures for this cruel disease, and we are grateful for HHS's work. We look forward to working with you in the coming weeks and months to ensure that people living with ALS are able to access promising therapies in line with Congressional intent.

Sincerely,

Mike Quigley
Member of Congress

Jeff Fortenberry
Member of Congress

Chris Coons

Christopher A. Coons
U.S. Senator

Lisa Murkowski

Lisa Murkowski
U.S. Senator

Cc: Representative Rosa DeLauro
Representative Kay Granger
Senator Patrick Leahy
Senator Richard Shelby
Representative Tom Cole
Senator Patty Murray
Senator Richard Burr
Representative Sanford Bishop
Representative Andy Harris
Senator Tammy Baldwin
Senator John Hoeven