Congress of the United States
Washington, DC 20515

[[DATE]]

The Honorable Robert Aderholt
Chairman, Labor, Health and
Human Services Subcommittee
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

The Honorable Rosa DeLauro
Ranking Member, Labor, Health and
Human Services Subcommittee
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

The Honorable Ken Calvert
Chairman, Defense Subcommittee
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

The Honorable Betty McCollum
Ranking Member, Defense Subcommittee
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

The Honorable Andy Harris
Chairman, Agriculture, Rural
Development, Food and Drug
Administration Subcommittee
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

The Honorable Sanford Bishop Jr.
Ranking Member, Agriculture, Rural
Development, Food and Drug
Administration Subcommittee
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Chairs Aderholt, Calvert, and Harris and Ranking Members DeLauro, McCollum, and Bishop:

Thank you for your continued strong support of ALS (amyotrophic lateral sclerosis) research. Your support for ALS research is instrumental in speeding the development of new treatments and a cure for ALS at the National Institutes of Health (NIH), the Centers for Disease Control and Prevention's (CDC) National ALS Registry, the Department of Defense's (DOD) ALS Research Program (ALSRP), and the Food and Drug Administration's (FDA) Rare Neurodegenerative Disease Grant Program is instrumental.

As you know, ALS is a fatal neurodegenerative disease that can affect anyone, at any time, and progressively destroys a person's ability to control muscle movement. As the disease advances, people become trapped inside a body they can no longer control. Their minds, however, often remain sharp so that they are aware of their surroundings, the people in their lives, and what is happening to them. The average life expectancy for a person living with ALS is just 2-5 years after diagnosis. There is no cure and few treatments available.

You can make a meaningful difference to every American family living with ALS today and to those who will be diagnosed by supporting research to find effective treatments and a cure, to optimize the treatments and technologies available today, and to prevent future cases. To achieve these goals and end ALS, Congress must increase federal funding for ALS research across

multiple agencies. Without an investment in ALS research, we will not be able to find new treatments and a cure for this devastating disease, optimize current treatments and technologies, and prevent future cases.

LABOR, HEALTH AND HUMAN SERVICES SUBCOMMITTEE

National Institutes of Health (NIH)-ALS Research
Currently NIH spends $131 million on ALS research each year.[1] We request an increase in funding of at least $30 million at NIH to increase ALS research that leads to measurable differences in the health of people living with ALS. We also request maintaining the FY24 funding at $75 million for Expanded Access Grants to provide treatment with investigational drugs for people with ALS who are not eligible for clinical trials and collect relevant data as authorized by the *Accelerating Access to Critical Therapies (ACT) for ALS* (P.L. 117-79), as well as fully funding Section 3 and 5 of that law at the Food and Drug Administration (FDA).

Report Language: The Committee recommends increasing funding for extramural research by $30 million to reduce the burdens of people with ALS as quickly as possible. It is crucial for people living with ALS and people diagnosed with ALS in the future, that NIH dramatically grows its ALS research portfolio and the research workforce. This additional funding could focus new drugs for ALS, ALS diagnosis protocols, enhancing quality of care, and new biomarkers. NIH research can lead the country to measurable changes in the lives of people living with ALS.

The Committee recommends funding at $75 million as authorized by the Accelerating Access to Critical Therapies (ACT) for ALS, (P.L. 117-79) Expanded Access Grants for the development of ALS research and treatments. Expanded Access Grants provide treatment with investigational drugs for people with ALS who are not eligible for clinical trials and collect relevant data. Furthermore, after the review and awards of eligible applications under Section 2, the Committee recommends NIH apply any unused funds to programs authorized under ACT for ALS including Section 3 public-private research partnership and Section 5 Rare Neurodegenerative Disease Grant Program at FDA.

National ALS Registration and Biorepository
The Committee recommends a funding level of $15 million for the National ALS Registry and Biorepository at the Centers for Disease Control and Prevention. This funding will ensure that critical research into risk factors and the prevention of ALS is supported, that biological samples are collected and made available to private and governmental researchers, and that people living with ALS are informed about new clinical trial opportunities. Most importantly, we urge the CDC to fund research and activities that will lead to the prevention of ALS, including funding translational research on ALS risk factors and risk reduction strategies. In addition, we recognize that active military personnel and veterans are at increased risk of developing ALS, and the National ALS Registry is the largest ALS prevention program in the country. We are directing the CDC to initiate a new research initiative with an additional $5 million over FY24 levels, to research causes and prevention strategies that will lower the incidence of ALS among active-duty personnel and veterans.

[1] "Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)," National Institutes of Health, Table published May 16, 2022, https://report.nih.gov/funding/categorical-spending#/.

Report Language: The Committee recommends a funding level of $15 million for the National ALS Registry and Biorepository at CDC. We urge the CDC to continue its investment in research that will reduce incidence of ALS through ALS prevention and risk mitigation strategies among civilians, active military personnel and veterans in the United States. Additionally, we urge the CDC to continue to collaborate with the Departments of Defense and Veterans Affairs on risk reduction strategies that will lower the incidence of ALS among active-duty personnel and veterans.

DEFENSE SUBCOMMITTEE

Department of Defense ALS Research Program-
We request $80 million for the ALS Research Program (ALSRP) – a $40 million increase over FY2024. It is especially vital to increase DOD research to reduce the incidence of ALS in active military members and veterans who are more likely to develop and die of ALS, regardless of when they served. ALSRP is uniquely positioned to expand its portfolio into early phase clinical trials to bridge the so-called "valley of death" in ALS drug development between promising preclinical research and human studies. These additional funds are vital to increase preclinical research and early phase ALS clinical trials that accelerate the development of treatments and a cure. It is especially vital for active military members and veterans who are twice as likely to develop and die from ALS. We believe it continues to be important for DOD to identify and research all diseases that may be related to service in the U.S. military, including ALS.

Report Language: The Committee recommends increasing funding to $80 million to maintain the pre-clinical research in the ALS Research Program (ALSRP) and expanding the program to grant funds in support of clinical trials. We recognize military veterans are more likely to be diagnosed with ALS, regardless of when they served. The ALSRP has a unique ability to fund clinical trials for new ALS treatments and cures with additional funding while making an impact in pre-clinical research. Since FY07, the ALSRP has funded 222 projects that have led to 5 new treatments currently being tested in clinical trials or in preclinical development.

AGRICULTURE SUBCOMMITTEE

Food and Drug Administration's (FDA) Rare Neurodegenerative Disease Grant Program-
We appreciate FDA's ALS Action Plan for Rare Neurodegenerative Diseases including Amyotrophic Lateral Sclerosis which is driving efforts to foster the rapid development of new treatments.[2] The *ACT for ALS Act* also established the FDA Rare Neurodegenerative Disease Grant Program for clinical grants ALS and other diseases. The FDA has already demonstrated admirable focus and speed in the projects it supported through partial funding of the *ACT for ALS Act*. Congress should provide the full authorized funding for this law and allocate $25 million for research that can further accelerate the approval of new therapies and cures for ALS and other neurodegenerative diseases.

Report Language: The Committee recommends $25 million as authorized in the Accelerating Access to Critical Therapies (ACT) for ALS Act (P.L. 117-79) to fund research grants in Section 5 of the law, the FDA Rare Neurodegenerative Disease Grant Program. We recognize the importance of FDA's Rare Neurodegenerative Disease Grant Program research into regulatory science tools to expedite the

[2] U.S. Food and Drug Administration, *Action Plan for Rare Neurodegenerative Diseases Including Amyotrophic Lateral Sclerosis, 2022.* https://www.fda.gov/media/159372/download

development and approval of new drugs and devices and accelerate the FDA regulatory approval process. The Committee also directs the FDA to fund Section 3 of ACT for ALS, the HHS Public-Private Partnership for Rare Neurodegenerative Diseases to foster a network of research with funds from HHS, FDA, and NIH.

CONCLUSION

We appreciate your consideration of our FY2025 appropriations requests for ALS research. People living with ALS urgently need these investments in research to eradicate the disease. We need a cure and more preclinical research projects for successful clinical trials. These endeavors will help people living with ALS to live longer, improve quality of life for people living with ALS and their families, prevent loved ones from getting ALS in the future, and allow thousands of Americans to live longer in a world without ALS.

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