

March 2023

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 through, 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 in speeding the development of new treatments and a cure for ALS.

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.

You can provide hope to every American family living with ALS today and to 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.

## **LABOR, HEALTH AND HUMAN SERVICES SUBCOMMITTEE**

### **National Institutes of Health (NIH)-ALS Research**

We appreciate the forethought of the new NIH ALS strategic plan, and it is critical that NIH uses this plan to make measurable differences in the health of people living with ALS, and not just generate academic knowledge. Congress should direct NIH to significantly increase its focus and spending to find treatments and cures for people living with ALS today, optimize the treatments already available and help people access them, and leverage various research initiatives to prevent ALS and its associated burdens.

Currently NIH spends \$120 million on ALS research each year.<sup>1</sup> 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 FY23 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 by 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 portfolio and the research workforce with additional grant funding every year and increases its focus on research that will lead 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 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 to develop ALS, and the National ALS Registry is the largest ALS prevention program in the country. We are directing the CDC to initiate new a research initiative with an additional \$5 million over FY23 levels, to research causes and prevention strategies that will lower the incidence of ALS among active-duty personnel and veterans.

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<sup>1</sup> “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 in the United States. The Committee instructs the CDC to provide reports to other agencies and the public that include state-by-state data on the incidence and prevalence of ALS as soon as possible and no later than 60 days after enactment. The Committee directs that \$5 million of this funding be used to support research to prevent ALS among active military personnel and veterans.*

*Additionally, we urge the CDC to collaborate with the Departments of Defense and Veterans Affairs to provide a publicly available report on the incidence and prevalence of ALS among military veterans. This report, due 1-year after enactment, must include a strategy to develop and test 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 FY2023. 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 to active military members and veterans who are twice as likely to develop and die from ALS. We believe it continues to be important for the 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 expand the program to grant funds in support of clinical trials. We recognize military veterans are more likely to be diagnosed with ALS. 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 148 projects that have led to 7 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.<sup>2</sup> 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.

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

*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 development 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 FY2024 appropriations requests for ALS research. With these strategic investments, we can urgently find treatments and cures by increasing the number of preclinical research projects and 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.