

# United States Senate

WASHINGTON, DC 20510

May 8, 2024

The Honorable Jon Tester  
Chair  
Defense Subcommittee  
Committee on Appropriations  
Washington, D.C. 20515

The Honorable Tammy Baldwin  
Chair  
LHHS Subcommittee  
Committee on Appropriations  
Washington, D.C. 20515

The Honorable Martin Heinrich  
Chair  
Agriculture Subcommittee  
Committee on Appropriations  
Washington, D.C. 20515

The Honorable Susan Collins  
Ranking Member  
Defense Subcommittee  
Committee on Appropriations  
Washington, D.C. 20515

The Honorable Shelley Moore Capito  
Ranking Member  
LHHS Subcommittee  
Committee on Appropriations  
Washington, D.C. 20515

The Honorable John Hoeven  
Ranking Member  
Agriculture Subcommittee  
Committee on Appropriations  
Washington, D.C. 20515

Dear Chairs Tester, Baldwin, and Heinrich and Ranking Members Collins, Capito, and Hoeven:

We write to thank you for your strong support of the ALS community by continuing to provide funding for ALS (amyotrophic lateral sclerosis) research. Your support for ALS research through the Department of Defense (DOD), the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA) has been instrumental in advancing the fight to find cures for ALS. We believe that increases in funding tempered by rigorous evaluation and accountability are critical to fulfilling the promise of the last several years.

As you know, ALS, also known as Lou Gehrig's disease, is a fatal neurodegenerative disease that destroys a person's ability to control muscle movement. As the disease progresses, people become trapped inside a body they no longer control – aware of the world around them, but powerless to do anything about it. The average life expectancy for a person with ALS is just two to five years after their diagnosis. Currently, there is no effective treatment for the disease, no known cause, no cure and no survivors.

While ALS affects people of all ages, genders, and backgrounds, the veteran population in the United States is diagnosed with ALS at a rate of up to two times the general population. Although the cause of this increase in prevalence among veterans remains a mystery, the correlation between military service and ALS is well established.

In 2021, Congress passed and the President signed into law the Accelerating Access to Critical Therapies (ACT) for ALS Act, Public Law 117-79, which represented a watershed moment in the fight against this brutal disease. The Act authorizes new grants to deepen research into investigational therapies for ALS through expanded access programs, increased interagency and public-private collaboration on the ALS research agenda, and new clinical research grants.

We ask that you fully fund the bill this year by:

- Including \$75 million at the National Institutes of Health for the expanded access research program under section 2 of ACT in the Labor, Health and Human Services, Education, and Related Agencies appropriations bill;
- Including \$25 million at the Food & Drug Administration for new clinical investments under section 5 in the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill; and
- Directing the Department of Health and Human Services, NIH, and FDA to distribute funds to support the Public-Private Partnership under section 3.

This funding will both save lives now and bring us closer to the day that we are able to have effective treatments for this rapidly progressing, always fatal disease.

The DOD's ALS Research Program (ALSRP) specifically supports innovative and impactful research that is instrumental to the development of new therapeutics for ALS. Congress has a long history of recognizing the critical role of this program and has appropriated funding since 2007. Several years ago, Congress recognized that we are at a pivotal moment in developing treatments and cures for ALS and doubled the funding for ALSRP, funding the program at the level of \$40,000,000 for fiscal year (FY) 2021, but funding has since remained level, leaving more than half of applications unfunded. This year, we request to increase the funding for the ALSRP to the level of \$80,000,000 for FY 2025.

The DOD ALSRP possesses both the strategic vision and coordinated plan to utilize this funding level for scientifically significant advances in the near term. To date, the ALSRP has supported several ALS drug candidates, some of which have advanced to early phase clinical trials, all representing potential ALS treatments. At the new funding level, the program would be able to support these types of projects and carry them through the treatment development and clinical trials phases, bringing us dramatically closer to a viable cure and making a difference for our veterans and everyone living with ALS. The ALSRP leverages that vision with DOD's scale and military rigor to deliver extraordinarily efficient value for the relatively small investment for a disease that cost both DOD and the Department of Veterans Affairs (VA) a combined \$4.6 billion between 2015 and 2020. Further, an October 2021 report prepared for Appropriators by the DOD and VA cited annual costs associated with ALS rose from \$6.6 million to \$15 million at the DOD and from \$207 million to \$340 million at the VA between 2015 and 2020. DOD's critical ALSRP investments reflect the fact that veterans are twice as likely to be diagnosed with ALS as those who did not serve in the U.S. military; recognizing this pattern, the VA designated

ALS as a service-related disability. We believe increased funding is warranted because of the value of those investments to our active duty, veteran, and civilian community.

The NIH plays a vital role in ALS research, such as discovering important connections between ALS and other neurodegenerative diseases, including Parkinson's, Alzheimer's and Multiple Sclerosis, identifying the cellular mechanisms that underlie the disease's progression, and developing new and more effective treatments. These investments in research are critical, but unfortunately, limited funding means that only about 25 percent of awards each year are made for new grants. As such, we hope you will join us in supporting an increase in funding to provide \$160,000,000 for FY 2025 for ALS research at the NIH.

Over the last year, the NIH has become even more attuned to the needs of the ALS community, and a funding increase will ensure it continues to provide invaluable targeted leadership in the effort to fight this horrible disease. We recognize and applaud the Committee for the increased funding for research into treatments and cures for ALS, which has allowed for a more comprehensive ALS research agenda overall. This research synchronization now supports efforts to understand and cure the disease from numerous angles, ranging from identification of clinically-useful biomarkers to isolating specific genes that are linked to the disease.

If we use them wisely, these harmonized streams of increased funding for ALS research at the DOD ALSRP and NIH will together continue the momentum seen in the last few years and incentivize exploration of novel therapeutic pathways, provide support for clinical trials, speed the identification of relevant biomarkers, and allow researchers to continue to study newly discovered genes linked to certain forms of ALS. We ask that you join us in supporting these requests fully, to help us finally find treatments and a cure for ALS.

Critical to understanding a disease is the ability to track its epidemiology. The CDC National ALS Registry is a program that plays a vital role in addressing the disease by providing information about ALS disease patterns and changes over time, thereby bolstering researchers' abilities to understand common risk factors. The Registry has been consistently funded since it was established in 2009 and has since collected information that is pivotal to the fight against ALS. We would like to acknowledge and encourage the efforts the CDC is making to evaluate, update, and improve upon the National ALS Registry program, so that it can continue to provide up-to-date information to researchers and connect ALS patients to the latest clinical trials, treatment, and research resources. This year, we would like to request funding for the National ALS Registry at \$15,000,000 for FY 2025.

Again, we thank you for your continued support for ALS research and care. We appreciate your consideration of our FY 2025 requests and hope you will join us in supporting funding to help make ALS a livable disease. Your support will help bolster and extend the current research momentum that has enabled remarkable recent advances in ALS understanding and drug development leading us closer and closer to a cure for ALS that will end the fight against this devastating disease.

Sincerely,

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