United States Senate
WASHINGTON, DC 20510

March 31, 2023

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 were grateful you were able to include funding for these priorities in the final Fiscal Year 2022 package and significantly build on that in FY23. We ask that you fully fund the bill this year by including in the Labor, Health and Human Services, Education, and Related Agencies appropriations bill $75 million at the National Institutes of Health for the expanded access research program under section 2 of *ACT* and in the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill $25 million at the Food & Drug Administration for new clinical investments under section 5 and direct 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 speed 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 FY2021, 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 FY2024.

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 will 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 $4.6B between 2015 and 2020. Further, an October 2021 report prepared for Appropriators by DOD and VA cited annual costs associated with ALS rose from $6.6M to $15M at DOD and from $207M to $340M at 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 an increase is warranted because of that value 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 of no less than $30,000,000 over the FY2023 level 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 for the disease. 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, such as by ensuring the Registry is being maximized to provide the most up-to-date information to researchers and the greatest benefit to ALS patients by connecting them with 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 FY2024.

Again, we thank you for your continued support for ALS research and care. We appreciate your consideration of our FY2024 requests the committee and hope you will join us in supporting funding to help make ALS a livable disease within a decade. 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,

Chris Coons

Christopher A. Coons
United States Senator

Bill Cassidy, M.D.

Bill Cassidy, M.D.
United States Senator

Sherrod Brown

Sherrod Brown
United States Senator

Edward J. Markey

Edward J. Markey
United States Senator

Sheldon Whitehouse
United States Senator

Robert Menendez

Robert Menendez
United States Senator

Maria Cantwell
United States Senator

Tammy Duckworth

Tammy Duckworth
United States Senator

Angus S. King, Jr.

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Dick Durbin

Richard J. Durbin
United States Senator

Jack Reed
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Peter Welch
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Alex Padilla
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Jeffrey A. Merkley
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Michael F. Bennet
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Richard Blumenthal
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Kyrsten Sinema
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Brian Schatz
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Catherine Cortez Masto
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Mark Kelly
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Elizabeth Warren

Elizabeth Warren
United States Senator

Cory A. Booker
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Chris Van Hollen
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Ben Ray Luján

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Tina

Tina Smith
United States Senator

Jacky Rosen
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Kirsten Gillibrand

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Amy Klobuchar

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United States Senator

Ron Wyden

Ron Wyden
United States Senator

Raphael Warnock
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Tom Carper

Thomas R. Carper
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Debbie Stabenow

Debbie Stabenow
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