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ALS IN THE MILITARY

UNEXPECTED CONSEQUENCES OF MILITARY SERVICE

February 4, 2013



INTRODUCTION

Seventy years ago, baseball legend Lou Gehrig gave his name to a mysterious and rare disease called amyotrophic lateral sclerosis (ALS). He stood on the field at Yankee Stadium on July 4, 1939 and delivered one of the most memorable speeches in American history, announcing to the world that “today I consider myself the luckiest man on the face of this earth.” Lou Gehrig was an American hero.

Today, we know that besides being a hero, Gehrig had something else in common with the men and women serving in the armed forces of our country - His disease; ALS.

Existing evidence supports the conclusion that people who have served in the military are at a greater risk of developing ALS and dying from the disease than those with no history of military service. As outlined in this paper, study after study continues to demonstrate this to be true: If you serve in the military, regardless of the branch of service, regardless of whether you served in the Persian Gulf War, Vietnam, Korea, or World War II, and regardless of whether you served during a time of peace or a time of war, you are at a greater risk of dying from ALS than if you had not served in the military. The questions we are asking today are these: Why is there a greater risk of ALS with military service? And what are we, as a nation, going to do about it?

It is the goal of The ALS Association that this paper raise awareness of the important work that so far has been done on the relationship between ALS and military service. In this effort, we hope to impress upon the Congress, the Administration and the American public the seriousness of this issue and the need to act now.

As we work to address the risk of ALS in military veterans, we must not lose sight of the fact that ALS is a disease that impacts both the veteran and non-veteran communities. Therefore, research into ALS and the military should be broad based and should not be conducted at the expense of other important research into ALS. After all, the disease knows no boundaries, and research into the many potential causes and treatments for ALS surely will benefit veterans and non-veterans alike.

We must also bear in mind that while research is needed to solve the mysteries of ALS, resources also are needed to care for and serve those living with the disease today—to help improve quality of life, to provide access to necessary medical care, and to assist people with ALS in meeting the day to day challenges the disease has imposed on their lives. The ALS Association, the only national not-for-profit health association dedicated solely to the fight against ALS, serves as a resource for people with ALS and their families.

The Association and our more than 40 Chapters and affiliates across the country advocate for increased funding for ALS research, public policies that respond to the needs of people with ALS, as well as vital state and federal resources that are needed to immediately assist patients and families affected by this horrible disease. The ALS Association and our local Chapters are a central resource for information, assistance, and support for people with ALS and their families.

By committing the resources necessary to better understand the apparent link between ALS and military service, we can take action to help ensure that our military men and women, today and in the future, are at no greater risk of ALS than other Americans and that their medical and care giving needs are met. A concerted national effort to understand this connection may also yield important clues about ALS, what causes the disease, how it may be prevented, treated and, ultimately, cured - advances that truly will benefit us all.

The ALS Association

ABOUT ALS

Amyotrophic Lateral Sclerosis was first identified as a disease in 1869, more than 135 years ago. Although much more is known about the disease today, we still do not know what causes the disease or how it can be prevented, effectively treated, or cured. Indeed, the prognosis for a person diagnosed with ALS in 2009 is largely the same as it was for a person diagnosed with the disease in 1869: death in an average of two to five years.

ALS is a progressive, neurodegenerative disease that attacks nerve cells and pathways in the brain and spinal cord. Motor neurons reach from the brain to the spinal cord and from the spinal cord to muscles throughout the body. It is through these neurons that we are able to control all muscle movement, whether it be moving our arms and legs, or simply breathing or opening and closing our eyelids. As ALS progresses and these motor

neurons cease to function and die, our ability to initiate and control muscle movement is lost, ultimately resulting in total paralysis in the later stages of the disease.

However, what makes ALS particularly devastating is that as people progressively lose the ability to walk, move their arms, talk and even breathe, their minds remain sharp; acutely aware of the limits ALS has imposed on their lives.

The average life expectancy for a person with ALS is two to five years from the time of diagnosis. We currently do not know what causes ALS or how it can be prevented and cured. Moreover, only one drug, approved by the FDA in late 1995, currently is available to treat ALS. Thus far, the drug, Rilutek, only has shown limited effects, prolonging life by just a few months.

GULF WAR VETERANS REPORT SYMPTOMS OF ALS

Research conducted on ALS through the years has yielded some clues as to potential causes of the disease. For example, we know that about 10% of ALS cases are hereditary, known as familial ALS (fALS), in which a person develops the disease as a result of their family's genetic predisposition to the disease. The other 90% of cases, known as sporadic ALS, occur in people who have no family history of the disease. While a number of risk factors may possibly be associated with the disease, including lifestyle factors like tobacco use, diet, and excessive physical activity, no clear associations have been established. Environmental factors, such as exposure to toxins, also are believed to play a role in the disease. However, it is not clear how great that role may be or what toxins may cause ALS. Any evidence that demonstrates an environmental risk of ALS could yield vital clues about ALS, its causes and method of action. Such evidence linking ALS to the 1991 Persian Gulf War emerged when veterans of the war began reporting symptoms associated with the disease in the 1990s.

Soon after the first Persian Gulf War in 1991, veterans who had been deployed to the Gulf during the war initially began to report many of the symptoms common to ALS and other neurological diseases. Those symptoms include increasing muscle weakness, especially involving the arms and legs, slurred speech, and difficulty swallowing or breathing. Veterans also reported memory loss, headaches, joint pain and chronic fatigue in greater than expected numbers. Because many of these symptoms could not be classified as specific diseases, they ultimately became collectively known as "Gulf War Syndrome," now referred to as Gulf War Illness. At the time, it was thought that because only a relatively few cases of ALS had been diagnosed among Gulf War veterans (compared to tens of thousands who reported symptoms consistent with Gulf War Syndrome), ALS occurred at a rate similar to that which is found among the civilian population.

Indeed, a series of expert panels convened by the Department of Veterans Affairs examined the initial evidence linking ALS to service in the

Gulf. A mortality study was conducted which concluded that ALS deaths were not occurring at a greater rate among Gulf War veterans than the general population. Other studies conducted within the Department and not published also did not find higher mortality rates among Gulf War veterans.

However, ALS is a disease that occurs predominately between the ages of 40 and 70 years-old, with an average age of 55 at the time of diagnosis. By contrast, the vast majority of Gulf

War veterans, including those diagnosed with ALS, were young, outside of the ages at which ALS is more common. Because of these concerns, two further studies were conducted, both of which concluded that those deployed to the Southwest Asian theater of operations during the Gulf War are at an increased risk of ALS — that **Gulf War veterans are approximately twice as likely to develop ALS as those not deployed to the Gulf.**

Table 5. Age-Specific ALS Rates in Gulf Veterans, Nondeployed Veterans, and a Comparison Population
(number of ALS cases per 100,000 population)

Age at ALS Onset	Gulf War Veterans ²²⁶ (40 ALS cases)	Nondeployed Veterans ²²⁰ (67 ALS cases)	Men in the state of Washington ²⁶² (127 ALS cases)
< 25	0.08	0.00	0.11
25-34	0.45	0.26	0.79
35-44	1.77	0.80	1.63
45-54	5.64	4.81	2.49
55-64	31.19	8.89	6.42

STUDIES LINK ALS TO 1991 PERSIAN GULF WAR

Two separate studies were conducted in response to reports that ALS was occurring in Gulf War veterans at an unexpected rate, particularly in young veterans who were not yet of the age at which ALS is more common. The two studies

used different methods to examine the issue, yet they produced similar conclusions: That Gulf War veterans were approximately twice as likely to develop ALS as veterans who had not served in the Gulf.

Table 4 Age-adjusted risk ratios* of ALS among military personnel according to alternative definitions of deployment status during the Gulf War and of an eligible case

Population	DMDC-reported Deployment Status:			Self-reported Deployment Status:		
	Strict Diagnostic Criteria† (n = 86)	Onset Post-July 1991 (n = 91)	Men Only (n = 105)	Strict Diagnostic Criteria† (n = 86)	Onset Post-July 1991 (n = 91)	Men Only (n = 105)
Total	2.07‡ (1.34, 3.19)	1.84‡ (1.20, 2.83)	1.75‡ (1.17, 2.61)	2.53‡ (1.65, 3.87)	2.67‡ (1.77, 4.05)	2.54‡ (1.72, 3.73)
Unit						
Active	2.22‡ (1.36, 3.63)	2.01‡ (1.23, 3.28)	1.99‡ (1.26, 3.13)	2.54‡ (1.57, 4.12)	3.14‡ (1.97, 5.00)	2.93‡ (1.90, 4.51)
Reserves/National Guard	3.37‡ (1.01, 11.27)	2.73 (0.89, 8.40)	2.17 (0.75, 6.31)	8.55‡ (1.85, 39.44)	3.89‡ (1.19, 12.71)	4.14‡ (1.29, 13.31)
Service branch						
Air Force	3.06‡ (1.40, 6.70)	2.11 (0.91, 4.91)	2.60‡ (1.20, 5.62)	4.64‡ (2.23, 9.67)	4.39‡ (2.12, 9.05)	4.97‡ (2.48, 9.94)
Army	2.14‡ (1.07, 4.30)	2.69‡ (1.35, 5.38)	1.78 (0.95, 3.35)	2.15‡ (1.07, 4.33)	2.38‡ (1.20, 4.74)	1.79 (0.95, 3.37)
Marine Corps	0.90 (0.16, 4.93)	1.13 (0.27, 4.79)	1.09 (0.26, 4.59)	0.90 (0.16, 4.93)	1.13 (0.27, 4.79)	1.09 (0.26, 4.59)
Navy	1.92 (0.72, 5.15)	0.99 (0.33, 3.00)	1.41 (0.59, 3.40)	2.42 (0.93, 6.27)	2.71‡ (1.09, 6.77)	2.84‡ (1.28, 6.29)

* Risk ratios are based on the age-adjusted, average annual cumulative incidence rate per 100,000 persons during the 10-year period beginning August 2, 1990 among deployed and nondeployed military personnel. Total study population used as the standard. Ratios indicate the relative risk of ALS among military personnel deployed to the Gulf Region during the Gulf War. Nondeployed military Gulf-era personnel are the referent population.

† Strict diagnostic criteria are defined as the following World Federation of Neurology criteria of diagnostic certainty: definite, probable, and probable with laboratory evidence. Deceased cases with ALS as an underlying cause of death are considered definite ALS.

‡ Risk ratios are significantly elevated ($p < 0.05$).

DMDC = Defense Manpower Data.

Department of Veterans Affairs/Department of Defense Study

The first study was led by Ronnie D. Horner, Ph.D., of the National Institute of Neurological Disorders and Stroke at the National Institutes of Health and was funded by the Department of Veterans Affairs and the Department of Defense. The study, "Occurrence of amyotrophic lateral sclerosis among Gulf War veterans," was published in the September 23, 2003 issue of *Neurology*, the scientific journal of the American Academy of Neurology.

The study sought to identify all of the cases of ALS that occurred in the military after the start of the Gulf War and determine whether Gulf War veterans have an elevated rate of the disease. After examining a total study population of nearly 2.5 million military personnel who were on active duty during the war, researchers found that those

serving in the Gulf were nearly twice as likely to develop ALS as those not serving in the Gulf. The Study found an increased risk of ALS among all branches of the military, although Army and Air Force personnel experienced the greatest risk.

University of Texas Southwestern Medical Center Study

The second study, "Excess incidence of ALS in young Gulf War veterans," also published in the September 23, 2003 edition of *Neurology*, was conducted by Robert Haley, MD, of the University of Texas Southwestern Medical Center at Dallas and was funded by a grant from the Perot Foundation. The study examined ALS in Gulf War veterans age 45 and younger and found that ALS occurred in these veterans at more than twice the rate as in the general population. Particularly alarming about the findings of this study is that the rate of ALS increased over time.

During the first four years after the war, the rate of ALS was about the same as that to be expected in the general population. However, from 1995 to 1998, the rate of ALS increased each year, and in 1998, the last year included in the study, more than three times as many Gulf War veterans developed ALS as would be expected in the general population. As these veterans continue to age, and reach the ages more commonly

associated with ALS, the rate of the disease may continue to increase in this population. Although the author of the report acknowledged that the environmental exposures that may have caused ALS in Gulf War veterans is unknown, he did conclude that the increased incidence of ALS in young veterans suggested an environmental trigger.

Both of these reports clearly indicate that Gulf War veterans are at an increased risk of ALS. Both reports also recommended that further studies be performed to determine environmental or other factors that may contribute to the elevated

risk of ALS. Another question that arises from these studies is whether the increased risk of ALS is confined to just veterans of the Gulf War or whether it also applies to veterans of other conflicts and in other eras.

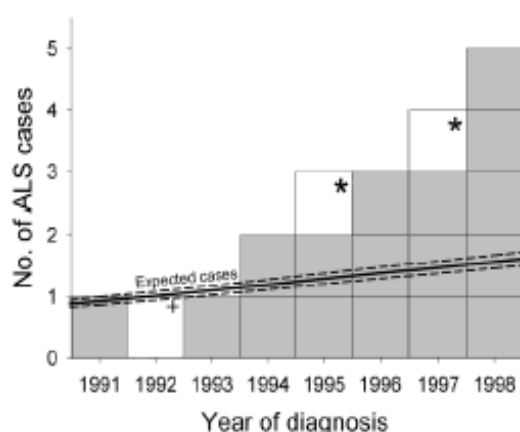


Figure 2. The numbers of definite cases (shaded boxes), possible cases (open boxes), and expected cases (solid line) of ALS in young (aged <45 years) Gulf War veterans by year of diagnosis. The solid line indicates the expected incidence of ALS (number of cases expected from analysis of the age distribution of the Gulf War veteran population and the age-specific ALS death rates of the US population, 1979 to 1998); the dashed lines indicate the 95% CI of the expected incidence. The possible ALS cases (open boxes), excluded from all statistical analyses, comprise two with muscle weakness and fasciculations not yet meeting El Escorial criteria (asterisks) and one who elected not to participate (cross). The ALS cases shown appear to be fewer than half the number documented in Gulf War veterans by the VA and the ALS Association.⁷

HARVARD STUDIES LINK ALS AND MILITARY SERVICE

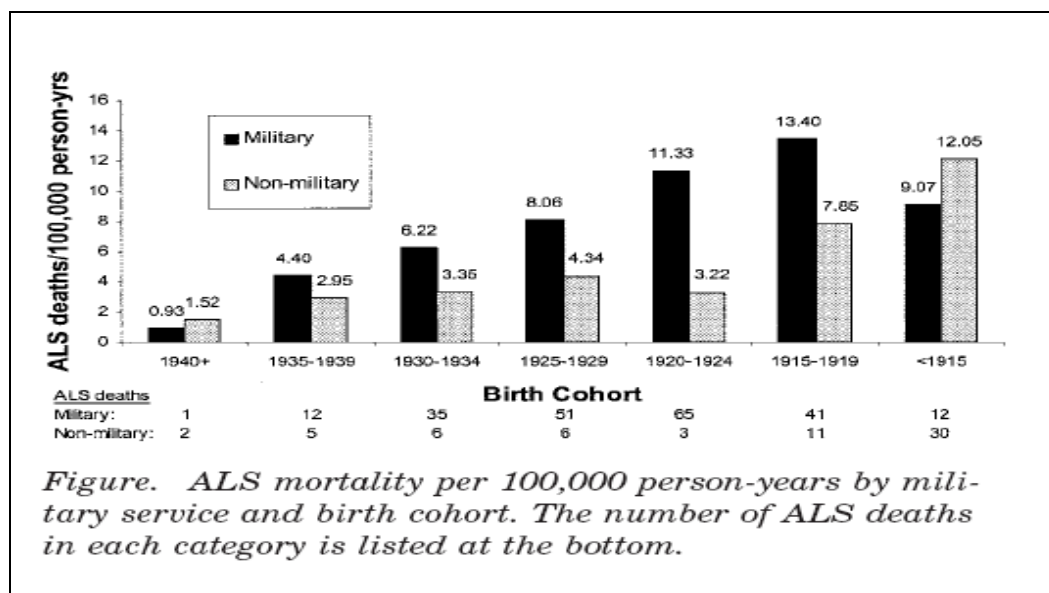
Studies published in 2005 and 2009 found that men with **any** history of military service in the last century are at a nearly 60% greater risk of ALS than men who did not serve in the military. Conducted by epidemiologists at Harvard University's School of Public Health, the studies concluded that "Military personnel have an increased risk of ALS. This increase appeared to be largely independent of the branch of service and the time period served."

The studies, "Prospective Study of Military Service and Mortality from ALS" (Weisskopf, Ph.D.; et. al.) and "Prospective Study of Military Service, Chemical Exposures, and Risk of

Amyotrophic Lateral Sclerosis and Parkinson's Disease," assessed the relationship between military service and mortality from ALS. They examined men who served in the military in different time periods, from 1910-1982, and different branches of the service by looking at those who participated in the Cancer Prevention Study II cohort of the American Cancer Society, which comprises over 500,000 men. The study conducted in 2009 examined data through 2002 and confirmed the earlier 2005 findings of an increased risk of ALS in all veterans. It did not find an increased risk of Parkinson's Disease. However, both studies also found that the risk of ALS was similar for those serving in World War

II, Korea and Vietnam. Of note is that the studies did not examine military service in the Gulf War, as service reported by all participants in the study was before the Gulf War. In fact less than 2% of those included in the studies who served in the military were age 45 or younger in 1990, the time of the Gulf War. By contrast 98% of those deployed to the Gulf were younger than 45.

Another important aspect of the Harvard studies is that researchers did not have data on deployment during wartime, which was the primary focus of the two Gulf War studies. Therefore, it is possible that the risk of ALS could have been found to be greater for men who served during wartime had the study not mixed those who served during a period of war and those who did not. The lower risk of ALS, 1.6 times versus 2 times in the Gulf War studies, is consistent with this explanation.



UNANSWERED QUESTIONS

Do the studies linking ALS to military service answer all of the questions we have about this relationship? No. We do not know for certain what about military service seems to result in a greater number of deaths from ALS. Environmental factors may play a role, such as exposure to chemicals during military service. Traumatic activity or intense physical activity associated with military service may play roles as well. However, researchers and health care professionals agree that more work needs to be

done to answer these questions. So too does a federal advisory committee created by Congress in 1998. In its 2004 and 2008 reports, that committee not only reinforced the findings of earlier studies of the Gulf War, it also produced a series of recommendations to federal agencies and Congress that, if followed, may help answer the remaining questions and yield important new insights into both the relationship between ALS and the military and the disease itself.

RESEARCH ADVISORY COMMITTEE ON GULF WAR VETERANS' ILLNESSES

The Research Advisory Committee on Gulf War Veterans' Illnesses, a panel of scientific experts and veterans established by Congress in 1998, released its first major report at the end of 2004 and followed with a second report in November 2008. In both reports, the panel reached a number of important conclusions and offered recommendations that may help to answer many of the questions that have been raised about ALS and military service. After reviewing hundreds of scientific studies and government reports, the 2004 report confirmed that **"Gulf War veterans exhibit evidence of neurological problems, including a significant excess in the rate of amyotrophic lateral sclerosis (ALS), or Lou Gehrig's disease."** The 2008 report stated that **"The most serious condition reported to affect Gulf War veterans at a higher than expected rate is amyotrophic lateral sclerosis."** Both reports also noted concerns about the rate of ALS

in veterans, particularly in younger veterans, with the 2004 report saying "It is of great concern that the full impact of this disease on Gulf War veterans might not be known for decades." The reports also agreed with the findings of one of the earlier Gulf War ALS studies in that environmental factors likely played a role, finding that "evidence supports a probable link between exposure to neurotoxins and the development of Gulf War veterans' illnesses." The 2008 report noted studies linking ALS to exposure to pesticides and aluminum adjuvants used in vaccines, like the anthrax vaccine. Importantly both the 2004 and 2008 report recommended that research into the causes of Gulf War-related illnesses should be a top funding priority. Specifically, the 2008 report stated that the VA should continue to fund the VA ALS Registry (see page 9 of this paper) and called for epidemiologic studies to identify rates of ALS. The 2008 report also stated that **"Research to better understand the causes of ALS and identify treatments is extremely important."** Among the findings: "A renewed federal research commitment is needed to identify effective treatments for Gulf War Illness and address other priority Gulf War health issues." Issues that include ALS.

INSTITUTE OF MEDICINE: 2006 REPORT

Because of the studies reported in this paper, the Department of Veterans Affairs requested that the National Academies conduct an independent assessment of the relationship between military service and the development of ALS. The National Academies assigned the task to the Institute of Medicine (IOM), which advises the federal government on public health issues and health care policy. The IOM appointed an expert committee to evaluate the existing scientific literature on ALS in the veteran population and in November, 2006 issued its report, finding that the existing evidence supports the increased risk of ALS in veterans.

Of particular importance, the IOM noted among the strongest evidence to show the connection between ALS and military service was the Harvard study, which found an increased risk of

the disease in veterans from all eras, not just the 1991 Persian Gulf War. According to the IOM, **"[T]he implication is that military service in general – not confined to exposures specific to the Gulf War – is related to the development of ALS. The findings, if validated in other studies, suggest that exposures during military services, even among those with no wartime service, might be responsible."**

The committee called for new, high quality studies to further investigate the connection between ALS and military service and to examine those aspects of military service that may cause the disease.

VA ALS REGISTRY/NATIONAL ALS REGISTRY

In 2003, the Department of Veterans Affairs developed a nationwide registry of veterans with ALS. The registry is designed to: identify as completely as possible all living veterans with ALS and to track the health status of these veterans; collect data, including DNA samples and clinical information, which will be available for approved studies examining the causes and treatment of ALS; and to provide a way for the VA to inform veterans with ALS about research studies for which they may be eligible to participate. The VA stopped enrollment in the registry at the end of FY 2007. However, the registry continues to supply data for research.

From 2003 to 2007, the registry enrolled 2,121 veterans with ALS, approximately 500 of whom currently are living, and it collected more than 1,200 DNA samples from veterans with ALS. The registry has identified veterans with ALS who have served in every era dating from before World War II and includes veterans who have served in the military since the start of the current conflict in Iraq.

In 2008, Congress enacted the ALS Registry Act to establish a nationwide registry that will seek to identify cases of ALS throughout the country, including cases of ALS in veterans and non-veterans. The registry, which is managed by the Centers for Disease Control and Prevention/Agency for Toxic Substances and

Disease Registry (CDC/ATSDR), is expected to be fully operational in the latter half of 2010 (www.cdc.gov/als, https://ssl.capwiz.com/alsa/attachments/ALS_Registry_Update_Jan_2010_.pdf). In identifying cases of ALS, the CDC/ATSDR is partnering with other federal agencies, including the VA, to identify ALS cases. In this way, the National ALS Registry is continuing to identify ALS cases in military veterans. Both the VA registry and the National ALS Registry are and will be important resources for ALS research. In fact, the VA registry has provided information for numerous ALS research studies, including studies to identify the genetic epidemiology of ALS in veterans and biomarkers for ALS among active duty military personnel.

However, it is absolutely critical that Congress and the Administration support funding for the research and federal programs that will take advantage of the data collected by the registry. Congress should encourage that both the DOD and VA continue to support ALS research, including the **ALS Research Program (ALSRP) at the DOD**, which is funding ALS translational research and is the only ALS-specific research program at DOD. After all, the data collected by the VA ALS Registry is only valuable if we can learn from it, use it to advance our understanding of ALS and develop ways to prevent, treat, and ultimately cure this disease.

PRESUMPTION OF SERVICE CONNECTION FOR ALS

On September 23, 2008, the Department of Veterans Affairs implemented regulations to establish a presumption of service connection for ALS. Importantly, the regulation acknowledges the link between military service and increased risk of ALS. Under the regulation, the VA presumes that the development of ALS was incurred or aggravated by a veteran's service in the military. Unlike other presumptions, which generally are limited to a specific time period (e.g., the Gulf War) or exposure (e.g., Agent Orange), the presumption for ALS is broad,

among the most comprehensive that the VA has ever issued. It applies to veterans diagnosed with ALS at any time following service in the military and is not limited to where or when a veteran served in the military. As a result, veterans with ALS and their survivors are now eligible for full health care and disability benefits.

While the regulation recognized the link between ALS and military service and provides critical benefits to veterans, it is important that the federal government take additional steps to help veterans by finding a cause and treatment for the disease.

CONCLUSIONS

Although many questions remain unanswered, the preponderance of the evidence strongly demonstrates that something about military service increases a person's risk of ALS. The extensive research conducted on Gulf War veterans support that conclusion as do the Harvard studies showing a link between ALS and any military service. And the work of the IOM, also helps to demonstrate that those who have served in the military are at a greater risk of ALS than those with no history of military service.

However, it is important to note that ALS is a rare disease, with an incidence in the general population of about two per 100,000. Although the risk of ALS may be higher for military veterans, ALS remains a rare disease among the veteran population as well.

Federal Action Necessary

The ALS Association strongly believes that the existing evidence compels this nation and the Congress to act and commit the resources and funding that is necessary to answer remaining questions. Congress, the Department of Veterans Affairs and the Department of Defense also must respond to the recommendations of the Institute of Medicine and the Research Advisory Committee on Gulf War Veterans' Illnesses by committing the funding necessary and set a national goal of finding treatments for veterans afflicted with ALS and determining what about military service increases risk of the disease. This is vital, for ALS is among the only specific diseases for which research has thus far comprehensively found to occur at a significantly higher rate for all veterans, regardless of their era of service.

Congress should act to ensure continued funding for the ALS Research Program (ALSRP) at the Department of Defense, the only ALS-specific program at the DOD. Congress appropriated \$6.4 million in funding for the program in FY 2012 and a total of over \$30 million has been provided since its inception in FY 2007. The ALSRP is a particularly critical program. Unlike, most other programs which focus on basic research, the ALSRP is focused on translational research, with the specific goal of finding new treatments for ALS. Support for this and other federal programs that can advance ALS research is needed to meet the goal of finding treatments for ALS in the near future. These efforts not only hold promise for our military men and women living with ALS today and in the future, but also the thousands of other Americans whose lives continue to be impacted by this horrific disease.

This point cannot be overstated, for in our effort to address the risk of ALS in military veterans, we must be mindful that ALS is a disease that, although rare, can strike anyone regardless of whether they served in the military. The disease also has many potential causes and risk factors, including environmental, genetic and lifestyle. Therefore, research into ALS should not be confined to studies on ALS and the military. Rather, it should be broad in nature so that advances can benefit the entire ALS community.

American Heroes

Although increased government efforts focused on ALS will benefit all Americans, it is particularly timely today that we draw attention, both in Congress and in state legislatures around the country, to the risks of this disease for the heroes serving our country in the armed forces. More than 100,000 American men and women currently are defending our country and the cause of freedom in Iraq and Afghanistan. Hundreds of thousands of others serving in the US and across the globe also risk their lives each day in support of this country. Like Gehrig, they are all American heroes. And we can support them by committing the resources necessary to make ALS a disease of the past and eliminate it from the face of the earth.

The ALS Association is the only non-profit organization fighting Lou Gehrig's Disease on every front. By leading the way in global research, providing assistance for people with ALS through a nationwide network of chapters, coordinating multidisciplinary care through certified clinical care centers, and fostering government partnerships, The Association builds hope and enhances quality of life while aggressively searching for new treatments and a cure. For more information about The ALS Association, visit our website at www.alsa.org or call 202-638-6997.