RESTLESS LEGS
SYNDROME
FOUNDATION

2021 Restless Legs Syndrome Foundation Virtual RLS Advocacy Week

The Restless Legs Syndrome Foundation Hill Day is planning for a *Virtual RLS Advocacy Week* from April 26-April 30! Help us get the word out to Members of Congress – increase their awareness of Restless Legs Syndrome and how they can help us. Congressional offices have been monitoring daily developments of the coronavirus and have adapted new ways of connecting with constituents based on new CDC guidelines. We are encouraging our community to call and/or email your representatives to discuss the policy priorities of the RLS community.

Take action:

- Email or call your two Senators and your Member of the House of Representatives to share your experience with RLS and to ask them to help us (specific asks included in templates provided).

Making Contact

To find and contact your U.S. Senator:

1. Visit the Senate website: www.senate.gov

2. Conduct a search using the **Find Your Senators** pull-down menu in the upper right corner (select your state and click Go).

3. On the results page is a link to the Senators' website, contact information and links to an online contact form (forms vary by Senator).

To find and contact your U.S. Representative:

1. Visit the House of Representatives website www.house.gov

2. Conduct a search using the **Find Your Representative** zip code search box in the upper right corner (enter your zip code and click Go).

3. On the results page is a photo of your Representative(s), links to the Representative's personal website, online contact form and a local map.

4. In the event your zip code overlaps with multiple congressional districts, the results page will include boxes for you to enter your nine digit zip code or mailing address to find the correct Representative.

SAMPLE CALL SCRIPT

Good Morning/Afternoon,

My name is [Insert name], and I am a constituent of yours, living in [Insert town and state].

I am calling you today regarding the Restless Legs Syndrome Foundation, which advocates for all persons affected by RLS and supports a legislative and policy agenda that meets the needs of the RLS community. The foundation's mission is to improve the lives of men, women, and children who live with RLS, working to raise awareness, improve treatments, and—through research—to find a cure for this often-devastating disease.

RLS is a neurological disorder that causes sensory disturbances and an urgent need to move the legs and/or, in some cases, other parts of the body, such as the arms. Patients describe the feelings in a variety of ways, which can range from relatively mild to severe, from only rarely experienced to an intense daily torture. RLS can have profoundly disruptive effects on the quality and quantity of sleep and on virtually every other aspect of daily life as well. Currently in the United States, it is estimated that nearly 12 million adults and children suffer from RLS. I am one of them. [or substitute an appropriate sentence connecting you to your advocacy efforts for RLS.]

[Tell your own story about RLS—ideally in a paragraph or two.]

I am calling today to ask for your help in supporting several measures that will benefit the RLS community. There is currently no cure for RLS, and treatment options are limited. Research remains critical to improving the health and quality of life of individuals suffering from this disease. We advocate a funding level of $46.1 billion for the NIH in the FY 2022 Labor-HHS-Education Appropriations bill. This level of funding will support the progress that the NIH has made in medical research regarding RLS and other chronic diseases.

Over the past decade, "sleep disorders" has been listed as a condition eligible for study through the Department of Defense Peer-Reviewed Medical Research Program (PRMRP). Please work with your colleagues to ensure that "sleep disorders" is listed once again in the FY 2022 Defense Appropriations Bill. The RLSF, as part of the sleep research community, asks that your office contact your colleagues on the Defense Appropriations Subcommittee to communicate your support for this request.

In cases of severe RLS in which all other medical therapies have failed, ample scientific research supports the use of low-total-daily-dose opioid therapy to treat the underlying neuropathology associated with RLS, which is **not** the same as chronic pain. Research continues to show that addiction and dependence are not common complications for affected individuals, because the total daily dose of opioids used to manage RLS is quite low, and patients continue on the same total daily dosage for years and even decades. However, the low-total-daily-dose opioid medications must be kept at the same level to manage symptoms. If patients with severe RLS lose access to opioid therapies, they suffer extreme loss of sleep, continuous misery, and worse. The needs of RLS patients who depend on the use of low-total-daily doses of opioids to manage their disease must be considered in crafting legislation, policies, and regulations aimed at drug abuse and addiction. Please work with your colleagues in Congress to ensure that RLS patients retain access to physician-directed care and treatment for severe cases of RLS.

Poor provider education about Restless Legs Syndrome routinely leads to misdiagnosis, delays, and inappropriate treatment, which often results in irreparable harm to patients. Improved provider education can drastically improve effective treatment outcomes. The CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) supports several programs that work to increase public awareness and improve professional education for chronic diseases such as RLS. Please provide $5 million for the National Neurological Conditions Surveillance System (NNCSS) and $5 million for the Chronic Diseases Education and Awareness Program (CDEA). Through a competitive grant process, the new CDEA program will greatly enhance understanding, education, and public health awareness for a variety of chronic diseases, including RLS.

Thank you for your consideration of these vital issues, and please consider the RLS Foundation as a resource for you and your office about health-related and patient issues.

Sample Email Copy

My name is [Insert name], and I am a constituent of yours, living in [Insert town and state].

I am writing to you regarding the Restless Legs Syndrome Foundation (RLSF), which advocates for all persons affected by RLS and supports a legislative and policy agenda that meets the needs of the RLS community. The foundation's mission is to improve the lives of men, women, and children who live with RLS, working to raise awareness, improve treatments, and—through research—to find a cure for this often-devastating disease.

RLS is a neurological disorder that causes sensory disturbances and an urgent need to move the legs and/or, in some cases, other parts of the body, such as the arms. Patients describe the feelings in a variety of ways, which can range from relatively mild to severe, from only rarely experienced to an intense daily torture. RLS can have profoundly disruptive effects on the quality and quantity of sleep and on virtually every other aspect of daily life as well. Currently in the United States, it is estimated that nearly 12 million adults and children suffer from RLS. I am one of them. [or substitute an appropriate sentence connecting you to your advocacy efforts for RLS.]

[Tell your own story about RLS—ideally in a paragraph or two.]

I am writing today to ask for your help in supporting several measures that will benefit the RLS community. There is currently no cure for RLS, and treatment options are limited. Research remains critical to improving the health and quality of life of individuals suffering from this disease. We advocate a funding level of $46.1 billion for the NIH in the FY 2022 Labor-HHS-Education Appropriations bill. This level of funding will support the progress that the NIH has made in medical research regarding RLS and other chronic diseases.

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Thank you for your consideration of these vital issues, and please consider the RLS Foundation as a resource for you and your office about health-related and patient issues.

Sincerely,

[Your name
Your street address
Your city and State]

RLS

RESTLESS LEGS
SYNDROME
FOUNDATION

Restless Legs Syndrome Foundation
Legislative Agenda
117th Congress, 1st Session

About the Foundation

The Restless Legs Syndrome Foundation is a 501(c)(3) nonprofit organization dedicated to improving the lives of men, women and children who live with restless legs syndrome (RLS), an often-devastating disease. Founded in 1989, the Foundation's goals are to increase awareness, improve treatments and, through research, find a cure for RLS. The Foundation serves healthcare providers, researchers, 5,600 members, and millions of people in the U.S. and around the world who have RLS. The RLS Foundation has members in every state, local and virtual support groups, and a research grant program that has awarded nearly $2 million to fund medical research into the causes and cures for RLS.

About Restless Legs Syndrome

RLS is a serious neurological disease that devastates the lives of millions of Americans. An estimated 12 million men, women and children in the U.S. have RLS. One in 33 adults (3%) needs daily clinical treatment. There is no cure; treatment is life-long. People with RLS experience an overwhelming, agitating, and uncontrollable urge to move their legs, which is only relieved by moving or walking. RLS is at its strongest in the evening and at night, severely disrupting sleep. It is 3 to 4 times more common in women than men, and twice as common in elderly Americans.

The sleep loss caused by RLS robs people of the ability to work and live normally, and may lead to depression, anxiety and suicidal thoughts. The RLS Foundation loses members every year to suicide because their symptoms become unbearable. Profound sleep loss puts people with RLS at risk for hypertension, diabetes, heart attack, stroke and Alzheimer's disease.

RLS treatment options are limited; FDA-approved RLS treatments do not provide life-long coverage. First-line medications don't work for some patients, and over time actually make the disease worse for many others due to a serious side effect known as augmentation.

For the millions of people who have chronic, unrelenting, nightly RLS symptoms, opioids are an established, highly effective treatment option when first-line therapies have failed. Opioids, taken in low-total daily doses, bring dramatic relief to an estimated 90% to 95% of RLS patients.

It's important to note that RLS is not chronic pain; it has a distinctly different underlying neuropathology. RLS is a neurological disease impacting sleep and is best managed by neurologists and sleep specialists. Clinical experience among experts who treat severe RLS with opioids has not shown the degree of drug misuse, dependency or addiction that is commonly associated with opioid treatment for chronic pain. RLS expert experience also indicates that the dose of opioids used to manage RLS is significantly lower than that used to treat chronic pain effectively. Evidence-based clinical guidelines, published in two seminal Mayo Clinic Proceedings articles, outline for clinicians' recommendations for RLS treatment, management and the appropriate use of opioids in refractory RLS.

From the Patient's Perspective

Steve Smith

"About a year ago, I had one of those nights when my RLS was out of control and I knew that I wasn't going to get any sleep at all. So, I called my doctor's night service and was instructed to go to the local hospital's Emergency Room and to tell them to call my doctor for further instructions.

Contrary to hospital policy, the ER doctor decided not to call, despite the fact that he didn't understand RLS or my resulting insomnia. Instead, he focused on my depressed feelings from insufficient sleep, my RLS pacing (which he interpreted as agitation) and the prescribed opioid that I take for RLS. He incorrectly concluded that I had a drug problem and was suicidal. I specifically denied his assertions, but he refused to listen. So, he placed me under a 72-hour psychiatric hold and sent me to a psychiatric hospital.

I was transported 180 miles confined to the back seat of a car with raging RLS. The psychiatric hospital didn't carry one of my RLS medications, Tramadol, which forced me to go into withdrawal rather than locate a supply. The abrupt withdrawal from Tramadol led to hours of shakes and sweats followed by an entire night of RLS pacing for the second night in a row. Since Tramadol also acts as an SNRI anti-depressant, the abrupt withdrawal caused me to develop SNRI Withdrawal Syndrome. This caused migraine headaches, severe anxiety and depression, nightmares centered on the horrible experience of being involuntarily confined to the psychiatric hospital—all because an ER doctor didn't understand or recognize my RLS—a neurological, not psychiatric, disorder. These symptoms went on for months and required medication and psychotherapy treatment for anxiety and severe depression."

Legislative and Policy Priorities

Medical Research

- **Please provide the National Institutes of Health (NIH) with at least $46.1 billion in fiscal year (FY) 2022.** Important research on RLS is funded across NIH Institutes and Centers, including the National Institute of Neurological Disorders and Stroke (NINDS), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute on Drug Abuse (NIDA), and the National Institute of Mental Health (NIMH). Sustained funding commitments are needed to identify better treatments and a cure for this devastating disorder.

- **Please continue to include "sleep disorders" in the Department of Defense Peer-Reviewed Medical Research Program (PRMRP) and the Combat Readiness Medical Research Program for FY 2021 and FY 2022**. RLS is a major sleep disorder that affects an estimated 40,000 active-duty military personnel.

Patient Access to Appropriate Treatments

- **Please accommodate the needs of patients who rely on the regular use of low-total daily doses of opioids to manage their RLS.** As you consider any legislation and work with federal agencies to address the opioid epidemic, please support a diagnosis-appropriate *safe harbor* for RLS patients, so they do not face arbitrary barriers. RLS patients need for their physicians to be able to prescribe opioids appropriately and without undue restriction.

Education and Awareness

- **Please provide $5 million for the National Neurological Conditions Surveillance System (NNCSS) for FY 2022.** The NNCSS at the Centers for Chronic Disease Control and Prevention (CDC) collects and synthesizes data to help increase our understanding of neurological disorders and to support further neurologic research. RLS remains a severely misunderstood and underdiagnosed neurological disorder, and increased surveillance is vital to improving patient outcomes.

- **Please provide at least $5,000,000 for the Chronic Diseases Education and Awareness Program at the Centers for Disease Control and Prevention (CDC).** With the cessation of the National Healthy Sleep Awareness Project (NHSAP), CDC presently has no active public health activities dedicated to sleep or sleep disorders, despite the fact that sleep affects nearly every body system and many chronic diseases. Please allow the valuable scientific and public health efforts started during the NHSAP to continue.

ISSUE BRIEF

"Increase Funding for the National Institutes of Health"

(This will be of particular interest to members of the House and Senate Appropriations Committees)

Background

The National Institutes of Health (NIH) is the world's foremost biomedical research enterprise. Much of the research activities supported by NIH do not take place in Washington, DC, but at academic medical centers across the country. Medical researchers compete for funding for their projects by submitting grants and going through a peer-review process that ensures the highest-quality grants receive funding.

Presently, NIH supports important research on RLS across different Institutes and Centers, including the National Institute of Neurological Disorders and Stroke (NINDS), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute on Drug Abuse (NIDA), and the National Institute of Mental Health (NIMH).

The Issue

Each year, Congress balances medical research against other federal priorities and decides how much funding will be provided to NIH through the appropriations process. Over the past few years, NIH has received meaningful funding increases, but for more research to be conducted on RLS, the overall budget of NIH needs sustained growth.

In FY 2021, Congress provided NIH with a total funding level of $42.9 billion. This trend needs to continue to expand and advance research activities. We are asking for an increase to $46.1 billion to ensure that meaningful research can continue leading to better outcomes for our patients.

ISSUE BRIEF

"Continue to include sleep disorders as a condition in the Peer-Reviewed Medical Research Program"

(This will be of particular interest to members of the House and Senate Appropriations Committees)

Background

The Department of Defense (DOD) supports medical research into conditions that affect veterans and active-duty military personnel through its Peer-Reviewed Medical Research Program (PRMRP). Unlike the National Institutes of Health, which fund any meritorious research proposal, the PRMRP only funds research into conditions that have been connected to military service. These are named on a list within the Committee Report accompanying the annual Defense appropriations bill. Appearing on the list deems the condition "eligible for study" for approximately one fiscal year.

"Sleep disorders" has been listed regularly as an eligible condition for almost a decade, and, as a result, important RLS research projects are eligible for funding by the PRMRP. For "sleep disorders" to continue to be listed as a condition eligible for study, it must be included in the FY 2022 Defense appropriations bill. For this to occur, there must be strong support for this action in both the House and Senate, particularly among key members of the House and Senate Defense Appropriations Subcommittees.

Talking Points

- Over the past decade, “sleep disorders” has been listed as a condition eligible for study through the Department of Defense Peer-Reviewed Medical Research Program (PRMRP).

- Please work with your colleagues to ensure that “sleep disorders” is listed once again in the FY 2022 Defense Appropriations Bill.

- The RLS and sleep research community asks that your office contact your colleagues on the Defense Appropriations Subcommittee to communicate your support for this request.

ISSUE BRIEF

Maintain Appropriate Access to Low-Total Daily Doses of Opioids for RLS Patients

Background

The opioid epidemic has devastated communities across the country. While Congress debates solutions to this crisis, they must consider and protect the needs of patient communities who depend on appropriate access to low-total daily doses of opioid therapies to manage debilitating conditions.

Current treatment recommendations for RLS include several medications that do not provide life-long relief. For many patients, after months or a few years of relief, some prescribed medications worsen the disease, as a result of a phenomenon called “augmentation.” When this occurs, low-total daily doses of opioid medications are often the *only* effective treatment available. Clinical studies have shown that addiction and dependence are not common complications for affected individuals, since the total daily dose of opioids used to manage RLS is quite low.

Talking Points

- RLS is not a chronic pain condition; opioids, taken in low-total daily doses, are used to treat the underlying neuropathology issues associated with RLS, not a sensation of pain. If patients ever lose access to opioid therapies, they will lose the ability to manage their RLS, resulting in severe loss of sleep, continuous misery, and worse.

- Any emerging proposals or rules aimed at combating the opioid epidemic must provide *safe harbor* for the low-total daily dosage effective in treating RLS.

- As Congress considers proper definitions of expected norms for opioid prescribing, the RLS community implores legislators to consider the perspective of prescribers practicing in specialty and subspecialty care that utilize opioid therapies in low-total daily doses, particularly for neurological conditions and movement disorders.

- When low-total daily doses of opioids are indicated to treat RLS, the condition specifically requires that opioid medications are not reduced over time. Research continues to show that addiction and dependence are not common complications for affected individuals, as the total daily dose of opioids used to manage RLS is relatively low.

- The needs of RLS patients who depend on regular use of low-total daily doses of opioids to manage their disease must be considered in crafting legislation, policy, and regulations aimed at drug abuse and addiction. Please work with your colleagues in Congress to ensure that RLS patients retain access to physician-directed care and treatment.

ISSUE BRIEF

Support Increased Prevention and Awareness

Background

RLS is a serious neurological disease that devastates the lives of millions of Americans. An estimated 12 million men, women and children in the US have RLS. One in 33 adults (3 percent) needs daily clinical treatment. Treatment is life-long, and there is no cure for RLS.

Poor professional and public awareness remain serious barriers to early and effective treatment. CDC leads public awareness campaigns on health issues, conducts surveillance and epidemiology studies, and tracks emerging and established public health threats.

Through its National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), the CDC supports several programs that work to improve chronic disease education and awareness. These programs work to:

- Find out how these diseases affect populations in the United States
- Study interventions to find out what works best to prevent and control these diseases
- Share information to help Americans understand risk factors and how to reduce prevalence

Talking Points

- Poor provider education on Restless Legs Syndrome routinely leads to misdiagnosis and under-treatment for patients. Delay and misdirection of treatment often results in irreparable harm to patients. Improved provider education can drastically bolster effective treatment outcomes for patients. The CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) supports several programs that work to increase public awareness and improve professional education.

- Please work with your colleagues to provide the Centers for Disease Control and Prevention (CDC) with a funding level of at least $10 billion for FY 2022 and encourage collaboration with stakeholders.

    - Please provide $5 million for the National Neurological Conditions Surveillance System (NNCSS) for FY 2022. The NNCSS at the Centers for Chronic Disease Control and Prevention (CDC) collects and synthesizes data to help increase our understanding of neurological disorders and to support further neurologic research.

- **Please provide at least <u>$5,000,000 for the Chronic Diseases Education and Awareness Program at the Centers for Disease Control and Prevention (CDC).</u>** With the cessation of the National Healthy Sleep Awareness Project (NHSAP), CDC presently has no active public health activities dedicated to sleep or sleep disorders, despite the fact that sleep affects nearly every body system and many chronic diseases. Please allow the valuable scientific and public health efforts started during the NHSAP to continue.