

| ACTION ALERT! |

Meet with your legislators locally during the upcoming congressional recess to educate them about RLS and ask for their assistance with key policy issues.

Background

Members of Congress will be in their districts numerous times over the next few months, especially throughout the August Recess. Legislators use this time away from Capitol Hill to meet with their constituents and learn about the issues impacting the people they represent. Grassroots advocates for the restless legs syndrome community can use this opportunity to schedule meetings with the local offices of their Senators and Members of Congress to educate legislators and their staff about their condition and how they can assist and support affected individuals.

You do not need to be an expert in government to be effective, you just need to be willing to tell your story. The RLS Foundation will assist you with the rest. Taking action is easy:

- Inform the Foundation of your interest in making a local congressional visit by contacting RLSF Washington Representative Peter Herzog, at herzog@hmcw.org. At this time, please provide us with your address (including your zip code), so the Foundation can identify your legislators.
- The Foundation will send you the contact information for the local congressional office nearest you. Please call this office and work to schedule a recess meeting at a time that is convenient for you or your group's schedule.
- Familiarize yourself with the attached issue briefs and talking points. We have also included advocacy materials to provide to the office(s) that you meet with. These materials include comprehensive information that can assist you with discussing these topics.
- Consider making a local visit as a group, either with family members or other affected individuals from your area that you are in contact with.
- Meet with the local office, tell your story, ask them for their assistance on key issues, provide them with the leave behind materials, and then report back to the Foundation with a brief summary of your discussion and whether you believe any follow up is needed.
- The Foundation's Washington Representatives at the Health and Medicine Counsel of Washington (HMCW) are available to advise and assist you with making an effective local visit. Please don't hesitate to reach out with any questions or concerns!

SAMPLE MEETING OUTLINE AND TALKING POINTS

- Thank the congressional staff member for meeting with the group.
- All participants should introduce themselves and provide some personal background. The constituent(s) should lead the discussion and talk about where they are from.
- Educate the staffer about RLS and the RLS Foundation. Tell patient stories about how RLS has affected your life.
- **Introduce the Medical Research “asks”:**

There is currently no cure for Restless Legs Syndrome and treatment options are limited. Research remains critical to ultimately improving the health of individuals suffering from this debilitating disease.

 1. **National Institutes of Health (NIH):** We urge you to **support a funding level of \$41.6 billion for NIH** in the fiscal year (FY) 2020 Labor-HHS-Education Appropriations bill. This level of funding will support the progress NIH has made on medical research. Additionally, please ensure continued growth in the RLS portfolio.
 2. **Department of Defense (DOD):** RLS and other sleep disorders disproportionately affect active duty service members and first responders. In this regard, **please support including “sleep disorders” as a category eligible for study in the FY20 Peer-Reviewed Medical Research Program (PRMRP).** The Department of Defense (DOD) supports research on conditions which affect military personnel through this program.
- **Introduce the Access to Appropriate Treatments “ask”:**

Efforts to combat the opioid epidemic have resulted in access challenges for RLS patients who use opioids appropriately and as a last resort to manage their often debilitating disorder.

 1. **Appropriate Access to Low-Total Daily Doses of Opioids for RLS Patients:** 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 new 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.
- **Introduce the Education and Awareness “asks”:**

Poor provider education on Restless Legs Syndrome routinely leads to misdiagnosis and under-treatment for patients. The **Centers for Disease Control and Prevention (CDC)** National Center for Chronic Disease Prevention and Health Promotion (NCDPHP) supports provider education and public awareness efforts for prevalent chronic diseases.

 1. **National Neurological Conditions Surveillance System (NNCSS):** Please provide \$5 million for the National Neurological Conditions Surveillance System (NNCSS) for FY 2020. The NNCSS collects and synthesizes data to help increase our understanding of neurological disorders and to support further neurologic research.
 2. **Sleep Disorders Education and Awareness:** Please provide at least \$250,000 in line-item funding for sleep and sleep disorders public health activities at the CDC’s Center for Chronic Disease Prevention and Health Promotion. 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.
- Hand the staffer the leave-behind packet of information and ask if they have any questions. If you don’t know the answer to their questions off-hand, tell them you will find the answer and follow up.
- Thank them again for their time to meet, and ask for their business card, so the constituent(s) can follow up after the meeting.

Restless Legs Syndrome Foundation
Legislative Agenda
116th Congress, 1st Session

About the Foundation

The Restless Legs Syndrome (RLS) 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, 5500 members, and millions in the United States and around the world who have RLS. The RLS Foundation has members in every state, local support groups, and a research grant program that has awarded over \$1.8 million to fund medical research on RLS causes and treatments.

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 US have RLS. One in 33 adults (3 percent) needs daily clinical treatment. Treatment is life-long, and there is no cure for RLS. People with RLS experience an overwhelming, agitating and uncontrollable urge to move their legs, which can only be relieved by moving or walking to abate the sensation. RLS is at its strongest in the evening and night time hours, severely disrupting sleep. It is 3-4 times more common in women than men and is twice as common in older 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 of therapy 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 bring dramatic relief to an estimated 90-95 percent of RLS patients.

However, RLS is not chronic pain; RLS has a distinctly different underlying neuropathology. Clinical experience among experts who use opioids to treat severe RLS has not shown the degree of drug misuse, dependency or addiction that is commonly associated with opioid use to treat chronic pain. RLS is a neurological disease impacting sleep and is best managed by neurologists and sleep specialists. RLS expert experience indicates that the dose of opioids used to manage RLS is significantly lower than used to treat chronic pain effectively. Guidelines published in Mayo Clinic Proceedings are available for clinicians to appropriately prescribe opioids for RLS.

From the Patient's Perspective



“I have suffered with RLS for almost 15 years following a total knee replacement. I used to be on Requip, but following my augmentation, this medication only makes my symptoms worse. For 5 years, I have been fortunate to be on a very effective treatment regimen that includes a low dose of Oxycontin at bedtime. In the last year, I moved to Florida and have yet to find a physician willing to continue this treatment, despite my efforts to educate them by sharing clinical guidelines on safe and proper prescribing of opioids for RLS. I am worried that I may lose the ability to treat my disease and suffer needlessly, because state and federal policies are being misapplied to prevent the appropriate use of opioids to treat RLS.”

-Sandy Katanick, RLS Patient Advocate

Legislative and Policy Priorities

Medical Research

- **Please provide the National Institutes of Health (NIH) with at least \$41.6 billion in fiscal year (FY) 2020, a \$2.5 billion funding increase.** 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) for FY 2020.** RLS is a major sleep disorder that affects an estimated 40,000 active duty military personnel and readiness.

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 new 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 2020.** 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 \$250,000 in line-item funding for sleep and sleep disorders public health activities at the CDC’s Center for Chronic Disease Prevention and Health Promotion.** 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.

Restless Legs Syndrome Foundation
The Opioid Crisis and Patient Access to Effective Therapy
Statement of Principles

About The Foundation

The Restless Legs Syndrome (RLS) 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). Founded in 1989, the Foundation serves healthcare providers, researchers, 5500 members, and millions in the United States and around the world who have RLS. The RLS Foundation has members in every state, local support groups, and a research grant program that has awarded over \$1.8 million to fund medical research on RLS causes and treatments.

Restless Legs Syndrome and Opioid-Based Therapy

Restless legs syndrome (RLS) causes unpleasant or uncomfortable sensations in the legs together with an uncontrollable urge to move them. The National Institute of Neurological Disorders and Stroke (NINDS) describes RLS as a neurological sensory-motor disorder whose symptoms are produced within the brain. It is estimated that up to 5 to 7.5 percent of Americans may have RLS.

There is currently no cure for this disease and any symptomatic relief achieved with medications is not guaranteed to work forever. Therefore, all potential treatment options that are known to be effective treatments for RLS, need to be available to the individual.

Opioid medications in low-total daily doses are a recognized, effective treatment for managing RLS when alternative first-line medications do not work or become ineffective. Clinical studies and the experience of RLS-experts indicate that the average total-daily dose of opioids used to manage RLS is significantly lower than doses prescribed to treat chronic pain. Research has also demonstrated that utilization of these therapies to manage RLS does not show clinical indications of addiction or drug tolerance.

Due to the devastating nature of RLS, if patients were to lose access to these therapies, they would also lose the ability to effectively manage their disease.

Key Issues for Policymakers:

- RLS is a neurologically-based sleep disorder, and therefore, management should not fall under the exclusive purview of pain-management specialists when opioids are indicated. The underlying neuropathology in RLS is quite different from that associated with chronic pain. Therefore, long-term outcomes for opioid use in RLS should not be extrapolated from their use in chronic pain.
- The total daily dose of opiates commonly used to treat RLS is often lower than that used in managing chronic pain, which dramatically reduces the risk of tolerance and dependency.
- RLS patients and their physicians need assurance that regulations designed to curb abuse of opiates do not inadvertently penalize patients suffering from a serious disease who have exhausted other treatments. Regulations that seek to limit refills, require frequent doctors' visits and co-payments, or erect other barriers can have a devastating effect on RLS patients with no countervailing public health or safety benefit.
- Any legislation, policy, or regulation must account for the specific needs of RLS patients and not paint them with the same broad brush as other communities utilizing (and often struggling with) opioid-based treatments.

- ISSUE BRIEF -
Support Meaningful Funding for NIH Medical Research

Background

The National Institutes of Health (NIH) forms the cornerstone of the nation's biotechnology industry. NIH supports basic, translational, and clinical research into various diseases and disorders, including Restless Legs Syndrome. This federally-funded research often serves as a catalyst with industry turning medical breakthroughs and scientific advancements into innovative therapies and cutting-edge diagnostic tools.

Congress provides funding for the NIH through the annual appropriations process. Last year, Congress provided a \$2 billion funding increase for NIH and brought total funding up to \$39.1 billion. For the past few years, Congress has provided NIH with notable increases, and these increases (along with good science) have allowed the RLS portfolio to expand and advance.

NIH research has been woefully under-funded for years, and recent funding increases have reversed many of the challenges in the research community. These increases need to continue moving forward, and the entire research community is asking Congress to continue prioritizing this important research.

Talking Points

- The National Institutes of Health (NIH) supports research into Restless Legs Syndrome, primarily through the National Institute of Neurological Disorders and Stroke (NINDS) and related institutes and centers.
- Our community would like to thank Congress for providing a \$2 billion increase for NIH in fiscal year (FY) 2019 and for providing significant funding to research the opioid epidemic. The medical research community is still worried that years of near level-funding have blunted research activities at a time when there are many emerging opportunities to advance our scientific understanding of RLS. We are concerned that without meaningful financial support, the development of treatment options will be delayed, and we may lose the next generation of talented young investigators to foreign competition and other fields.
- Please work with your colleagues to provide the NIH with at least \$41.6 billion in FY 2020, a \$2.5 billion increase over FY 2019, in order to fully capitalize on research projects that will expand and advance RLS research.

- ISSUE BRIEF -
Support Research at the Department of Defense

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. In order for “sleep disorders” to continue to be listed as a condition eligible for study, it must be included in the FY 2020 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 2020 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 ravaged 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 actually 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 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 quite low.
- The needs of RLS patients who depend on regular use of low-total daily doses of opioids to manage their disease must be taken into account 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 \$7.8 billion for FY 2020 and encourage collaboration with stakeholders.
 - Please provide \$5 million for the National Neurological Conditions Surveillance System (NNCSS) for FY 2020. 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 \$250,000 in line-item funding for sleep and sleep disorders public health activities at the CDC's Center for Chronic Disease Prevention and Health Promotion. 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.

DO & DON'T TIPS FOR AN EFFECTIVE CONGRESSIONAL VISIT

DO

DO thank them for taking the time to meet with you and for considering your perspective.

DO be forthright and informative in your communications.

DO stick to the agenda.

DO keep it simple and brief.

DO tell the staffer what you would like for them to do.

DO provide the staffer with a persuasive argument, allowing each group member to contribute to the conversation when appropriate.

DO cite specific issues and data.

DO offer to provide additional background information on the subject you are discussing.

DO offer to assist the legislator's staff in any way possible.

DO let the staffer know why you care about the issue by sharing personal stories.

DO tell the staffer how this subject affects their constituents.

DO expect your legislator to be responsive to your views.

DON'T

DON'T be narrowly ideological or close-minded.

DON'T be threatening or confrontational.

DON'T be overly technical.

DON'T lose track of time. Congressional staffers are extremely busy and you should respect their schedules.

DON'T expect your legislators to drop everything and focus on your concerns.