

**REPORT OF THE
LEGISLATIVE TASK FORCE
ON PERIPHERAL NEUROPATHY**



Findings and Recommendations

**Report to the Legislature
March 31, 2009**

Pursuant to ACR 87 (Hayashi, Statutes of 2008) the Legislative Task Force on Peripheral Neuropathy convened in Sacramento, California on Wednesday, March 25, 2009. The goal of the group was to submit recommendations to the state Legislature on public and physician awareness of the diseases, as well as promoting early diagnosis, treatment and management of peripheral neuropathy. The task force was comprised of providers specializing in neuropathy, researchers of the disease, patient advocates and pharmaceutical companies. The task force meeting was sponsored by the Neuropathy Action Foundation, a non-profit advocacy organization dedicated to ensuring neuropathy patients receive proper treatment and information.

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INTRODUCTION

Peripheral neuropathy is one of the most common diseases affecting more than 20 million Americans, yet remains an enigma to many. Neuropathy means disease of one or more nerves. Neuropathies can be sensory, motor or autonomic. Sensory nerves tell us how things feel. Motor nerves stimulate muscle contraction and initiate movement. Autonomic nerves control functions that our bodies don't consciously regulate, such as breathing and heart rate. Symptoms present depend on the type of nerve and the location. The symptoms are usually numbness, tingling, pain and/or weakness. Someone with a neuropathy may notice one of these symptoms or he or she may notice that it is harder than normal to do something, such as raising an arm over the head, getting up from a seated position or walking up stairs. There are more than 100 types of PN, but the exact type in any given case depends on exactly how nerves are injured.

There are several causes of peripheral neuropathy including medical problems such as diabetes, genetic, nutritional deficiencies, toxins, compression/trauma and infiltration by tumor. In about 30 percent of patients, a specific cause of neuropathy cannot be found—even after an exhaustive search. These neuropathies are called idiopathic.

Neuropathic pain is costly. Individuals affected by neuropathic pain are oftentimes high users of the health care system as they search for relief from persistent suffering. Much of the available cost data defines costs relative to chronic pain in general so that costs attributable to neuropathic pain are contained with those numbers. Direct

and indirect costs of persistent pain, including neuropathic pain, are derived from economic, human, and societal components.

The economic burden relates to direct medical costs and productivity loss in the workplace. Chronic pain sufferers may become unemployable or remain underemployed. The National Institute for Occupational Safety and Health estimates that chronic pain costs \$100 billion annually in lost workdays, medical expenses, and other benefit costs. In terms of human costs, living with chronic pain affects patients' day-to-day ability to function. Physical and mental problems include difficulties in sleeping, impaired concentration, and decline in cognitive abilities. Pain contributes to disruption of sleep patterns, which can foster irritability, leading to enhanced sensitivity to pain, and the patient becomes caught up in a vicious cycle.

While there is no cure for peripheral neuropathy, medications and treatments can, in certain instances, provide a treatment option that will allow the individual to live a reasonably normal life. An estimated 20 million Americans (2 million Californians) have neuropathy, although the number of individuals diagnosed is far lower. It is quite common for neuropathies to be misdiagnosed or undiagnosed for years. It is because of this lack of knowledge about the condition that this task force is so vitally important. Public awareness for neuropathies is important, not just for the general populace but for the medical community.

TASK FORCE DISCUSSION

After hearing presentations about Neuropathy and new research that could help better understand the roots of neuropathy, the task force focused its discussions on three goals:

- Public and physician awareness
- Access to proper treatment
- Early diagnosis and treatment

PUBLIC AND PHYSICIAN AWARENESS

Because patients can acquire peripheral neuropathy in myriad ways, it has often been difficult for patients and physicians – especially those who do not have experience in neurology or neuropathy – to diagnose. This leads to years of pain and discomfort for patients, who feel unheard. The Task Force identified several easy ways to increase awareness, some of which would require buy-in at the legislative level; others would require coordination of stakeholders and private funders. Those ideas are included in the attached recommendations, but range from finding lawmakers and staff who have neuropathy and can advocate on the issue, to having a Capitol Lobby Day to educate lawmakers and staff about the disease. The Task Force also discussed non-legislative ways to promote awareness among the public and physicians, which included seminars specifically for physicians who provided more general care.

ACCESS TO PROPER TREATMENT

The Task Force also placed significant focus on access to proper treatment. The problem, unfortunately, is that once an individual is diagnosed, it has become increasingly difficult for that individual to obtain access to therapies, such as IVIG and other medications that can treat the condition. For example, the main barrier to obtaining access to IVIG is that payers, most notably government payers such as Medicare and Medicaid are not providing adequate reimbursement for the therapy. As a result, physicians and hospitals that would normally purchase IVIG to treat peripheral neuropathies frequently avoid doing so because the reimbursement for the therapy is not sufficient to cover the costs associated with purchasing and administering the therapy. Following the example set by government payers, more and more private payers and managed care plans are also restricting access to neuropathy therapies.

Similarly, neuropathy patients are finding it difficult to access appropriate oral medications due to cost-saving measures by health plans. Step therapy, or “fail first” policies, are used by health plans to help control costs. Some plans require neuropathy patients to try up to five different medicines before they have access to the one their provider determined was best for them. By the time the patient cycles through the two to four medications to get to the one that works, the patient is angry and the provider has spent hours of his/her time, resulting in the actual costs of care being higher than just approving the right drug initially. Requiring patients to “fail first” may cause unnecessary delays in access, and compromises patient care.

Additionally, health plans often force neuropathy patients to take medications that are off-label for neuropathy; essentially requiring patients to use treatments and

medications that have not been FDA-approved for the disease. Plans are forcing neuropathy patients to try less expensive off-label drugs first before they approve a physician's request to use newer on-label drugs. This is dangerous because it is an example of an insurance company second-guessing a physician/provider's expertise and their ability to practice medicine.

EARLY DIAGNOSIS AND TREATMENT

Discussion of Early Diagnosis and Treatment significantly overlapped with the discussion about Physician and Patient Awareness on Neuropathy. This topic was closely related to the discussion about physician awareness. The Task Force discussed how it could borrow ideas from other successful campaigns to treat chronic disease, such as Diabetes. The American Diabetes Association distributed a simple questionnaire that could be adapted for use in identifying sufferers of peripheral neuropathy. Frequent mandated screenings as well as a Center of Excellence model to help get patients to physicians with experience on peripheral neuropathy could also help identify and treat patients earlier.

CONCLUSION

Health care costs increase at a pace that is three times inflation. Given that patients who suffer from peripheral neuropathy experience significant pain and are high users of the healthcare system, it is increasingly important that patients who suffer from peripheral neuropathy are diagnosed and treated sooner in order to control costs. Proper treatment of pain should be basic health care. Based on this first Task Force meeting, it is clear that there is much to do in order to advance the profile of peripheral neuropathy. This Legislative Task Force should continue to meet periodically, as part of a Neuropathy Coalition, in order to push its agenda forward.

APPENDIX I: TASK FORCE RECOMMENDATIONS

The Task Force is pleased to present the following recommendations to the Legislature, some of which require legislative or executive branch action while others require continued coordination among interested private parties:

PROMOTE PUBLIC AND PHYSICIAN AWARENESS

- Create a Statewide Public Affairs Campaign and Use Public Service Announcements (PSAs) and Billboards
- Create a Statewide Neuropathy Week or Month
- Host a Neuropathy Day at the Capitol in Sacramento
- Identify a Celebrity Spokesperson
- Identify Legislators and Legislative Staff who Have Neuropathy
- Educate Legislators and Their Staff About Neuropathy
- Encourage Legislators to Write About Neuropathy in Their Constituent Newsletters
- Hold Community Forums for Providers
- Request State Agencies Have Links to Neuropathy Organizations on Their Websites
- Regional Presentations on Neuropathy to Educate Primary Care Providers and Others About the Disease
- Explore Voluntary CME Sponsored Events to Satisfy Requirements for Pain Management Requirements
- Encourage Statewide Medical Specialty Organizations To Hold Seminars at Statewide Meetings
- Reach out to Medical Schools and Residency Programs to Encourage Neuropathy Education as Part of Curriculum, or as Part of Residency or Intern Program

ACCESS TO APPROPRIATE TREATMENT

- Introduce and Support Legislation that Would Prohibit Step Therapy, Fail-First and Forced Off-Label Policies
 - The Legislature should pass legislation that would prohibit health plans or insurers from requiring patients to use a different medication than the one prescribed by the physician/provider. The legislation should prevent the practice of "step therapy" or "fail first." Legislation should also restrict health care plans or insurers from switching patients to off-label prescriptions, which requires patients to use medications or treatments that have not been FDA-approved for their particular condition. This policy takes healthcare decisions away from the physician/provider and has the potential to harm patients.
- Introduce and Support IVIG Standards of Care Legislation
 - The Legislature should pass legislation to enact state standards of care for IVIG. The standards would specify what would be required in order to provide IVIG and also would require that medical institutions throughout the state either stock IVIG or have direct access product in order to obtain IVIG in a short period of time. Standards would also require insurance coverage for the screening and testing procedures necessary to detect peripheral neuropathies. Lastly, such standards would also require that insurers cover all brands of IVIG, and other treatments that may be required for the treatment of peripheral neuropathies. Because IVIG is a biologic manufactured from human blood plasma, each brand of IVIG is formulated differently and has variations in its compositions. As a result, the varying brands of IVIG have different labeled indications and many physicians use their judgment, as well as trial and error, in determining which brand may work most ideally. It is not uncommon for a neuropathy patient to react quite well with one brand, while with another brand face adverse conditions and unsuccessful treatment. Therefore, it is imperative that California payers, both public and private, cover all brands of IVIG,

allowing the physician to work with their patient to administer the brand that will lead to the best medical results.

- Promote the Premise That Patients Should Have Access to Their Needed Therapies and Medications Based on Clinical Need Without Influence By Payers
- Educate Patients on the Differences Between Insurance Policies/Types of Insurance
- Educate Legislators on IVIG and Other Neuropathy Treatments
- Create A Neuropathy Coalition That Develops A “Best Practices” Model Through the Department of Public Health, Using The Diabetes Coalition’s Efforts as a Template
- Pass Legislation that Would Require Similar Formulary-Challenge Ability at the Department of Insurance Side, Which Already Exists on Department of Managed Health Care-Level

PROMOTE UNDERSTANDING OF EARLY DIAGNOSIS, TREATMENT AND MANAGEMENT

- Conduct Frequent Statewide Mandatory Awareness Screenings
- Create a Questionnaire Screening
- In Elementary, Middle, and High School, Mandate a Curriculum that Includes Physical Activity
- Identify Experts in Neuropathy – Create Regional Centers of Excellence Focused on Neuropathy

**APPENDIX II: LEGISLATIVE TASK FORCE ON PERIPHERAL
NEUROPATHY MEMBERSHIP**

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APPENDIX III: ACR 87 (HAYASHI, STATUTES OF 2008)

ACR 87, Hayashi. Legislative Task Force on Peripheral Neuropathy.

This measure would establish a Legislative Task Force on Peripheral Neuropathy, consisting of specified members, to suggest ways to promote public and physician awareness of peripheral neuropathy, promote understanding of the importance of early diagnosis and proper treatment and management, create programs to promote public and physician awareness of various treatments to improve patient care, determine how many people are affected by each type of peripheral neuropathy, and, on or before March 31, 2009, prepare a report to be submitted to the Legislature containing their suggestions.

WHEREAS, Peripheral neuropathy is a disorder that results from functional impairment or damage to nerves peripheral to the brain and spinal cord; and

WHEREAS, An estimated 20 million people in the United States suffer from peripheral neuropathy, which manifests itself in many forms, including acute motor paralysis, subacute sensorimotor paralysis, and chronic sensorimotor paralysis; and

WHEREAS, Peripheral neuropathy can result from various causes, including metabolic disease, viral and bacterial infection, physical injury, poisoning, malnutrition, and genetic disorder; and

WHEREAS, Clinical symptoms can indicate the existence of peripheral neuropathy, but precise diagnosis requires review and analysis of medical history, physical examination, medical testing, and exclusionary treatments; and

WHEREAS, Peripheral neuropathy is preventable only to the extent that the underlying cause is preventable, requiring an individual patient's alert awareness of bodily deficiency, illness, infection, or injury that can cause peripheral neuropathy, and an individual's willingness to seek early diagnosis and treatment; now, therefore, be it

Resolved by the Assembly of the State of California, the Senate thereof concurring, That the Legislative Task Force on Peripheral Neuropathy is hereby established, which shall consist of 22 members, as follows:

(a) Four members shall be Members of the Assembly, appointed by the Speaker of the Assembly.

(b) Four members shall be Senators, appointed by the Senate Committee on Rules.

(c) The Speaker of the Assembly shall appoint one representative from the Neuropathy Action Foundation, one representative from the American Diabetes Association, two members representing neuropathy patient leaders, two pharmaceutical representatives, and one member representing researchers from private universities in California.

(d) The Senate Committee on Rules shall appoint one representative from the National Institute of Neurological Disorders and Stroke, one representative from the National

Institutes of Health, one representative from the Guillain-Barre Syndrome/Chronic Inflammatory Demyelinating Polyneuropathy Foundation International, three members representing California physicians specializing in neuropathy, and one member representing researchers from private universities in California; and be it further

Resolved, That state funds shall not be used to support task force activities, but that the task force may solicit funding from private foundations, and make use of available private funds; and be it further

Resolved, That the task force shall suggest ways to promote public and physician awareness of peripheral neuropathy, promote understanding of the importance of early diagnosis and proper treatment and management, create programs to promote public and physician awareness of the use of intravenous immune globulin (IVIG) and other treatments to improve patient care, determine how many people are affected by each type of peripheral neuropathy, and, on or before March 31, 2009, prepare a report, to be submitted to the Legislature, containing its suggestions; and be it further

Resolved, That the Chief Clerk of the Assembly transmit copies of this resolution to the author for appropriate distribution.