

# **The Voice of the Patient**

A series of reports from the U.S. Food and Drug Administration's (FDA's)  
Patient-Focused Drug Development Initiative

## **Neuropathic Pain Associated with Peripheral Neuropathy**

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**Report Date: February 2017**

Center for Drug Evaluation and Research (CDER)  
U.S. Food and Drug Administration (FDA)

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## Introduction

On June 10, 2016, FDA held a public meeting to hear perspectives from people living with neuropathic pain associated with peripheral neuropathy. FDA conducted this meeting to hear about the disease, its impact on their daily life, and currently available therapies. The meeting was also part of the agency's Patient-Focused Drug Development initiative, an FDA commitment under the fifth authorization of the Prescription Drug User Fee Act (PDUFA V) to more systematically gather patients' perspectives on their condition and available therapies to treat their condition. As part of this commitment, FDA is holding at least 20 public meetings over the five-year period of PDUFA program authorization, each focused on a specific disease area.

More information on this initiative can be found at

<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm>.

## Overview of Neuropathic Pain Associated with Peripheral Neuropathy

Peripheral neuropathy, resulting from damage to the peripheral nervous system, affects an estimated 20 million people in the United States. More than 100 types of peripheral neuropathy have been identified. Neuropathic pain is a common and difficult to manage symptom of sensory nerve damage, which often occurs in association with peripheral neuropathy. Neuropathic pain may lead to an over-sensitization of nerves causing people to sometimes feel severe pain from stimuli that are normally painless. Neuropathic pain associated with peripheral neuropathy may follow different patterns which vary over a period of days, weeks, or years. Symptoms of peripheral neuropathy vary greatly depending upon the type of nerves that are damaged. This condition may cause numbness, prickling, or tingling sensations. Other common symptoms may include sharp, throbbing, or burning pain, and extreme sensitivity to touch. Peripheral neuropathy commonly affects nerves located within the extremities such as toes, feet, legs, fingers, hands, and arms. Most people who develop peripheral neuropathy are over age 55, but people can be affected at any age.

Many patients use customized treatment regimens aimed at managing symptoms that impact them the most. Types of medications often used to manage peripheral neuropathy include pain relievers, such as opioids, or over-the-counter pain medications, or anti-seizure medications, such as Lyrica (pregabalin), Topamax (topiramate), and Neurontin (gabapentin). Other prescription drugs used to manage peripheral neuropathy symptoms may include anti-depressants and muscle relaxants. Non-drug therapies and lifestyle modifications such as exercise, physical therapy, acupuncture, and limiting physical activity may also be utilized for symptom management.

## Meeting overview

This meeting provided FDA the opportunity to hear directly from patients, caretakers, and advocates about their perspectives and experiences on neuropathic pain associated with peripheral neuropathy, and its treatments. The discussion focused on two key topics: (1) disease symptoms and daily impacts that matter most to patients, and (2) patients' perspectives on current approaches to treating neuropathic pain associated with peripheral neuropathy. The questions for discussion (Appendix 1) were published in a [Federal Register notice](#) that announced the meeting. For each topic, a panel of patients (Appendix 2) shared comments to begin the dialogue. Panel comments were followed by a facilitated discussion inviting comments from other patients and patient representatives in the audience. The

discussion was led by an FDA facilitator, and a panel of FDA staff (Appendix 2) asked follow-up questions. Participants who joined the meeting via live webcast were invited to submit comments throughout the discussion. Additionally, in-person and web participants were periodically invited to respond to polling questions (Appendix 3), which provided a sense of the demographic makeup of participants and how many participants shared a particular perspective on a given topic.

Approximately 37 patients who experience neuropathic pain associated with peripheral neuropathy or patient representatives attended the meeting in-person, and over 54 web participants provided input through the live webcast and polling questions. According to their responses to the polling questions and registration data, in-person and web participants represented a range of patients, with a slightly higher proportion of women, adults aged 18-70+, and patients living with the disease for more than 10 years and others only living with the disease less than 1 year. Although participants may not fully represent all of the population living with neuropathic pain associated with peripheral neuropathy, FDA believes that the input received reflects a range of experiences with symptoms and treatments of the condition.

To supplement the input gathered at the meeting, patients and others were encouraged to submit comments on the topic to a public docket, which was open until August 10, 2016. Approximately 105 comments were submitted to the public docket,<sup>1</sup> the majority by individual neuropathic pain associated with peripheral neuropathy patients and caregivers. FDA also received comments from advocacy groups. Two of the submitted comments from advocacy organizations contained data from surveys of neuropathic pain patients.

More information on the meeting, including the archived webcast recording and meeting transcript, is available on the meeting website:

<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm490866.htm>

## Report overview and key themes

This report summarizes the input provided by patients and patient representatives at the meeting and through the webcast. It also includes a summary of comments submitted to the public docket. To the extent possible, the terms used in this report to describe specific neuropathic pain associated with peripheral neuropathy symptoms, impacts, and treatment experiences reflect the words used by in-person attendees, web participants, and docket commenters. The report is not meant to be representative in any way of the views and experiences of any specific group of individuals or entities. There may be symptoms, impacts, treatments, or other aspects of the disease that are not included in the report.

Several key themes emerged from this meeting:

- Patients struggled daily with their symptoms. Patient experienced numerous pain sensations including, but not limited to: numbness, tingling, burning, and stabbing in various locations of the body; particularly their hands and feet. Patients experience neuropathic pain unpredictably and suddenly, limiting their ability to obtain adequate pain control on a consistent basis.

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<sup>1</sup> A *docket* is a repository through which the public can submit electronic and written comments on specific topics to U.S. federal agencies such as FDA. More information can be found at [www.regulations.gov](http://www.regulations.gov).

- Patients experienced difficulty in achieving pain relief. Participants described using a complex regimen of both drug and non-drug treatments when pursuing symptom control with a vast range of variability in effectiveness. They noted the significant burden of trial and error therapy regimens, the difficulty of weighing benefits and adverse effects when making treatment decisions, and the challenges they faced in obtaining access to prescription drug products.
- Patients and families shared the devastating toll neuropathic pain takes on their lives. Many participants described loss or significant changes to their careers, limited social interactions, decreased quality time with family, and feelings of hopelessness due to their disease.
- Patients emphasized the need for increased awareness and research of neuropathic pain associated with peripheral neuropathy across the medical community. Participants expressed a desire for focused research in the areas of pain management and nerve regeneration.

The patient input generated through this Patient-Focused Drug Development meeting and public docket strengthens FDA's understanding of the burden of neuropathic pain associated with peripheral neuropathy on patients and the treatments currently used to manage its symptoms. FDA staff will carefully consider this input as it fulfills its role in the drug development process; including advising sponsors on their drug development programs and assessing benefit-risk for products under review for marketing approval (see Appendix 4). This input may also be of value to the drug development process more broadly. For example, the report may be useful to drug developers as they explore potential areas of unmet need for neuropathic pain associated with peripheral neuropathy patients in areas such as pain control and nerve regeneration. It could also point to the potential need for development and qualification of new outcome measures in clinical trials.

## **Topic 1: Disease Symptoms and Daily Impacts That Matter Most to Patients**

The first discussion topic focused on patients' experiences with neuropathic pain associated with peripheral neuropathy symptoms and the resulting effects on their daily lives. FDA was particularly interested in hearing about specific activities that patients can no longer do at all, or as fully as they would like, because of their condition.

Four panelists with peripheral neuropathy (Appendix 2) provided comments to start the dialogue: a thirty-year-old man detailed his experiences of developing the disease in his young adult years, a sixty-one-year-old man described his balance issues due to the disease, a sixty-nine-year-old woman shared her experiences of developing the disease following treatment for cancer, and a fifty-nine-year-old woman highlighted specific challenges with her condition due to disease progression. All panelists reported a range of neuropathic pain symptoms which exhibited variable levels of intensity.

The panelists' testimonies provided a vivid description of what it is like to live with neuropathic pain associated with peripheral neuropathy. They described their challenges with diagnosis, their experiences with treatment and achieving pain control, as well as the day to day impact of living with their condition. The panelists also described the significant physical and social impacts they have experienced. In the large-group facilitated discussion that followed the panel discussion, nearly all participants indicated that their experiences were reflected in the panelist comments. The remainder of this section summarizes input from in-person and web participants on their most significant symptoms and their

broader impacts on daily life.

## Perspectives on most significant symptoms

Many patients stated that the painful sensations they experience are the most significant symptoms of living with neuropathic pain associated with peripheral neuropathy. Participants expressed variation in the frequency, intensity, and type of pain they experience. Participants were able to describe these experiences with vivid detail as highlighted in the content below.

### *Pain*

In-person and web participants provided in-depth perspectives on pain experienced throughout the body or in one or more localized areas. Participants used a variety of terms to describe the intensity of their pain such as: “sharp,” “constant,” “bruising,” “crushing,” and “soreness.” A few participants also noted experiencing “flares” during which pain increases in intensity. During the large-group facilitated discussion over one-third of participants indicated they were currently in pain during the meeting. In a polling question (Appendix 3, Q9), participants were asked to describe how their neuropathic pain manifests. Participants shared varying experiences with the onset and frequency of their pain, including:

- “This pain is 24/7, it doesn’t go away.”
- “[My pain] is more of a week to week or a month to month fluctuation.”
- “My pain isn’t just different day to day. It’s different moment to moment.”

Some participants also noted that the pain they experience may be dependent upon their level of activity throughout the day:

- “If I were to stand for... 10 minutes [or] walk a half to three-quarters of a mile, I would start getting deep muscular pain.”
- “Sometimes it’s painful when I’ve been sitting for a long time and get up.”
- “[Pain] usually happens when I am overtired [or if] I’ve been standing or walking for more than a few minutes.”

In a polling question (Appendix 3, Q8), participants were asked to identify what part(s) of the body they experience the most severe neuropathic pain. In-person and web comments identified feet, legs, hands, and arms as the primary areas of severe pain. Additional areas identified included neck, face, shoulders, and stomach. Participants noted throughout the discussion that the pain they feel is often not localized and can manifest in various locations throughout the body.

The facilitated discussion provided insight into how aspects of neuropathic pain manifest and the interrelation between various pain sensations. Participants were able to articulate the specific types of neuropathic pain most bothersome in their life. Participants also contrasted differences between the types of pain sensations in vivid detail.

Many participants identified **numbness and tingling** as two of the most bothersome aspects of their disease. Some noted that the numbness and tingling were the first sensations they experienced when developing peripheral neuropathy. One participant stated, “The symptoms [of peripheral neuropathy] began slowly... [this] sort of tingling and numbness in my hands.”

Although participants described numbness as a lack of feeling, they stressed that they can also still experience pain in the same part of the body. One panelist best described this by stating, “Because you are numb doesn’t mean you don’t feel pain. You can have numbness and still feel severe pain.” The association of numbness with pain resonated with the audience. Another participant noted that he experienced, “more numbness than pain.” The large-group facilitated discussion provided insight into the sensations associated with numbness. Some participants noted that they experience numbness continuously, while others expressed their symptoms may come and go. When discussing numbness participants described the experience with vivid details further expanded upon below:

- “[It is] the sensation of our feet or legs going to sleep...you move your foot and wiggle your toes and you can see it, but you can’t feel anything.”
- “[Numbness] feels like I am walking with two prosthetic legs.”
- “I would get this weird sensation that I was wearing socks, but I wasn’t.”

Participants articulated **tingling** as a distinct sensation from numbing, as illustrated by these examples:

- “The tingling is like something that’s creepy, crawling all through under your skin, every which way. [With numbness] you can’t distinguish the feeling. If you were to squeeze my leg, I can’t really tell.”
- “The tingling is sort of like when the sensation [from a period of numbness] is starting to return and you start getting that first feeling of the sensation coming back.”
- “[Numbness] it’s having you big toenail ripped off and not knowing it. The tingling, it can be like jabs and darts.”
- “[Numbness and tingling are] not mutually exclusive. When you’re numb, you may also be feeling tingling at the same time.”

Many participants described experiencing **shocks** due to peripheral neuropathy. Participants likened this sensation to the feeling of electrical shocks. One participant described it as, “sticking your finger in a light socket.” Another participant described it as, “lightning bolts, severe sunburn, and numbness all at once and in levels.” Participants noted that shocks may be triggered by interactions with different surfaces. One participant shared, “my child’s hand on mine can feel like 12,000 volt electric shock.” Participants also noted that shocks may occur in “short burst” and in addition to other sensations.

Several participants commented on experiencing a **burning sensation**. Participants described “being on fire,” “intense sunburn,” “stepping on frying pans,” and “applying a blow torch to your body.” Participants shared how debilitating the burning sensation can become in their day to day life either because of its intensity or because of its sudden onset. A few participants noted that their burning is intensified when they are overtired or have been standing or walking for more than a few minutes. One participant shared that the burning sensation usually began as a tingling sensation which became more intense. A few participants mentioned using ice or ice buckets to manage this symptom temporarily.

A few participants experienced **stabbing pain**, which one participant described as “someone inserting spikes, a knife, or an ice pick into their body.” One participant illustrated the stabbing pain as, “pounding a nail into [the same location] over and over and over again.”

### *Other Symptoms*

In addition to numbness, tingling, and burning, participants highlighted a number of other sensations and symptoms that have a significant impact on their daily lives.

- Many participants noted issues with **balance and coordination** due to the lack of awareness of certain areas of their body and their surroundings. One participant described this feeling as “losing contact with the ground.” Participants detailed their experiences with falling due to lack of balance and numbness throughout the meeting. One participant shared, “I fell a couple of times because [of] not knowing where my feet were.”
- Several participants described issues with **inconsistent sleep patterns and insomnia** due to neuropathic pain. Many participants credited their lack of sleep to painful sensations occurring throughout the night. One participant noted, “Pain often wakes me very early, and as this has become a nightly experience, I now dread going to bed.” Another participant stated, “[once awakened by pain] getting back to sleep is not an option.”
- **Other symptoms** mentioned by participants included hot or cold sensitivity, prickling sensations, soreness, itching, and cramps.

### **Overall impact of neuropathic pain associated with peripheral neuropathy on daily life**

Both in-person and web participants described in rich detail the impact that their condition has on daily life, including:

- **The ability to perform activities.** Participants expressed how neuropathic pain associated with peripheral neuropathy has affected their ability to perform activities. One participant described the restrictions by sharing, “anything that would require one to stay on their feet for an extended period of time can be dramatically impacted.” Participants also noted that pain while sitting down can also impact activity. One participant shared, “I can’t sit for long periods. So even just going to the movies or plays, a game is uncomfortable.” Participants also experienced driving difficulties. One participant expressed, “when I drive I have to keep my foot on the hump to make sure I don’t go through the brake pedal and the gas pedal.” Another participant mentioned an experience of unknowingly stepping on the gas pedal instead of the brake.
- **Impact on work and careers.** Several participants discussed hardships at work they experienced due to peripheral neuropathy. One participant stated that she reduced her work hours from 60 per week to 8 per week due to the inability to stand for long periods of time. Another participant stated that she decided to sell her business due to “unpredictable pain, sleeplessness, and lack of focus.”
- **The impact on relationships.** Participants also addressed how symptoms of neuropathy often limit their interactions within relationships. One participant shared, “[due to increased sensitivity to cold] I can’t take my grandkids ice skating or teach them how to ski.” Another participant stated, “I must often choose between meeting [family] responsibilities or taking the time to accommodate my pain and treatment.” One participant described difficulties in intimate situations, saying “if there is any friction [on my stomach] it is a great deal of pain.” Another



participant attributed her lack of libido due to her treatment regimen for neuropathy and painful symptoms.

- **Worry about the future.** Several participants focused on their concerns about the future, particularly regarding disease progression. One participant described his biggest fear as “some dramatic uptick in symptoms which would ... quite literally disable me.” Another participant stated, “I’m concerned that I’ll be walker-dependent and ultimately wheelchair-bound before my time.” A few participants also expressed concern about their ability to adequately manage their pain as their symptoms worsen (described further in the next section).

## **Topic 2: Patient Perspectives on Treatments for Neuropathic Pain Associated with Peripheral Neuropathy**

The second discussion topic focused on patients’ experiences with therapies used to manage their neuropathic pain associated with peripheral neuropathy. Four panelists provided comments to start the dialogue: a forty-seven-year-old woman detailed her experiences with a wide range of treatments which included use of epidurals, medical procedures, physical therapy, and various over the counter and prescription medications; a man diagnosed 7 years ago shared his experiences of managing peripheral neuropathy via complementary medicine, lifestyle changes, and meditation; one woman diagnosed 18 years ago shared her issues with achieving pain control and balancing the need to increase medication dosage and frequency; a seventy-two-year-old woman highlighted the difficulties of managing peripheral neuropathy while also managing Lyme disease. Each panelist described the complex process of utilizing drug and non-drug modalities to manage their condition. Out of the four panelists, only one described their pain as well managed.

### **Perspectives on current treatments**

In the large-group facilitated discussion, patients and patient representatives in the audience indicated by a show of hands that their experiences (or those of loved ones) were reflected within the comments expressed by the panelists. The facilitated discussion included experiences shared with prescription drugs, surgery, over-the-counter, non-drug, and alternative therapies. Participants described a complex trial and error process to find an effective regimen which fit their needs, with respect to pain management and adverse effects. Participants’ perspectives on the benefits and downsides of these therapies are summarized below.

#### *Prescriptions and over-the-counter drugs*

In a polling question (Appendix 3, Q12), participants were asked to identify what drug therapies they utilized to treat neuropathic pain. In-person and web participants frequently identified taking or having taken a prescription medication to manage their peripheral neuropathy symptoms. Overall prescription and over-the-counter drug products were described as varying widely in effectiveness, often leading to limited or decreased benefits over time. Some participants stated that continuing treatment has been difficult due to side effects, even when the treatment is effective. Their experiences with specific drug classes and products are described below.

### *Anticonvulsant Drugs*

Meeting participants discussed in detail their experiences with anticonvulsant drug products, particularly Lyrica (pregabalin) and Neurontin (gabapentin). Several participants described anticonvulsants as providing tolerable pain management, but not completely eliminating pain (“taking the edge off”). However, participants noted that even a modest reduction in pain due to anticonvulsants often allowed them a level of functionality that they would not otherwise have. As one participant stated, “Without [gabapentin], I couldn’t function. My pain level today is greatly reduced.” Another panelist shared her experiences with pregabalin stating, “at the beginning [of treatment], my pain [level] was an eight or nine. Now I have days at five or six.”

Participants also described the downsides of their anticonvulsant use. Participants experienced a variety of cognitive effects including drowsiness, difficulty focusing, and short-term memory loss. Participants often referred to these cognitive effects as “brain fog.” One participant provided an example of this experience, stating: “sometimes I’ll be talking to people and in the middle of a sentence, I won’t be able to remember what I was saying when the sentence started.” Another participant described the mental effects as “being in a speed boat and somebody throws an anchor over the side.” Other side effects mentioned included weight gain and dizziness. While many participants expressed a willingness to cope with the side effects in exchange for the level of pain control they receive, others were unwilling or unable to continue use of anticonvulsants.

Several participants shared their anxiety regarding long-term side effect of anticonvulsants use. One participant stated, “I know how [Lyrica] affects me with the brain fog now and I think long-term what might that do to me.” Another participant asked how the potential impacts of anticonvulsants taken for 10 or 20 years are evaluated by FDA.<sup>2</sup>

### *Pain Relievers*

Throughout the facilitated discussion, participants also shared their experiences with prescription and over-the-counter pain medications. Drugs mentioned included naproxen, acetaminophen, diclofenac, ibuprofen, morphine, lidocaine, fentanyl, tramadol, hydrocodone, oxycodone, methadone, and opioid combination products such as Percocet (oxycodone and acetaminophen) and Vicodin (hydrocodone and acetaminophen). Some participants described using these medications as needed, while others indicated that they take pain medications daily. Throughout the meeting participants repeatedly noted the use of pain relievers with other medications as part of their treatment regimen.

Due to the range of treatments, participants tended to comment on the effectiveness of their regimen as a whole instead of focusing on specific drug products. One participant expressed, “I take Lyrica three times a day, Neurontin twice a day, naproxen twice a day. I’m sitting here and I’m still in a lot of pain.” Another participant shared, “opioids and the Lyrica is helping to try to take [my pain] down and notch...so I can function.” A few participants stated specifically that opioid pain medications have been effective in managing their pain. One participant shared, “None of the drugs worked except for opiates.”

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<sup>2</sup> In response to this comment, a FDA panel member described FDA’s postmarketing surveillance and risk assessment programs to monitor for and assess potential drug adverse events. For more information on FDA’s postmarketing surveillance programs please refer to <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/ucm090385.htm>

One participant also noted using pain relievers helped with sleep issues. Participants also expressed concern due to lack of pain relief options. One panelist described her process of “hold[ing] back” by not using the maximum dose of a medication even when in severe pain, due to lack of remaining treatment options if her pain level is no longer managed by the maximum dose.

### *Other Treatments*

Other drug classes and medical procedures mentioned throughout the meeting include: antidepressants, muscle relaxants, steroids, epidurals, plasmapheresis, sleep aids, benzodiazepines, medical marijuana, cannabinoid oil, stem cell therapy, and laser treatments. A few participants shared their experiences with the use of medical devices to manage pain symptoms. Specific devices identified included TENS (Transcutaneous Electrical Nerve Stimulation), a Rebuilder unit, and low level light therapy devices. One participant highlighted her experiences of using a cervical traction unit in addition to epidurals, as only temporary alternatives to pain reduction.

In addition to medical treatments, several participants highlighted the importance of non-medical therapies as part of their treatment regimen. Participants mentioned a range including the following:

- Many participants shared their experiences using **physical activity**, such as swimming, hiking, weight lifting, and stretching, as a form of therapy to manage painful neuropathy symptoms. A few participants highlighted the benefits of yoga and tai-chi because of their focus on stretching. Participants did note that their condition can require limitations on their physical activities. For example, one participant described being limited to exercises that do not require standing. A few participants shared that they were unable to continue physical therapy because it aggravated pain symptoms.
- Some participants discussed **massage and acupuncture**. One participant noted the use of more targeted massage techniques such as craniosacral therapy and reflexology. A few described the benefits of these therapies as “effective as a short term remedy,” providing “temporary relief.” A few participants, however, did not find benefit in these therapies. For example, one participant stated, “Massage and acupuncture were not successful at all. Acupuncture was in fact quite excruciatingly painful.”
- A few participants also described **mindfulness and meditation** as a means to improve pain control. These participants expressed satisfaction in not only the physical benefits of meditation, but also the psychological results.
- Additional non-medical therapies mentioned by participants included therapeutic beds and pillows, ice, heat, hydrotherapy, use of an inversion table, dietary changes, homeopathic remedies, Epsom salt, and orthopedic footwear.

### **Perspectives on an ideal treatment for neuropathic pain associated with peripheral neuropathy**

Throughout the meeting, participants provided perspectives on ideal treatment for neuropathic pain associated with peripheral neuropathy. Participants stressed the need for “broad” pain control which would cover a wider range of painful sensations. One participant stated that broader pain control would reduce the amount of drug products needed to cover the full range of painful neuropathy symptoms.

Participants also desired an ideal treatment with fewer long-term and short-term side effects. As one participant explained, “I would just like something I could take and wouldn’t have to worry so much about the consequence.”

In the meeting, FDA expressed interest in hearing patient perspectives on two possible approaches to treating peripheral neuropathy: (1) drug products that target symptomatic pain (e.g., reducing sensations of pain), and (2) disease-modifying drug products that slow or reverse the loss of feeling and numbness. Overall, participants felt that one treatment goal should not take priority over the other, since both aspects of treatment are important and address an unmet need in the peripheral neuropathy community. One participant explained that an individual patient’s perspective on one approach over another will be influenced by what state of disease progression the patient is at. Another participant illustrated this concept stating, “I first chose to stop the progression... But once the progression was stopped, I [didn’t] have any pain relief.” Another participant explained that, “I’m on both sides of this issue. The pain control, when you’re in that level of pain, you can’t go on without it. But the disease modifying, where all of a sudden you don’t need the pain control, is definitely worth research dollars, of which neuropathy gets very few.”

### **Considerations regarding a hypothetical treatment**

FDA was also interested in understanding the factors patients take into account when making decisions about treatment. To help guide the discussion, participants were asked to imagine a scenario in which a new medication for neuropathic pain associated with peripheral neuropathy was recently approved by FDA (see full text in Appendix 3). This hypothetical treatment demonstrated a 50% reduction in pain in clinical trials and was associated with a mix of common side effects, such as nausea, and rare severe side effects such as nerve damage.

Participants were asked to comment on the first thoughts that came to mind as they heard this scenario. Overall participants expressed general interest in this hypothetical treatment; however they commented that the lack of specific information in the scenario regarding severe side effects and long term outcomes of the product were aspects would cause concern. A few participants commented on specific details of the study that they would want to know, including:

- “What the protocols are when I start, what do I do before, what do I do during [treatment] and how long after to look for the nerve damage.”
- “The statistical likelihood of the serious side effect.”
- “How many people were in this study and if there had been any longer term studies.”

### **Summary of Comments Submitted to the Public Docket**

FDA received approximately 105 comment submissions to the public docket that supplemented the input received at the Patient-Focused Drug Development meeting on neuropathic pain associated with peripheral neuropathy. The majority of comments were submitted by patients and caregivers. Collated input from multiple patients was submitted by The Western Neuropathy Association and Guillain-Barre Syndrome (GBS)/ Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Foundation International. Two surveys were submitted by advocacy organizations: Neuropathy Support Network and Foundation for Peripheral Neuropathy. The submitted surveys and collated comments varied in content and in number of participants.

Overall, the docket comments were widely reflective of the experiences and perspectives shared at the meeting on the symptoms that affect their lives the most, the impacts of their disease on daily life, and their experiences with treatment. The comments also provided additional context which supports the input received during the meeting.

*Submitted comments on symptoms of neuropathic pain associated with peripheral neuropathy*

The docket comments, including surveys and collated comments, emphasized the debilitating nature and significant impact of the disease on a patient's life. Similar to the public meeting participants, the docket comments vividly described pain sensations and impacts attributed to neuropathic pain associated with peripheral neuropathy. In the information that follows particular focus was placed on experiences or perspectives that were not raised or addressed in detail at the meeting.

- Many commenters described the **pain** they experience as intense, life-changing, debilitating, sudden, sharp, stabbing, chronic, intense, and “concentration-stealing.” Commenters also described the unpredictability associated with their pain symptoms. One commenter stated, “I never know day to day what will hurt, how long it will hurt, and how badly.” Some commenters also described their pain as continuous or chronic. One commenter described their pain as “constant, 24 hours a day, 7 days a week.” Other comments expressed variability in pain symptoms. One comment shared, “some days are good where others are sheer hell.” Comments regarding pain closely mirrored feedback received during the in-person meeting.
- Many commenters described a number of common **neuropathic symptoms** including numbness, tingling, electric shocks, and pins and needles. Commenters often described their pain with vivid illustrations such as: bee stinging, ants biting with acid, ice picks in the eye, walking on hot coals, and lightning. One commenter stated, “[it feels] like my feet are being squeezed in vice grips or encased in concrete.” Additional sensations described by meeting participants included muscle spasms, temperature sensitivity, stabbing and stinging sensations.
- Several **pain locations** were also mentioned throughout the docket comments. Comments described experiencing pain in their legs, arms, feet, and hands. Commenters shared the experience of pain spreading to different locations of their body. One docket commenter detailed a progression of her pain which began as “episodes of burning legs” and became “burning [in her] face and jaw” and “painful stabbing feelings” in her left chest and left arm. Of note, a few commenters also mentioned experiencing mouth and facial pain due to burning mouth syndrome, a rare disease associated with peripheral neuropathy, and trigeminal neuralgia. Additional locations of pain mentioned by participants included buttocks, groin, neck, as well as chest.
- Many commenters described **balance issues**. Similar to meeting participants, commenters attributed balance issues to numbness and lack of awareness of their feet and legs while standing. One commenter summarized this sentiment stating, “Keeping my balance is difficult and dangerous because of numbness and the feeling that the bottoms of my feet are blocks of wood.” Commenters’ also attributed balance issues to lack of ability to focus and concentrate.
- **Sleeping difficulties** were also noted within docket comments. Several comments expressed experiencing “constant fatigue, daytime sleepiness, and pain” due to lack of sleep. Many commenters noted that pain often occurs at night making it extremely difficult to remain

sleeping. One commenter shared, “I will lay in bed for hours, sometimes I will be awake all night [due to pain].” Another commenter mentioned experiencing insomnia due to the need to take pain medication every six or seven hours.

*Submitted comments on the overall impact on daily life of neuropathic pain associated with peripheral neuropathy*

The docket comments and survey results submitted by patient advocacy groups also reflected the input received during the meeting on the debilitating impact that neuropathic pain associated with peripheral neuropathy has on patients’ daily lives, and the toll the disease has on patients and their families.

- Many commenters focused on the impacts on **personal and family life**, which primarily included taking care of themselves, their children and managing their household. Commenters expressed experiencing loss of family connections due to their disease. One commenter expressed, “I couldn’t kiss my husband or kids, or grandson. I couldn’t even have my family over [due to the pain].” Another commenter shared, “I spent two hours after work writhing in pain...I couldn’t cook supper for my husband and two children.” Other commenters focused on the inability to care for themselves and partake in daily activities such as preparing meals, laundry, and daily hygiene. A few comments focused on effects of reduced sexual intimacy within their marriage and close relationships.
- Many commenters shared the **social impacts** of peripheral neuropathy symptoms. Some commenters attributed social impacts due to lack of understanding of peripheral neuropathy by those around them. One commenter described: “It [is] difficult for family, friends, and even your work associates [to understand] when you can never commit to any long-term plans, as you never know when your pain will flare up leaving you incapacitated.” Additional commenters attributed their lack of social engagement to remaining mainly “house-bound” or “bed-ridden” due to pain. A few commenters noted that pain has affected their mood and caused them to become “very intolerant,” impatient, and short-tempered when interacting with others.
- Many commenters addressed impacts on **job performance**. Commenters shared various experiences ranging from not being able to work at all to limitations on time at work. Commenters described the following restrictions to job performance: inability to walk and stand for extended periods of time, inability to drive, cognitive issues, lack of concentration, and lack of energy.
- Many commenters emphasized the **emotional burdens** of neuropathic pain associated with peripheral neuropathy. Commenters described severe periods of emotional strain due to their condition. Commenters expressed experiencing periods of frequent crying, suicidal thoughts, extreme hopelessness, and depression.
- Few commenters discussed **worry about the future**. Commenters expressed concern that progression of pain symptoms will reduce their ability to perform activities and limit remaining treatment options. Commenters also shared fears of becoming housebound.
- Several commenters also reiterated concerns and frustration regarding the **lack of understanding in the medical community**. Many shared experiences of the difficulties in

finding doctors who understood their condition, being prescribed helpful medications, and the stigma surrounding the use of medications which target pain. In addition commenters expressed the need for more research in the peripheral neuropathy community.

*Submitted comments on current treatments for neuropathic pain associated with neuropathy*

The submitted comments reflected the challenges of managing the many symptoms of neuropathic pain associated with peripheral neuropathy, while making difficult decisions about treatments. Both drug and non-drug treatments were mentioned within docket comments. The ranges of experiences expressed by commenters were similar to those from public meeting participants and are provided below.

- Commenters shared their experiences using a range of **anticonvulsants** including Lyrica (pregabalin), Neurontin (gabapentin), Keppra (leviracetam), Tegretol (carbamazepine), Topamax (topiramate) and Vimpat (Lacosamide). Drug products mentioned frequently by commenters included Lyrica (pregabalin) and Neurontin (gabapentin). Similar to meeting participants, many commenters expressed that use of anticonvulsants has provided some pain relief but does not fully cover all of their pain symptoms. One commenter expressed lack of relief with anticonvulsants due to becoming “maxed out of approved levels with each medication.” Additional commenters also highlighted the need to increase anticonvulsant dosages regularly to obtain pain relief. Of note, commenters also expressed difficulties with withdrawal symptoms following attempts to reduce medication dosage. Downsides expressed by commenters included cognitive impairment, fatigue, dizziness, and weight gain.
- Many commenters focused on the use of **pain relievers**. The common classes of pain relievers expressed throughout the docket included NSAIDs (non-steroidal anti-inflammatory drugs), and opioid pain medications. Commenters described use of different types of pain medications for different symptoms. One commenter noted using lidocaine patches nightly for pain control and tramadol as needed when burning or stabbing pain sensations became too intense. Several commenters expressed difficulty in obtaining prescription pain medication due to insurance restriction and being stigmatized as a “drug seeker.”
- Many commenters described their experiences with **antidepressants**. Antidepressants mentioned by commenters included Cymbalta (duloxetine), Zoloft (sertraline), Elavil (amitriptyline), Doxepin (sinequan) and Effexor (venlafaxine). Commenters expressed varying levels of pain control achieved by antidepressants ranging from “modestly effective” to “absolutely worthless.” One commenter expressed that amitriptyline is the only medication that helps with pain management on a daily basis.
- **Other drug therapies** mentioned by commenters included: muscle relaxants, IVIG (intravenous immunoglobulin), compounded pain relief creams, and medical marijuana.
- Discussion on **non-drug therapies** and medical devices was very similar to input received during the meeting. Several comments focused on exercise, meditation, herbal supplements, acupuncture, electrical stimulation of nerve cells, and behavioral techniques.

### *Submitted comments on ideal treatments for neuropathic pain associated with peripheral neuropathy*

Several perspectives were provided on ideal treatments for neuropathic pain associated with peripheral neuropathy. These perspectives on ideal treatments were very similar to input received from meeting participants. Commenters expressed the desire for a treatment which improved pain control without side effects. One commenter shared, “an ideal pain medication would be non-sedating, not habit-forming or addictive, [and] tolerated for long-periods of time without needing increases in dosage.” Other aspects of ideal treatments included affordability and minimal health impacts when used long-term. Participants also highlighted the need for, increased knowledge in the medical community on neuropathic pain and peripheral neuropathy.

## **Conclusion**

This meeting was the nineteenth of the Patient-Focused Drug Development meetings. It allowed FDA to hear patients’ in-depth point of view on the severity of neuropathic pain associated with peripheral neuropathy, its impact on daily life, and available treatment options. FDA recognizes that patients are uniquely able to contribute to our understanding of the broader context of this disease, which is important to our role, and that of others, in the drug development process. We are very grateful to all of the participants who so thoughtfully and courageously shared such personal stories and perspectives.



## Appendix 1: Meeting Agenda and Discussion Questions



### Neuropathic Pain Associated with Peripheral Neuropathy Patient-Focused Drug Development Meeting



June 10, 2016

12:00 – 1:00 pm	<b>Registration</b>
1:00 – 1:05 pm	<b>Welcome</b> Soujanya Giambone, MBA Office of Strategic Programs (OSP), Center for Drug Evaluation and Research (CDER), FDA
1:05 – 1:10 pm	<b>Opening Remarks</b> Pamela Horn, MD Medical Officer Team Lead, Division of Anesthesia, Analgesia, and Addiction Products (DAAAP), CDER, FDA
1:10 – 1:20 pm	<b>Overview of FDA’s Patient-Focused Drug Development Initiative</b> Sara Eggers, PhD OSP, CDER, FDA
1:20 – 1:30 pm	<b>Background on Pain Neuropathies and Available Treatments</b> Steven Galati, MD Medical Officer, DAAAP, CDER, FDA
1:30 – 1:35 pm	<b>The Road from PFDD Meetings to Clinical Trial Endpoints</b> Nikunj Patel, Pharm.D. Clinical Outcome Assessments Staff, CDER, FDA
1:35 – 1:40 pm	<b>Overview of Discussion Format</b> Soujanya Giambone, MBA OSP, CDER, FDA
1:40 – 2:10 pm	<b>Panel #1 Discussion on Topic 1: Disease Symptoms and Daily Impacts</b> Topic 1: A panel of patients and caregivers will provide comments followed by a large-group facilitated discussion with participants in the audience.
2:10 – 2:45 pm	<b>Large-Group Facilitated Discussion: Topic 1</b> Patients and patient representatives in the audience will be invited to add to the dialogue.
2:45 – 2:55 pm	<b>Break</b>
2:55 – 3:25 pm	<b>Panel #2 Discussion on Topic 2: Current Approaches to Treatment</b> Topic 2: A panel of patients and caregivers will provide comments to start the discussion on current approaches to treating neuropathic pain associated with peripheral neuropathy
3:25 – 4:25 pm	<b>Large-Group Facilitated Discussion: Topic 2</b> Patients and patient representatives in the audience will be invited to add to the dialogue.
4:25 – 4:55 pm	<b>Open Public Comment</b>
4:55 – 5:00 pm	<b>Closing Remarks</b> Sharon Hertz, MD Director, DAAAP, CDER, FDA

## Discussion Questions

### Topic 1: Disease symptoms and daily impacts that matter most to patients

- 1) How would you describe your pain associated with peripheral neuropathy? What terms would you use to describe the most bothersome aspects of pain? (Examples may include stabbing sensations, electric shocks, burning or tingling, etc.)
- 2) Are there **specific activities** that are important to you but that you cannot do at all or as fully as you would like because of your neuropathic pain? (Examples of activities may include sleeping through the night, daily hygiene, participation in sports or social activities, intimacy with a spouse or partner, etc.)
- 3) How does your neuropathic pain affect your daily life on the **best days**? On the **worst days**?
- 4) How has your neuropathic pain **changed over time**?
- 5) What **worries you most** about your condition?

### Topic 2: Patients' perspectives on current approaches to treatment

- 1) **What are you currently doing** to help treat your neuropathic pain associated with peripheral neuropathy? (Examples may include prescription medicines, over-the-counter products, and other therapies including non-drug therapies such as physical therapy).
  - a) How has your treatment regimen changed over time, and why?
- 2) **How well** does your current treatment regimen control your neuropathic pain?
  - a) How well have these treatments worked for you as your condition has changed over time?
  - b) Would you define your condition today as being well managed?
- 3) What are the most significant **downsides to your current treatments**, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, going to the hospital or clinic for treatment, time devoted to treatment, restrictions on driving, etc.)
- 4) Assuming there is no complete cure for your neuropathic pain, what specific things would you look for in an **ideal treatment** for your neuropathic pain?
  - a) What would you consider to be a meaningful improvement in your condition (for example specific symptom improvements or functional improvements) that a treatment could provide?
- 5) If you had the opportunity to consider participating in a clinical trial studying experimental treatments for neuropathic pain, what things would you consider when deciding whether or not to participate? (Examples may include how severe your neuropathic pain is, how well current treatments are working for you, your concern about risks, etc.)

## **Appendix 2: Patient and FDA Panel Participants**

### **Patient Panel, Topic 1**

- Adam Halper - Patient
- Elizabeth Lannon - Patient
- David Morrow - Patient
- Susan Waldrop - Patient

### **Patient Panel, Topic 2**

- Jackie Evangelista - Patient
- Cherie Pagett - Patient
- Louis Schmitt - Patient
- Linda Spinella - Patient

### **FDA Panel**

- Sharon Hertz (Division of Anesthesia, Analgesia and Addiction Products (DAAAP), Center for Drug Evaluation and Research (CDER))
- Steve Galati (Division of Anesthesia, Analgesia and Addiction Products (DAAAP), CDER)
- Pamela Horn (Division of Anesthesia, Analgesia and Addiction Products (DAAAP), CDER)
- Mary Parks (Office of Drug Evaluation III, Office of New Drugs (OND), CDER)
- Nikunj Patel (Clinical Outcomes Assessment (COA) Staff, Office of New Drugs (OND), CDER)
- Sara Eggers (Office of Strategic Programs, CDER)

## Appendix 3: Meeting Polling Questions

The following questions were posed to in-person and web meeting participants at various points throughout the June 10, 2016, Neuropathic Pain Patient-Focused Drug Development meeting. Participation in the polling questions was voluntary. The results were used as a discussion aid only and should not be considered scientific data.

### Demographic Questions

1. Where do you live?
  - a. Within Washington, D.C. metropolitan area (including the Virginia and Maryland suburbs)
  - b. Outside of the Washington, D.C. metropolitan area
  
2. Have you ever been diagnosed as having neuropathic pain associated with peripheral neuropathy?
  - a. Yes
  - b. No

We will ask that the remainder of the questions be answered by participants who responded “yes” to Question 2, or by participants who are answering on behalf loved one diagnosed with neuropathic pain associated with peripheral neuropathy.

3. What is your age?
  - a. Younger than 18
  - b. 18-29
  - c. 30-39
  - d. 40-49
  - e. 50-59
  - f. 60 – 69
  - g. 70 or greater
  
4. Do you identify as:
  - a. Male
  - b. Female
  
5. What is the length of time since your diagnosis of neuropathic pain associated with peripheral neuropathy?
  - a. Less than 1 year ago

- b. 1 years ago to 2 years ago
  - c. 2 years ago to 5 years ago
  - d. 5 years ago to 10 years ago
  - e. More than 10 years ago
  - f. I'm not sure
6. What is the underlying cause of your neuropathic pain? **Check all that apply.**
- a. Trauma/ physical injury/ surgery
  - b. Metabolic/ endocrine disorders (such as diabetes)
  - c. Medication toxicity (such as chemotherapy drugs, radiation, antiretroviral drugs and other medications)
  - d. Viral or bacterial infection (such as shingles, herpes, Lyme disease)
  - e. Other condition not mentioned
  - f. I don't know
7. What comorbid condition(s) do you have (if applicable)? **Check all that apply.**
- a. Depression or anxiety
  - b. Diabetes
  - c. Cancer
  - d. Kidney disease
  - e. A chronic bacterial or viral infection
  - f. Other comorbid condition(s) not mentioned
  - g. I do not have any comorbid conditions that I am aware of

#### Question for Topic 1

8. What part(s) of your body do you experience your most severe neuropathic pain? **Check all that apply.**
- a. Head, face or neck
  - b. Hands or arms
  - c. Feet or legs
  - d. Trunk
  - e. Back
  - f. Genital area
  - g. Other areas not mentioned
9. How do your neuropathic pain symptoms typically manifest? **Check all that apply.**
- a. Pain appears suddenly and progresses rapidly
  - b. Pain appears subtly and progresses slowly

- c. Pain comes and goes (intermittent)
- d. Pain is continuous
- e. Pain worsens over time
- f. Other manifestations not mentioned above
- g. I don't know

10. What terms best describe the most bothersome aspects of your neuropathic pain? **Choose up to three terms.**

- a. Numbness
- b. Tingling
- c. Burning
- d. Stabbing
- e. Shooting
- f. Pricking/ "Pins and needles"
- g. Electric shocks
- h. Others not mentioned

11. What are the most bothersome impacts of your neuropathic pain on your daily life? **Please choose up to three impacts.**

- a. Ability to participate in or perform activities (such as work, participation in sports or social activities, driving, make or keep plans for activities, etc.)
- b. Ability to fall asleep at night
- c. Ability to sleep through the night
- d. Ability to concentrate or stay focused
- e. Ability to care for self, family, and others
- f. Impacts on Sexual intimacy
- g. Impacts on Social relationships
- h. Emotional impacts (such as fear, hopelessness, etc.)
- i. Other impacts not mentioned

## Questions for Topic 2

12. Have you ever used any of the following drug therapies to treat your neuropathic pain? **Check all that apply.**

- a. Antiarrhythmic drugs (such as Mexitil (mexiletine))
- b. Antidepressant drugs (such as Elavil (amitriptyline), Prozac (duloxetine), Effexor (venlafaxine))
- c. Anticonvulsant drugs (such as Neurontin (gabapentin), Lyrica (pregabalin), Topamax

- (topiramate), and Tegretol (carbamazepine))
- d. Transdermal or topical patches (such as such as lidocaine)
- e. Opioid pain medicines
- f. Prescription nonsteroidal anti-inflammatory drugs (such as diclofenac)
- g. Over-the-counter products (such as ibuprofen and naproxen)
- h. Other drug therapies not mentioned
- i. I'm not taking any drug therapies

13. Besides the therapies mentioned previously, what else are you doing to manage any symptoms you have experienced because of your neuropathic pain? **Check all that apply.**

- a. Surgical destruction of nerves
- b. Transcutaneous electrical nerve stimulation (TENS)
- c. Cannabinoids (such as medical marijuana)
- d. Dietary and herbal supplements
- e. Diet modifications and behavioral changes (such as limiting alcohol and tobacco use)
- f. Complementary or alternative therapies (such as acupuncture, massage)
- g. Physical or occupational therapy
- h. Other therapies not mentioned
- i. I am not doing or taking any therapies to treat symptoms

**SCENARIO: Hypothetical new treatment**

Imagine that a new medication to treat neuropathic pain associated with peripheral neuropathy has recently been approved by FDA. Your doctor believes that you may be a good candidate for this medication.

In the clinical trials that were conducted, one-half of adults treated for 12 weeks had a 50% reduction in their pain. Common side effects of this medication include: nausea, fatigue, and weight gain. Rare, but serious side effects of this medication include: nerve damage and liver damage.

The medication is unlikely to be addictive or to be used for abuse, such as to get high.

**What first thoughts come to mind when hearing this scenario?**

**What questions would you ask your doctor about this new treatment for neuropathic pain?**

14. Of the following factors, which two would you rank as most important to your decisions about using treatments to help reduce or control your neuropathic pain?

- a. How the medication is administered (such as topical, injection, oral, etc.)
- b. Your access to this treatment (for example, insurance coverage)
- c. Whether the drug showed improvement in specific pain symptoms that are most bothersome to you.
- d. The common side effects of the treatment (such as nausea, fatigue, and weight gain)

- e. The possibility of rare, but serious side effects (such as nerve and liver damage)
- f. The risk of developing drug abuse and addiction
- g. Your previous response to a similar treatment
- h. Whether you still have other treatment options



# Appendix 4: Incorporating Patient Input into a Benefit-Risk Assessment Framework for Neuropathic Pain Associated with Peripheral Neuropathy

## Introduction

Over the past several years, FDA has developed an enhanced structured approach to benefit-risk assessment in regulatory decision-making for human drugs and biologics.<sup>3</sup> The Benefit-Risk Assessment Framework involves assessing five key decision factors: *Analysis of Condition*, *Current Treatment Options*, *Benefit*, *Risk*, and *Risk Management*. When completed for a particular product, the Framework provides a succinct summary of each decision factor and explains FDA's rationale for its regulatory decision.

In the Framework, the *Analysis of Condition* and *Current Treatment Options* rows summarize and assess the severity of the condition and therapies available to treat the condition. The assessment provides an important context for drug regulatory decision-making, including valuable information for weighing the specific benefits and risks of a particular medical product under review.

The input provided by patients and patient representatives through the Neuropathic Pain Associated with Peripheral Neuropathy Patient-Focused Drug Development meeting and docket comments will inform our understanding of the *Analysis of Condition* and *Current Treatment Options* for this disease.

The information in the top two rows of the sample framework for Neuropathic Pain Associated with Peripheral Neuropathy below draws from various sources, including what was discussed at the Patient-Focused Drug Development meeting held on June 10, 2016. This sample framework contains the kind of information that we anticipate could be included in a framework completed for a drug under review for Neuropathic Pain Associated with Peripheral Neuropathy. This information is likely to be added to or changed over time based on a further understanding of the condition or changes in the treatment armamentarium.

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<sup>3</sup> Commitments in the fifth authorization of the Prescription Drug User Fee Act (PDUFA V) include further development and implementation of the Framework into FDA's review process. Section 905 of the FDA Safety and Innovation Act also requires FDA to implement a structured benefit-risk framework in the new drug approval process. For more information on FDA's benefit-risk efforts, refer to <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm>.

Dimensions	Evidence and Uncertainties	Conclusions and Reasons
Analysis of Condition	<ul style="list-style-type: none"> <li>– Peripheral neuropathy, resulting from damage to the peripheral nervous system, affects 20 million people in the U.S. Peripheral neuropathy often develops after age 55, but can occur at any age.</li> <li>– Neuropathic pain associated with peripheral neuropathy may follow different patterns which vary over a period of days, weeks or years. Symptoms vary depending on what nerves are damaged.</li> <li>– Pain symptoms are often experienced in the hands and feet. Pain sensations may include numbness, prickling or tingling.</li> <li>– Symptoms can have considerable detrimental effects on a patient’s quality of life, ability to function in daily activities, and overall social and societal engagement. Patients report living anxiety, depression, and fear of ongoing or worsening symptoms.</li> <li>– <i>See the Voice of the Patient report for a more detailed narrative.</i></li> </ul>	<p>Peripheral neuropathy associated with neuropathic pain is a debilitating disorder commonly diagnosed among the elderly. The disease can have a debilitating effect on patients’ day-to-day functioning and takes a significant physical, emotional, and social toll on patients’ quality of life.</p>
Current Treatment Options	<ul style="list-style-type: none"> <li>– Anticonvulsant drug products such as Lyrica (pregabalin) and Neurontin(gabapentin) are frequently used to manage neuropathic pain associated with peripheral neuropathy symptoms. The most frequently occurring adverse reactions include dizziness, somnolence, dry mouth, edema, blurred vision, weight gain and thinking abnormal (primarily difficulty with concentration/attention).</li> <li>– Patients also use a number of other drugs including anti-depressants, muscle relaxants, NSAIDs, opioids, narcotic pain relievers, epidurals, and topical pain relievers.</li> <li>– Non-drug therapies most commonly mentioned by patients include massage, physical therapy, acupuncture, and vitamin supplements.</li> <li>– Most patients included diet modifications, light exercise, and other lifestyle changes as part of their symptom management.</li> <li>– <i>See the Voice of the Patient report for a more detailed narrative.</i></li> </ul>	<p>Drug treatments are available for the symptoms of neuropathic pain associated with peripheral neuropathy; however, efficacy varies from patient to patient, and significant side effects can limit benefits or preclude use of these medications.</p> <p>Thus, there is a continued need for additional effective and tolerable treatment options for patients to improve their daily functioning and pain control for burdensome symptoms.</p>