

New Jersey Department of Health
Medicinal Marijuana Program
PO 360
Trenton, NJ 08625-0360

MEDICINAL MARIJUANA PETITION
(N.J.A.C. 8:64-5.1 et seq.)

INSTRUCTIONS

This petition form is to be used only for requesting approval of an additional medical condition or treatment thereof as a "debilitating medical condition" pursuant to the New Jersey Compassionate Use Medical Marijuana Act, N.J.S.A. 24:6I-3. Only one condition or treatment may be identified per petition form. For additional conditions or treatments, a separate petition form must be submitted.

NOTE: This Petition form tracks the requirements of N.J.A.C. 8:64-5.3. Note that if a petition does not contain all information required by N.J.A.C. 8:64-5.3, the Department will deny the petition and return it to petitioner without further review. For that reason the Department strongly encourages use of the Petition form.

This completed petition **must** be postmarked **August 1 through August 31, 2016** and sent by **certified mail** to:

New Jersey Department of Health
Office of Commissioner - Medicinal Marijuana Program
Attention: Michele Stark
369 South Warren Street
Trenton, NJ 08608

Please complete each section of this petition. If there are any supportive documents attached to this petition, you should reference those documents in the text of the petition. If you need additional space for any item, please use a separate piece of paper, number the item accordingly, and attach it to the petition.

1. Petitioner Information

Name: _____
Street Address: _____
City, State, Zip Code: _____
Telephone Number: _____
Email Address: _____

2. Identify the medical condition or treatment thereof proposed. Please be specific. Do not submit broad categories (such as "mental illness").

Peripheral Neuropathy

3. Do you wish to address the Medical Marijuana Review Panel regarding your petition?

- Yes, in Person
- Yes, by Telephone
- No

4. Do you request that your personally identifiable information or health information remain confidential?

- Yes
- No

If you answer "Yes" to Question 4, your name, address, phone number, and email, as well as any medical or health information specific to you, will be redacted from the petition before forwarding to the panel for review.

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**MEDICINAL MARIJUANA PETITION
(Continued)**

5. **Describe the extent to which the condition is generally accepted by the medical community and other experts as a valid, existing medical condition.**

Peripheral Neuropathy is often associated with Diabetes mellitus, but the condition can be caused by infections, alcoholism, traumatic injuries, autoimmune diseases, medications, infections, tumors and inherited disorders. It attacks the nerves in the outermost parts of the body, causing numbness in fingers, toes, feet along with severe burning and stabbing of the flesh. It starts quietly with feelings of pebbles in your shoes or crumbled socks and then progresses to the heat and burning alternating with cold and numbness causing paralysis in the legs. It spreads quickly upward into the legs, thighs and buttocks. It then renders the bladder unable to normally control urination and causes similar difficulties with the anus and bowel movements. It spreads quietly up the back and begins to numb the fingers.

6. **If one or more treatments of the condition, rather than the condition itself, are alleged to be the cause of the patient's suffering, describe the extent to which the treatments causing suffering are generally accepted by the medical community and other experts as valid treatments for the condition.**

Endocrinologists, orthopedic specialists, neurologists, acupuncturists, look you in the eye and say "there is very little that the medical field can offer you for neuropathy". Pain killers are the only option. They include Gabapentin, Lyrica and Cymbalta. They all cause extreme swelling of the legs and hands, dizziness, excessive weight gain, drowsiness and blurred vision. All these side effects might be worth it if they stopped the stabbing pains and extreme burning, but they don't. They knock you out so you don't feel the pain, but you can't sleep forever. When you awaken, the swelling, pain and burning is still there, you have urinated on yourself and now it's time to take another pill. Life as you have known it is gone.

7. **Describe the extent to which the condition itself and/or the treatments thereof cause severe suffering, such as severe and/or chronic pain, severe nausea and/or vomiting or otherwise severely impair the patient's ability to carry on activities of daily living.**

The pain, burning, alternating cold, numbness, paralysis drastically affects your life. Your life changes dramatically. Drive a vehicle can be the hardest to accept. Showering by yourself can be dangerous since the paralysis affects not only movement of the body, but the skin can no longer distinguish between hot and warm water. Severe burns are possible. Walking is almost impossible and falls are inevitable causing broken bones. Life as you knew it is gone. You are going to have to learn to live your life from a wheelchair which now means that your home requires making it adaptable or leaving your home entirely. You push yourself through life all the while stifling the screams you feel when the burning of the legs and buttocks continue.

8. **Describe the availability of conventional medical therapies other than those that cause suffering to alleviate suffering caused by the condition and/or the treatment thereof.**

None exists.

9. **Describe the extent to which evidence that is generally accepted among the medical community and other experts supports a finding that the use of marijuana alleviates suffering caused by the condition and/or the treatment thereof.** *[Note: You may attach articles published in peer-reviewed scientific journals reporting the results of research on the effects of marijuana on the medical condition or treatment of the condition and supporting why the medical condition should be added to the list of debilitating medical conditions.]*

Paper #1: Neuropathy - Medical Marijuana Research Overview

Paper #2: The Argument for Medical Marijuana for the Treatment of Chronic Pain

Paper #3: Science Daily "Inhaled cannabis shown effective for diabetic neuropathy pain"

Paper #4: Low-Dose Vaporized Cannabis Significantly Improves Neuropathic Pain

**MEDICINAL MARIJUANA PETITION
(Continued)**

10. Attach letters of support from physicians or other licensed health care professionals knowledgeable about the condition. List below the number of letters attached and identify the authors.

Please see #9 above. Four papers are attached and identify the several doctors/authors.

Paper #1: Too numerous to list. Please see the paper.

Paper #2: Authored by Greg T. Carter, MS, MD, Providence Medical Group, Olympia, Washington, USA.

Paper #3: Science Daily, authored by American Pain Society citing other Journal References

Paper #4: Results of study by NCRR, Grant Number UL1 RR024146. Barth Wilsey, Thomas Marcotte, Reena Deutsch, Ben Gouaux, Staci Sakai, Haylee Donaghe

I certify, under penalty of perjury, that I am 18 years of age or older; that the information provided in this petition is true and accurate to the best of my knowledge; and that the attached documents are authentic.

Signature 	Date August 10, 2016
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Neuropathy – Medical Marijuana Research Overview

Paper # 1

8 December 2015

The following information is presented for educational purposes only. Medical Marijuana Inc. provides this information to provide an understanding of the potential applications of cannabidiol. Links to third party websites do not constitute an endorsement of these organizations by Medical Marijuana Inc. and none should be inferred.

Neuropathy is the damage to the sensory, motor or automatic nerves that occurs from an underlying cause. Studies have shown cannabis is effective at significantly reducing neuropathic pain.

Overview of Neuropathy

Peripheral neuropathy, which is often simply referred to as neuropathy, is a condition where nerves are damaged, causing weakness, numbness and pain. Among the most common causes of neuropathy is diabetes mellitus, but the condition can also be caused by infections, alcoholism, traumatic injuries, autoimmune diseases, medications, infections, tumors, and inherited disorders.

The symptoms associated with neuropathy depend on what types of nerves are damaged. Damage to sensory nerves, which receive sensation and damage, can cause tingling and

patients suffering from neuropathic that had previously proven refractory to other treatments (Boychuck, Goddard, Mauro & Orellana, 2015). It's been shown to specifically reduce neuropathic pain caused by diabetes (Wallace, et al., 2015). Multiple sclerosis and central neuropathic pain patients experienced pain relief with only mild to moderate adverse effects while undergoing two years of THC and CBD treatment (Rog, Nurmikko & Young, 2007). CBD was shown to significantly reduce neuropathic pain in cancer patients without diminishing nervous system function or adversely effecting chemotherapy effectiveness (Ward, et al., 2014). One study found that in HIV-positive patients, 94% reported an improvement in muscle pain and 90% reported an improvement in nerve pain after cannabis use (Woolridge, et al., 2005). In another study, 12 of 15 chronic pain patients who smoke herbal cannabis for therapeutic reasons reported an improvement in pain (Ware, Gamsa, Persson & Fitzcharles, 2002).

Because of cannabis' effectiveness at reducing pain, its use is prevalent among the chronic pain population (Ware, et al., 2003). Luckily, studies indicate that long-term cannabis use for managing pain is safe. After a year of regular use, patients with chronic pain were found to be at no greater risk of serious adverse effects than non-cannabis users (Ware, et al., 2015).

States That Have Approved Medical Marijuana for Neuropathy

Currently, New Mexico, New York and Pennsylvania have approved medical marijuana for the treatment of neuropathy. In Washington D.C., any condition can be

a systematic review.

(<http://www.ncbi.nlm.nih.gov/pubmed/25635955>)

- **Patients with multiple sclerosis or central neuropathic pain receiving THC and CBD treatments for two years saw significant reductions in pain, with only minor side effects.** *Oromucosal delta9-tetrahydrocannabinol/cannabidiol for neuropathic pain associated with multiple sclerosis: an uncontrolled, open-label, 2-year extension trial.*
(<http://www.ncbi.nlm.nih.gov/pubmed/18035205>)

References

Baron, E.P. (2015, June). Comprehensive Review of Medicinal Marijuana, Cannabinoids, and Therapeutic Implications in Medicine and Headache: What a Long Strange Trip It's Been... *Headache*, 55(6), 885-916.

Boychuck, D.G., Goddard, G., Mauro, G., and Orellana, M.F. (2015 Winter). The effectiveness of cannabinoids in the management of chronic nonmalignant neuropathic pain: a systematic review. *Journal of Oral & Facial Pain and Headache*, 29(1), 7-14.

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Paper # 2

Schatman and Darnall

The Argument for Medical Marijuana for the Treatment of Chronic Pain

This patient has legitimate pain and still deserves treatment despite being at high risk for substance abuse. Untreated pain will only create more drug hunger [1]. Multimodal management would be best, including antidepressant and anticonvulsant medications, and physical modalities such as a transcutaneous electrical nerve stimulation unit [1]. However, medicinal cannabis can be considered a legitimate next treatment step, much preferred to a prescription for opioids.

Opioids and cannabinoids are both among the world's oldest drugs, with usage dating back thousands of years [2]. Both medications work via specific receptors and are created endogenously within the body as part of normal regulatory processes necessary for life. Without endorphins (opioids) and endocannabinoids (cannabinoids), our bodies would not function normally [3,4]. Opiates remain the mainstay of pain management despite known morbidity and mortality associated with their use [5]. Concurrently, research further documents the safety and efficacy of medicinal cannabis for chronic pain [4]. Cannabis has no known lethal dose, minimal drug interactions, is easily dosed via orally ingestion, vaporization, or topical absorption, thereby avoiding the potential risks associated with smoking completely [2,3,6].

Opioids and cannabinoids are both capable of triggering a relapse in this patient. Yet, from a harm-reduction viewpoint, cannabis has a more acceptable risk-benefit ratio [6]. Emerging evidence indicates that manipulating the endocannabinoid system via CB1 receptors might help treat addiction [7]. In terms of clinical efficacy in humans, a strong peer-reviewed evidence base is accessible through the National Library of Medicine (<http://www.ncbi.nlm.nih.gov/pubmed>). Denying this patient access to a compound that would likely help relieve his suffering and has an acceptable risk would impose undue mental stress [8] as well as unnecessary perpetuation of pain.

Prescription of the Schedule III drug dronabinol (Marinol) would be inappropriate in this case. Marinol is 100% tetrahydrocannabinol (THC), the most psychoactive ingredient in natural cannabis [4,6]. Natural cannabis contains 5–15% THC but also includes multiple other therapeutic cannabinoids, all working in concert to produce analgesia [4,6]. Yet, it remains classified as a Schedule I drug (i.e., a dangerous drug, without medical indications) [3]. Medicinal cannabis should have low THC but abundant cannabidiol (CBD), cannabinol (CBN), and many other non-intoxicating, therapeutic cannabinoids, many with anti-inflammatory properties [3].

Recently, an Israeli company cultivated a cannabis plant with no detectable THC but high amounts of CBD, CBN, and other non-intoxicating cannabinoids [9]. This strain apparently offers the same therapeutic benefits without the euphoric effect, although it remains to be seen whether it will be effective for pain management. It is clear that purified

isolates of a single cannabinoid are not as therapeutic as the natural cornucopia of cannabinoids found in the natural plant [3]. For now, I advocate for this patient to use an appropriate medicinal variety of natural cannabis, assuming he lives in a state in which medical marijuana is legal.

GREG T. CARTER, MS, MD
Providence Medical Group,
Olympia, Washington, USA,
University of Washington,
Seattle, Washington, USA

References

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Ethical Pain Care in a Complex Case

Drs. Bunt and Carter not only take highly disparate stances in regard to the question of whether medical

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Report # 3

Science News

from research organizations

Inhaled cannabis shown effective for diabetic neuropathy pain

Date: July 20, 2015

Source: American Pain Society

Summary: Inhaled cannabis reduces diabetic neuropathy and the analgesic effect is dose-dependent, new research suggests. Researchers conducted a randomized, double-blind study evaluating 16 subjects to assess the efficacy and tolerability of inhaled cannabis for treating pain caused by diabetic peripheral neuropathy (DPN).

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FULL STORY

New research reported in *The Journal of Pain*, published by the American Pain Society, shows that inhaled cannabis reduces diabetic neuropathy and the analgesic effect is dose-dependent.

Researchers at the University of California San Diego conducted a randomized, double-blind study evaluating 16 subjects to assess the efficacy and tolerability of inhaled cannabis for treating pain caused by diabetic peripheral neuropathy (DPN). They studied the effects of low, medium and high doses of inhaled cannabis on DPN pain and hyperalgesia. Subjects participated in four outpatient treatment sessions, separated by two weeks, in which they were exposed to placebo or three different doses of aerosol 1% THC, the most abundant and psychoactive compound in cannabis. As a drug delivery method for marijuana research, inhalation is preferred because the pharmacokinetics of inhalation are superior to smoking, as peak effects occur quickly and are more easily titrated.

DPN occurs in half of diabetes patients and 15 percent have pain, especially in the feet. Many patients do not achieve satisfactory relief from two FDA-approved treatments. Animal research in models of neuropathic pain suggest that cannabinoids may be effective in reducing pain, but no studies have focused specifically on painful DPN.

"We hypothesized that inhaled cannabis would result in a dose-dependent reduction in spontaneous and evoked pain with a concomitant effect on cognitive function," said lead author Mark S. Wallace, M.D., professor of anesthesiology, University of California San Diego School of Medicine.

Low-Dose Vaporized Cannabis Significantly Improves Neuropathic Pain

Barth Wilsey*, , Thomas Marcotte†, Reena Deutsch†, Ben Gouaux†, Staci Sakai†, Haylee Donaghe†

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Paper # 4

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Brett R. Stacey, Jeffrey L. Moller

Marijuana for Pain Relief: Don't Jump to Conclusions*The Journal of Pain*, Volume 14, Issue 10, October 2013, Pages 1250-1251[Purchase PDF - \\$35.95](#)

Abstract

We conducted a double-blind, placebo-controlled, crossover study evaluating the analgesic efficacy of vaporized cannabis in subjects, the majority of whom were experiencing neuropathic pain despite traditional treatment. Thirty-nine patients with central and peripheral neuropathic pain underwent a standardized procedure for inhaling medium-dose (3.53%), low-dose (1.29%), or placebo cannabis with the primary outcome being visual analog scale pain intensity. Psychoactive side effects and neuropsychological performance were also evaluated. Mixed-effects regression models demonstrated an analgesic response to vaporized cannabis. There was no significant difference between the 2 active dose groups' results ($P > .7$). The number needed to treat (NNT) to achieve 30% pain reduction was 3.2 for placebo versus low-dose, 2.9 for placebo versus medium-dose, and 25 for medium- versus low-dose. As these NNTs are comparable to those of traditional neuropathic pain medications, cannabis has analgesic efficacy with the low dose being as effective a pain reliever as the medium dose. Psychoactive effects were minimal and well tolerated, and neuropsychological effects were of limited duration and readily reversible within 1 to 2 hours. Vaporized cannabis, even at low doses, may present an effective option for patients with treatment-resistant neuropathic pain.

Perspective

The analgesia obtained from a low dose of delta-9-tetrahydrocannabinol (1.29%) in patients, most of whom were experiencing neuropathic pain despite conventional treatments, is a clinically significant outcome. In general, the effect sizes on cognitive testing were consistent with this minimal dose. As a result, one might not anticipate a significant impact on daily functioning.

Key words

Neuropathic pain; analgesia; cannabis; clinical trial; neuropsychological testing

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The authors have no conflicts of interest to report.