

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 <u>only</u> 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 <u>each</u> 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: Vivek T. Das, M.D. | |
| | Street Address: 501 Omni Drive | |
| | City, State, Zip Code: Hillsborough, NJ 08844 | |
| | Telephone Number: 908-904-1900 | |
| | Email Address: | |
| | | |
| 2. | Identify the medical condition or treatment thereof proposed. Please be specific. Do not submit broad categories (such as "mental illness"). | |
| | Complex Regional Pain Syndrome (Reflex Sympathetic Dystrophy) | |
| | | |
| 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. | |



SEP 6 2016

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. |
|----|---|
| | Complex Regional Pain Syndromes has valid ICD-10 codes: G90.50, G90.523, G90.511, G90.512, G90.521, G90.522, G90.59, G90.529, G90.519. |
| | |
| 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. |
| | Many of the medications used to treat Complex Regional Pain Syndrome have multiple side effects. Patients with refractory cases need to undergo invasive risky procedures including nerve blocks, spine injections, infusions, spinal cord stimulation and intrathecal pump implantation. |
| 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. |
| | Severe cases of Complex Regional Pain Syndrome are associated with severe, chronic debilitating pain. Also there is progressive loss of function and marked diminution in quality of life in refractory cases. |
| | |
| 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. |
| | A host of conventional and complementary/interdisciplinary treatements are readily available but there is no cure for this illness and due to its variable course some patients experience disease progression despite intensive state-of-the art treatment. |
| | |
| 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.] |
| | Please see attached. |
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| | |

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.

I am a licensed physician for the NJ MMP. I am Board Certified in Anesthesiology, Pain Medicine, Hospice and Palliative Medicine. I am in full support of this petition because I treat the pain and suffering caused by Complex Regional Pain Syndrome and I believe that those patients whose cases are refractory to conventional medical treatment should be allowed to particiciate in the NJ MMP on a compassionate basis. Thank you for your consideration.

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 of Petitioner | Morn | Date 08/31/2016 | |
|-------------------------|------|-----------------|--|
|-------------------------|------|-----------------|--|

| PubMed |
|--|
| Format: Abstract |
| Rev Med Suisse. 2015 Jun 24;11(480):1390, 1392-4. |
| [Clinical pharmacology of medical cannabinoids in chronic pain]. [Article in French] Ing Lorenzini K, Broers B, Lalive PH, Dayer P, Desmeules J, Piguet V. |
| Abstract In Switzerland, medical cannabinoids can be prescribed under compassionate use after special authorization in justified indications such as refractory pain. Evidence of efficacy in pain is limited and the clinical benefit seems to be modest. Their drug-drug interactions (DDI) profile is poorly documented. Cytochromes P450 (CYP) 2C9 and 3A4 are involved in the metabolism of tetrahydrocannabinol and cannabidiol, which implies possible DDI with CYP450 inhibitor and inducer, such as anticonvulsivants and HIV protease inhibitors, which may be prescribed in patients with neuropathic pain. |
| PMID: <u>26267945</u> |
| [PubMed - indexed for MEDLINE] |
| Publication Types, MeSH Terms, Substances |
| LinkOut - more resources |

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Full text links

ELSEVIER

Drug Alcohol Depend. 2015 Feb 1;147:144-50. doi: 10.1016/j.drugalcdep.2014.11.031. Epub 2014 Dec 10.

Experience of adjunctive cannabis use for chronic non-cancer pain: findings from the Pain and Opioids IN Treatment (POINT) study.

Degenhardt L1, Lintzeris N2, Campbell G3, Bruno R4, Cohen M5, Farrell M3, Hall WD6.

Author information

Abstract

BACKGROUND: There is increasing debate about cannabis use for **medical** purposes, including for symptomatic treatment of **chronic pain**. We investigated patterns and correlates of cannabis use in a large community sample of people who had been prescribed opioids for **chronic** non-cancer **pain**.

METHODS: The POINT study included 1514 people in Australia who had been prescribed pharmaceutical opioids for **chronic** non-cancer **pain**. Data on cannabis use, ICD-10 cannabis use disorder and cannabis use for **pain** were collected. We explored associations between demographic, **pain** and other patient characteristics and cannabis use for **pain**.

RESULTS: One in six (16%) had used cannabis for **pain** relief, 6% in the previous month. A quarter reported that they would use it for **pain** relief if they had access. Those using cannabis for **pain** on average were younger, reported greater **pain** severity, greater interference from and poorer coping with **pain**, and more days out of role in the past year. They had been prescribed opioids for longer, were on higher opioid doses, and were more likely to be non-adherent with their opioid use. Those using cannabis for **pain** had higher **pain** interference after controlling for reported **pain** severity. Almost half (43%) of the sample had ever used cannabis for recreational purposes, and 12% of the entire cohort met criteria for an ICD-10 cannabis use disorder.

CONCLUSIONS: Cannabis use for **pain** relief purposes appears common among people living with **chronic** non-cancer **pain**, and users report greater **pain** relief in combination with opioids than when opioids are used alone.

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KEYWORDS: Australia; Cannabis; Chronic pain; Medical cannabis use; Pharmaceutical opioids

PMID: 25533893 DOI: 10.1016/j.drugalcdep.2014.11.031

| PubMed ∨ | |
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Full text links

JAMA

JAMA. 2015 Jun 23-30;313(24):2474-83. doi: 10.1001/jama.2015.6199.

Medical Marijuana for Treatment of Chronic Pain and Other Medical and Psychiatric Problems: A Clinical Review.

Hill KP1.

Author information

Abstract

IMPORTANCE: As of March 2015, 23 states and the District of Columbia had medical marijuana laws in place. Physicians should know both the scientific rationale and the practical implications for medical marijuana laws.

OBJECTIVE: To review the pharmacology, indications, and laws related to **medical marijuana** use.

EVIDENCE REVIEW: The medical literature on medical marijuana was reviewed from 1948 to March 2015 via MEDLINE with an emphasis on 28 randomized clinical trials of cannabinoids as pharmacotherapy for indications other than those for which there are 2 US Food and Drug Administration-approved cannabinoids (dronabinol and nabilone), which include nausea and vomiting associated with chemotherapy and appetite stimulation in wasting illnesses.

FINDINGS: Use of marijuana for chronic pain, neuropathic pain, and spasticity due to multiple sclerosis is supported by high-quality evidence. Six trials that included 325 patients examined chronic pain, 6 trials that included 396 patients investigated neuropathic pain, and 12 trials that included 1600 patients focused on multiple sclerosis. Several of these trials had positive results, suggesting that marijuana or cannabinoids may be efficacious for these indications.

CONCLUSIONS AND RELEVANCE: Medical marijuana is used to treat a host of indications, a few of which have evidence to support treatment with marijuana and many that do not. Physicians should educate patients about medical marijuana to ensure that it is used appropriately and that patients will benefit from its use.

Summary for patients in

JAMA PATIENT PAGE. Medical Marijuana. [JAMA. 2015]

PMID: 26103031 DOI: 10.1001/jama.2015.6199

[PubMed - indexed for MEDLINE]

| PubMed ~ | |
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Full text links

SpringerLink

Schmerz. 2016 Feb;30(1):3-13. doi: 10.1007/s00482-015-0083-4.

Medical use of cannabis products: Lessons to be learned from Israel and Canada.

Ablin J¹, Ste-Marie PA^{2,3}, Schäfer M⁴, Häuser W^{5,6}, Fitzcharles MA^{2,3}.

Author information

Abstract

INTRODUCTION: The German government intends to reduce the barriers for the **medical** use of cannabis products. A discussion on the indications and contraindications of the **medical** use of cannabis and on the changes of the regulatory framework has already begun in Germany. It is useful to draw from the experiences of other countries with a more liberal **medical** use of cannabis.

METHODS: The Israeli and Canadian experience is outlined by physicians who have been charged with expertise on the **medical** use of canabis by their jurisdiction.

RESULTS: In Israel, only the plant-based cannabinoid nabiximol (mixture of tetrahydrocannabinol/cannabidiol) can be prescribed for spasticity/chronic pain in multiple sclerosis and for cancer pain. The costs of nabiximole are reimbursed by some, but not by all health maintenance organizations. The medical use of marijuana is permitted; however, it is strictly regulated by the government. Selected companies are allowed to produce marijuana for medical use, and only certain physicians are licensed to prescribe marijuana as a therapeutic drug for specific indications such as chronic neuropathic, and cancer pain, inflammatory bowel diseases, or posttraumatic stress disorder if conventional treatments have failed. The costs of marijuana are not reimbursed by health insurance companies. In Canada, synthetic cannabinoids and the plant-based (nabiximol) are licensed for neuropathic and cancer pain, HIV-related anorexia and chemotherapy-associate nausea. The costs of these synthetic cannabinoids are covered by health insurance companies. The medical use of marijuana as a treatment option is allowed for individual patients suffering from any medical condition when authorized by a medical practitioner or nurse. Licensed producers are the only source for patients to newly access medical cannabis, although those with previous permission to grow may continue cultivation at the present time. The costs of marijuana are not reimbursed by health insurance companies. There are multiple contraindications for the medical use of cannabis products in both countries.

CONCLUSIONS: The use of standardized, synthetic, and plant-based cannabis products should be allowed in Germany for defined **medical** conditions when high-level evidence of efficacy and safety exists. The costs should be reimbursed by the health insurance companies. Contraindications for the **medical** use of cannabis should be defined. Growing **marijuana** by patients for their **medical** use should not be allowed.

KEYWORDS: Cannabinoids; Herbal cannabis; Israel-Canada; Medical use; Regulatory framework

PMID: <u>26767992</u> DOI: <u>10.1007/s00482-015-0083-4</u>

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Full text links

Can Fam Physician. 2015 Aug;61(8):e372-81.





Efficacy and adverse effects of medical marijuana for chronic noncancer pain: Systematic review of randomized controlled trials.

Deshpande A, Mailis-Gagnon A, Zoheiry N, Lakha SF.

Abstract

OBJECTIVE: To determine if **medical marijuana** provides **pain** relief for patients with **chronic** noncancer **pain** (CNCP) and to determine the therapeutic dose, adverse effects, and specific indications.

DATA SOURCES: In April 2014, MEDLINE and EMBASE searches were conducted using the terms **chronic** noncancer **pain**, smoked **marijuana** or cannabinoids, placebo and **pain** relief, or side effects or adverse events.

STUDY SELECTION: An article was selected for inclusion if it evaluated the effect of smoked or vaporized cannabinoids (nonsynthetic) for CNCP; it was designed as a controlled study involving a comparison group, either concurrently or historically; and it was published in English in a peer-review journal. Outcome data on pain, function, dose, and adverse effects were collected, if available. All articles that were only available in abstract form were excluded. Synthesis A total of 6 randomized controlled trials (N = 226 patients) were included in this review; 5 of them assessed the use of medical marijuana in neuropathic pain as an adjunct to other concomitant analgesics including opioids and anticonvulsants. The 5 trials were considered to be of high quality; however, all of them had challenges with masking. Data could not be pooled owing to heterogeneity in delta-9-tetrahydrocannabinol potency by dried weight, differing frequency and duration of treatment, and variability in assessing outcomes. All experimental sessions in the studies were of short duration (maximum of 5 days) and reported statistically significant pain relief with nonserious side effects.

CONCLUSION: There is evidence for the use of low-dose **medical marijuana** in refractory neuropathic **pain** in conjunction with traditional analgesics. However, trials were limited by short duration, variability in dosing and strength of delta-9-tetrahydrocannabinol, and lack of functional outcomes. Although well tolerated in the short term, the long-term effects of psychoactive and neurocognitive effects of **medical marijuana** remain unknown. Generalizing the use of **medical marijuana** to all CNCP conditions does not appear to be supported by existing evidence. Clinicians should exercise caution when prescribing **medical marijuana** for patients, especially in those with nonneuropathic CNCP.