BEFORE THE IOWA MEDICAL CANNABIDIOL BOARD

Rebecca Lucas
Petition by *(Your Name)*

for the **(addition or removal)** of

Severe or Chronic pain

(*medical condition, medical treatment or debilitating disease*) to the list of debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial.

PETITION FOR
ADDITION or REMOVAL
(Circle one)

Petitioner's Information			
Name (First, Middle, Last or Name of Organization): Rebecca Lucas			
Home Address (including Apartment or Suite #): 1953 E Market street			
City: Des Moines	State: IA	Zip Code: 50317	
Telephone Number: 515-509-4556	Email Address: Rebecca.Lucas@Medpharmiowa.com		
Is this the person/ organization to whom information about the petition should be directed?		**Yes** ☑	No ☐

Representative's Information (*If applicable*)			
Name (First, Middle, Last):			
Mailing Address (including Apartment or Suite #):			
City:	State:	Zip Code:	
Is this the person/ organization to whom information about the petition should be directed?		Yes ☐	No ☐

Telephone Number:	Email Address:
[illegible]	

1. Please provide the name of the specific medical condition, medical treatment, or debilitating disease you are seeking to add to or remove from the list of debilitating medical conditions for which patients would be eligible to receive a medical cannabidiol registration card. *Please limit to **ONE** condition, treatment, or debilitating disease per petition.*

Recommended Action	Condition or Disease
☑ Add ☐ Remove	Severe or Chronic Pain

2. Please provide a brief summary statement that supports the action urged in the petition. *Attach additional pages as needed.*

See attached petition

3. Please provide a brief summary of any data or scientific evidence supporting the action urged in this petition. *Attach additional pages as needed*
//

4. Please provide a list of any reference material that supports your petition.
//

5. Please provide a list of subject matter experts who are willing to testify in support of this petition (if any). The list of subject matter experts must contain names, background, email addresses, telephone numbers, and mailing addresses. *Attach additional pages if needed.*			
Name	(1)	(2)	(3)
Background			
Email address			
Telephone number			
Mailing address			

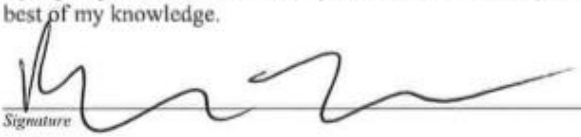
6. Please provide the names and addresses of other persons, or a description of any class of person, known by you to be affected by or interested in the proposed action which is the subject of this petition. *Attach additional pages if needed.*

7. Please indicate whether you have attached a brief in support of the action urged in the petition.	Yes	No
	✓	

8. Please indicate whether you are asking to make an oral presentation of the contents of the petition at a board meeting following submission of the petition.	Yes	No
	✓	

9. Acknowledgement and Signature

By signing this document I certify that the information provided in this petition is true and accurate to the best of my knowledge.



Signature

7-22-2019

Date (mm/dd/yyyy)

- Please fill out each section that is applicable to your petition. Failure to conform to what is required in this petition may result in a denial of consideration by the board.
  - You do not need to fill out sections asking for your representative's information if you do not have one.
  - For section **2**, please provide a short, essay-like summary of your argument.
  - For section **3**, please provide a short, essay-like summary of the articles and evidence that supports your position (if any).
  - For section **4**, please provide a list of articles that are in support of your position (if any).
  - For section **5**, please provide a list of experts that would be willing to testify in support of your position (if any). In the background section, please provide the reasons why they should be considered experts in the area: education, credentials, field of study, occupation, etc. This section is optional but will greatly aid in helping the board consider your petition.
  - For section **6**, please provide information about groups of people that will be affected if the petition were approved. This could include people suffering from a specific disease, advocacy groups, local government officials, etc.
  - Sections **7** and **8** are optional but may aid the board in considering this petition.
- Please be aware:
  - The board may request that you submit additional information concerning this petition. The board will notify you of the requested materials in the event that more information is needed.
  - The board may also solicit comments from any person on the substance of this petition. The board may also submit this petition for a public comment period where any interested person may comment.
  - The board has six months after you submit this form to either deny or grant the petition. If approved, you will be notified in writing that the board has recommended the addition or removal of the medical condition, treatment, or debilitating disease to the board of medicine. If denied, the board will notify you in writing the reasons for denial.

Severe or Chronic Pain Petition

State of Iowa

8/2/2019

Background:

In 2017, the Iowa Legislature passed an initial list of approved conditions for treatment within the medical cannabis program. One of these conditions was untreatable pain which was defined as: "any pain whose cause cannot be removed and, according to generally accepted medical practice, the full range of pain management modalities appropriate for the patient has been used without adequate result or with intolerable side effects.

This definition has proved confusing and difficult to work through for many healthcare practitioners in Iowa. Physicians have questioned the length they must go in order to have met this definition. Are intrusive and expensive surgeries necessary? Must a patient have gone through one or more opioid regimens? The term itself is contradictory. How can physicians treat someone suffering from a condition in which the very name suggests it is untreatable?

Many stakeholders, including the Iowa Dept. of Public Health, the Medical Cannabidiol Board, lawmakers, patients, and physicians realized the difficulty this definition was causing, and in the 2019 legislative session, House File 732, among other things, amended the definition of pain in Iowa's program to simply "severe or chronic pain".

House File 732 received bipartisan and nearly unanimous support in the legislature, and although the bill was ultimately vetoed by Governor Kim Reynolds in late May, it is clear that the reason for the veto was not this definitional change. In its letter to the General Assembly and the Governor, this Medical Cannabidiol Board stated "[n]early all of the proposed amendments [in House File 732] are direct reflections of recommendations made by this Board in its annual report filed with the General Assembly." Reviewing this letter and combined with comments made by Board both prior to and during the 2019 legislative session, it appears (to the petitioner, at least) that the Board was comfortable with this change, as the Board focused its comments of non-support not for this definition, but instead based on the THC gram cap proposed by House File 732.

Fortunately, the structure of Iowa's program allows this important improvement to the program to be made through action by the Board. It is clear that the legislature, which represents the people of Iowa, supported this change, evidenced by the strong vote counts in favor of House File 732. Even the Governor did not appear to oppose this aspect of the bill, as her comments vetoing the bill, like the Board's, instead focused on the THC gram cap.

Not only is this a change supported by the legislature and the people of Iowa, along with the medical community, it is an improvement that is backed by scientific literature. The remainder of this petition describes how cannabinoids have been shown to be effective in the treatment of severe and chronic pain. Additionally, this Board has opined before that it has not accepted certain petitions because the Board believed the particular conditions were covered under the definition of untreatable pain. The fact that petitions were submitted for "pain" conditions and that patients have expressed difficulty

convincing their doctors that a particular condition is covered under "untreatable pain" demonstrate that the definition is problematic and that there is not a clear, uniform understanding of it across Iowa.

A final note on the mechanics of this change. The petitioner acknowledges that it may seem odd to have both untreatable pain and severe or chronic pain as conditions. The Board has the ability to recommend for 2020 that the legislature remove untreatable pain, leaving severe or chronic pain as the only pain category. If the Board approves this addition, it could also (on its own or in response to a petition), remove untreatable pain as a condition. If it takes this options, the petitioner would caution the Board to work with the Iowa Department of Public Health to ensure that there is not a gap during which a pain category is not an approved condition.

Literature

The below is a subset of literature related to pain and cannabis. Pain is one of the areas that has the most extensive research, therefore this is only a small subset.

Schleider et al "Prospective analysis of safety and efficacy of medical cannabis in large unselected population of patients with cancer"

This observational study of over 2500 cancer patients in Israel explored dosage, symptom improvement and pharmaceutical use after initiation of medical cannabis use.

- Patients taking up to 1000mg THC/day = 90g/90 days
- Over 90% reported improvement in their condition symptoms (sleep, pain, nausea)
- **Significant improvements in pain with treatment**
    - 45% of those taking cannabis decreased or stopped taking opioids

Haroutonian et al. "The Effect of Medicinal Cannabis on Pain and Quality-Of-Life Outcomes in Chronic Pain"

Prospective, open-label study to determine the long-term effect of medical cannabis treatment on pain in participants with treatment-resistant chronic pain

- **Pain severity and symptom scores improved in patients receiving medical cannabis**

MN Dept of Health "Intractable Pain Patients in the Minnesota Medical Cannabis Program: Experience of Enrollees During the First Five Months"

Report drawing from enrollment, purchasing, system and side effect ratings at time of each purchase, and survey results to describe the experience of patients newly enrolled in the program for intractable pain during the first five months of this as a qualifying condition (n=2290)

- **High level of benefit for pain seen with 60% of patients, and 43% of health care providers**
    - 6 or 7 rating on a 7-point scale
- Benefit second most mentioned was improved sleep
    - Of those receiving at least 30% reduction in pain scores, 8% of patients were taking 214mg THC/day = 19.2g/90 days' supply

- "disorientation as a side effect reported by <3% of patients

Ware et al. "Cannabis for the Management of Pain: Assessment of Safety Study" (COMPASS) (2015)

In this prospective cohort study, a standardized herbal cannabis product was evaluated vs control to assess safety (serious/non-serious adverse events) as well as secondary outcomes of pain, mood, quality of life.

- Control vs. Test (125mg/gram cannabis) x 1 year
- Studied primary outcome (serious/non-serious adverse events), safety outcomes, pain, mood, and quality of life
- 215 test subjects (141 current users and 58 ex-users) and 216 control subjects.
- Median dose = 2.5g/day = 300mg THC/day = 27g/90 days
- No difference in risk of serious adverse events between groups
- **Significant reduction in average pain intensity in cannabis user's vs control**

National Academies of Science "The Therapeutic effects of Cannabis and cannabinoids"

Comprehensive review done by the National Academies of Science on Cannabinoids in regard to their treatment of symptomology.

- **"There is conclusive or substantial evidence that cannabis or cannabinoids are effective for the treatment of chronic pain in adults"**

Below is the section described within this document

Systematic Reviews

Five good- to fair-quality systematic reviews were identified. Of those five reviews, Whiting et al. (2015) was the most comprehensive, both in terms of the target medical conditions and in terms of the cannabinoids tested. Snedecor et al. (2013) was narrowly focused on pain related to spinal cord injury, did not include any studies that used cannabis, and only identified one study investigating cannabinoids (dronabinol). Two reviews on pain related to rheumatoid arthritis did not contribute unique studies or findings (Fitzcharles et al., 2016; Richards et al., 2012). Finally, one review (Andreae et al., 2015) conducted a Bayesian analysis of five primary studies of peripheral neuropathy that had tested the efficacy of cannabis in flower form administered via inhalation. Two of the primary studies in that review were also included in the Whiting review, while the other three were not. It is worth noting that the conclusions across all of the reviews were largely consistent in suggesting that cannabinoids demonstrate a modest effect on pain.

For the purposes of this discussion, the primary source of information for the effect on cannabinoids on chronic pain was the review by Whiting et al. (2015). Whiting et al included RCTs that compared cannabinoids to usual care, placebo or no treatment 10 conditions. Where RCTs were unavailable for a condition or outcome, nonrandomized studies including uncontrolled studies were considered. This information was supplemented by a search of the primary literature from April 2015 to August 2016 as well as by additional context from Andreae et al. (2015) that was specific to the effects of inhaled

cannabinoids. The rigorous screening approach used by Whiting et al. (2015) led to the identification of 28 randomized trials in patients with chronic pain (2,454 participants). Twenty-two of these trials evaluated plant-derived cannabinoids (nabiximols, 13 trials; plant flower that was smoked or vaporized, 5 trials; THC oramucosal spray, 3 trials; and oral THC, 1 trial) while five trials evaluated synthetic THC (i.e., nabilone). All but one of the selected primary trials used a placebo control, while the remaining trial used an active comparator (amitriptyline). The medical condition underlying the chronic pain was most often related to a neuropathy (17 trials); other conditions included cancer pain, multiple sclerosis, rheumatoid arthritis, musculoskeletal issues, and chemotherapy-induced pain. Analyses across seven trials that evaluated nabiximols and one that evaluated the effects of inhaled cannabis suggested that plant-derived cannabinoids increase the odds for improvement of pain by approximately 40 percent versus the control condition (odds ratio [OR] 1.41, 95% confidence interval [CI] = 0.99–2.00; 8 trials). The effects did not differ significantly across pain conditions, although it was not clear that there was adequate statistical power to test for such differences.

Only one trial (n = 50) that examined inhaled cannabis was included in the effect size estimates from Whiting et al. (2015). This study (Abrams et al., 2007) also indicated that cannabis reduced pain versus a placebo (OR 3.43, 95% CI = 1.03–11.48). It is worth noting that the effect size for inhaled cannabis is consistent with a separate recent review of five trials of the effect of inhaled cannabis on neuropathic pain (Andreae et al., 2015). The pooled odds ratios (ORs) from these trials contributed to the Bayesian pooled effect estimate of 3.22 for pain relief versus placebo (95% CI = 1.59–7.24) tested across 9 THC concentrations. There was also some evidence of a dose-dependent effect in these studies.

Primary Literature

In the addition to the reviews by Whiting et al. (2015) and Andreae et al. (2015), the committee identified two additional studies on the effect of cannabis flower on acute pain (Wallace et al., 2015; Wilsey et al., 2016). One of those studies found a dose-dependent effect of vaporized cannabis flower on spontaneous pain, with the high dose (7 percent THC) showing the strongest effect size (Wallace et al., 2015). The other study found that vaporized cannabis flower reduced pain but did not find a significant dose-dependent effect (Wilsey et al., 2016). These two studies are consistent with the previous reviews by Whiting et al. (2015) and Andreae et al. (2015), suggesting a reduction in pain after cannabis administration.

Discussion of Findings

The majority of studies on pain cited in Whiting et al. (2015) evaluated nabiximols outside the United States. In their review, the committee found that only a handful of studies have evaluated the use of cannabis in the United States and all of them evaluated cannabis in flower form provided by the National Institute on Drug Abuse that was either vaporized or smoked. In contrast, many of the cannabis products that are sold in state regulated markets bear little resemblance to the products that are available for research at the federal level in the United States.

For example, in 2015 between 498,170 and 721,599 units of medical and recreational cannabis edibles were sold per month in Colorado (Colorado DOR, 2016, p. 12). Pain patients also use topical forms (e.g., transdermal patches and creams). Thus, while the use of cannabis for the treatment of pain is supported by well-controlled clinical trials as reviewed above, very little is known about the efficacy, dose, routes of administration, or side effects of commonly used and commercially available cannabis products in the

United States. Given the ubiquitous availability of cannabis products in much of the nation, more research is needed on the various forms, routes of administration, and combination of cannabinoids.

Conclusion: There is conclusive or substantial evidence that cannabis or cannabinoids are effect for the treatment of chronic pain in adults

Sagy et al "Safety and Efficacy of Medical Cannabis in Fibromyalgia" (2019)

Published after the National Academies of Science Review. This observational study followed fibromyalgia patients initiating medical cannabis treatment n=367

- Pain intensity (scale 0-10) reduced from a median of 9.0 at baseline to 5.0 ($p<0.001$)
- 81.1% of patients achieved treatment response
- Patients were allowed up to 1000mg THC/day = 90g/90 days
- Median patient dose after 6 months = 140mg THC/day = 12.6g/90 days
- **Medical cannabis appears to be safe and effective alternative for the treatment of fibromyalgia symptoms**