MMP-051

# 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. 24:61-3. 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:   |
|    | Street Addres   |
|    | City, State, Z  |
|    | Telephone N   |
|    | Email Addres  |
| 2. | Identify the medical condition or treatment thereof proposed. Please be specific. Do not submit broad categories (such as "mental illness").  |
| 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.   |

Chronic pain is defined as any pain lasting longer than 12 weeks.

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.

Allof the conventionally perscribed medications for chronic pain have sever adverse side effects including but not limited to... SEE ATTACHED PAGES

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.

SEE ATTACHED PAGES

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.

GEE ATTACHED PAGES

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.]

SUG ATTACHED PAGES

# MEDICINAL MARIJUANA PETITION (Continued)

|         | ach letters of support from physicians or other licensed health care professionals knowledgeable about the dition. List below the number of letters attached and identify the authors.                         |
|---------|--|
|         |  |
|         |  |
|         |  |
|         |  |
|         | tify, under penalty of perjury, that I am 18 years of age or older; that the information provided in this petition is and accurate to the best of my knowledge; and that the attached documents are authentic. |
| Signatu | Date   |
|         | 8 131/16   |

6.

NEURONTIM, GRALISE, & HORIZANT GENERIC NAME: GABAPENTIN ANTICONVULSANT

"Check with your doctor immediately if any of the following side effects occur:"

# More Common

- · Clumsiness or unsteadiness
- · continuous, uncontrolled, back-and-forth, or rolling eye movements

## More Common In Children

- Aggressive behavior or other behavior problems
- anxiety
- concentration problems and change in school performance
- crying
- depression
- · false sense of well-being
- hyperactivity or increase in body movements
- · rapidly changing moods
- · reacting too quickly, too emotional, or overreacting
- restlessness
- suspiciousness or distrust

# Less Common

- Black, tarry stools
- chest pain
- chills
- cough
- depression, irritability, or other mood or mental changes
- fever
- loss of memory
- · pain or swelling in the arms or legs
- painful or difficult urination
- shortness of breath
- sore throat
- sores, ulcers, or white spots on the lips or in the mouth
- swollen glands
- · unusual bleeding or bruising
- · unusual tiredness or weakness

"Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:"

#### More common

- Blurred vision
- · cold or flu-like symptoms
- delusions

- · dementia
- hoarseness
- · lack or loss of strength
- lower back or side pain
- · swelling of the hands, feet, or lower legs
- trembling or shaking

# Less common or rare

- · Accidental injury
- appetite increased
- back pain
- · bloated or full feeling
- body aches or pain
- burning, dry, or itching eyes
- change in vision
- change in walking and balance
- clumsiness or unsteadiness
- congestion
- constipation
- cough producing mucus
- · decrease in sexual desire or ability
- difficulty with breathing
- dryness of the mouth or throat
- earache
- excess air or gas in the stomach or intestines
- excessive tearing
- eye discharge
- · feeling faint, dizzy, or lightheadedness
- feeling of warmth or heat
- flushed, dry skin
- flushing or redness of the skin, especially on the face and neck
- frequent urination
- fruit-like breath odor
- impaired vision
- incoordination
- increased hunger
- · increased sensitivity to pain
- increased sensitivity to touch
- increased thirst
- indigestion
- noise in the ears
- pain, redness, rash, swelling, or bleeding where the skin is rubbed off
- passing gas
- · redness or swelling in the ear
- · redness, pain, swelling of the eye, eyelid, or inner lining of the eyelid
- runny nose
- sneezing
- sweating

- · tender, swollen glands in the neck
- tightness in the chest
- tingling in the hands and feet
- · trouble sleeping
- · trouble swallowing
- trouble thinking
- twitching
- · unexplained weight loss
- voice changes
- vomiting
- · weakness or loss of strength
- · weight gain

SITE -- http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0045606/#DDIC600709.side\_effects\_section

#### LYRICA

GENERIC NAME: PREGABALIN

Nerve Pain Medication

"Check with your doctor immediately if any of the following side effects occur:"

## Less common

- Difficult or labored breathing
- · shortness of breath
- · tightness in the chest

## Rare

- Blistering, peeling, or loosing of the skin
- chills
- cough
- diarrhea
- · difficulty with swallowing
- dizziness
- Fast heartbeat
- hives
- itching
- joint or muscle pain
- · puffiness or swelling of the eyelidsor around the eyes, face, lips, or tongue
- · red skin lesions, often with a purple center
- red, irritated eyes
- skin rash
- sore throat
- · sores, ulcers, or white spots in the mouth or on the lips
- · unusual tiredness or weakness

"Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:"

## More common

- Accidental injury
- · bloating or swelling of the face, arms, hands, lower legs, or feet
- blurred vision

- burning, tingling, numbness or pain in the hands, arms, feet, or legs
- · change in walking and balance
- · clumsiness
- confusion
- delusions
- dementia
- difficulty having a bowel movement(stool)
- · difficulty with speaking
- double vision
- dry mouth
- fever
- headache
- hoarseness
- · increased appetite
- lack of coordination
- loss of memory
- · lower back or side pain
- painful or difficult urination
- problems with memory
- rapid weight gain
- · seeing double
- sensation of pins and needles
- shakiness and unsteady walk
- sleepiness or unusual drowsiness
- stabbing pain
- swelling
- tingling of the hands or feet
- trembling, or other problems with muscle control or coordination
- unusual weight gain or loss

# Less common

- Anxiety
- bloated or full feeling
- burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings
- Chest pain
- cold sweats
- coma
- cool, pale skin
- · cough producing mucus
- decrease or change in vision
- depression
- · excess air or gas in the stomach or intestines
- eye disorder
- · false or unusual sense of well-being
- general feeling of discomfort or illness
- increased hunger
- joint pain
- · loss of appetite

- · loss of bladder control
- loss of strength or energy
- muscle aches and pain
- · muscle twitching or jerking
- · muscle weaknes
- nausea
- nervousness
- nightmares
- · noisy breathing
- pain
- · passing gas
- · rhythmic movement of the muscles
- runny nose
- seizures
- shivering
- · slurred speech
- sweating
- · trouble sleeping
- twitching
- · uncontrolled eye movements
- Vomiting

SITE -- http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0046069/#DDIC601627.side\_effects\_section

#### **TYLENOL**

## GENERIC NAME: ACETAMINOPHEN

#### ANALGESIC

"Call your doctor right away if you notice any of these side effects:"

- · Bloody or black, tarry stools
- Dark urine or pale stools, nausea, vomiting, loss of appetite, severe stomach pain, yellow skin or eyes
  - Fever or a sore throat that lasts longer than 3 days, or pain that lasts longer than 5 days
  - · Lightheadedness, fainting, sweating, or weakness
  - Unusual bleeding or bruising
  - Vomiting blood or material that looks like coffee grounds

"Do not drink alcohol while you are using this medicine. Acetaminophen can damage your liver, and alcohol can increase this risk. Do not take acetaminophen without asking your doctor if you have 3 or more drinks of alcohol every day."

Over 80,000 Americans visit ERs due to taking too much acetaminophen. Acetaminophen is now the leading cause of liver failure in this country.

SITE-- http://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0008785/?report=details#side effects

# **PERCOCET**

# GENERIC NAME: ACETAMINOPHEN/OXYCODONE

"Call your doctor right away if you notice any of these side effects:"

- Dark urine or pale stools, nausea, vomiting, loss of appetite, stomach pain, yellow skin or eyes
- · Extreme weakness, shallow breathing, uneven heartbeat, seizures, sweating, or cold or clammy skin

- · Lightheadedness, dizziness, or fainting
- Trouble breathing

"if you notice these less serious side effects, talk with your doctor:"

- · Mild lightheadedness, sleepiness, or drowsiness
- · Mild nausea or vomiting
- Headache

SITE -- http://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0011543/?report=details#side effects

#### OXYCONTIN

GENERIC NAME: OXYCODONE

#### NARCOTIC

"Call your doctor right away if you notice any of these side effects:"

- Blue lips, fingernails, or skin
- Extreme dizziness or weakness, shallow breathing, slow or uneven heartbeat, sweating, cold or clammy skin, seizures
  - · Lightheadedness, dizziness, fainting
  - · Severe constipation, stomach pain, or vomiting
  - Trouble breathing or slow breathing

"If you notice these less serious side effects, talk with your doctor:"

- Headache
- Mild constipation, nausea, or vomiting
- · Mild sleepiness or tiredness

SITE -- http://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0011542/?report=details#side\_effects

# **METHADONE**

## NARCOTIC

"Call your doctor right away if you notice any of these side effects:"

- · Blue lips, fingernails, or skin
- Extreme dizziness or weakness, shallow breathing, slow or uneven heartbeat, sweating, seizures, cold or clammy skin
  - · Fast, pounding, or uneven heartbeat
  - · Severe confusion, lightheadedness, dizziness, fainting
  - Severe constipation, stomach pain, or vomiting
  - · Trouble breathing or slow breathing

"If you notice these less serious side effects, talk with your doctor:"

- · Mild constipation, nausea, or vomiting
- Mild sleepiness or tiredness

SUTE --http://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0011124/?report=details#side effects

#### VICODIN

## GENERIC NAME: ACETAMINOPHEN/HYDROCODONE

#### NARCOTIC

"Call your doctor right away if you notice any of these side effects:"

- · Blistering, peeling, red skin rash
- · Change in how much or how often you urinate
- Dark urine or pale stools, loss of appetite, stomach pain, yellow skin or eyes
- Extreme weakness, shallow breathing, slow heartbeat, sweating, cold or clammy skin

- · Lightheadedness, dizziness, fainting
- Unusual bleeding or bruising

"If you notice these less serious side effects, talk with your doctor:"

- Constipation, nausea, vomiting
- Tiredness or sleepiness

SITE --http://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0010590/?report=details#side effects

## ZOHYDRO ER

GENERIC NAME: HYDROCODONE

# **NARCOTIC**

"Severity: Major

If any of the following side effects occur while taking hydrocodone, check with your doctor immediately:"

## Less common:

- · Bloating or swelling of the face, arms, hands, lower legs, or feet
- body aches or pain
- · chills
- · cough
- depression
- · difficult or labored breathing
- · ear congestion
- · fear or nervousness
- fever
- headache
- loss of voice
- · nasal congestion
- rapid weight gain
- runny nose
- sneezing
- sore throat
- tightness in the chest
- tingling of the hands or feet
- · unusual tiredness or weakness
- unusual weight gain or loss

"Check with them if any of the following side effects continue, or if you are concerned about them:"

## More common:

- · Difficulty having a bowel movement (stool)
- nausea

#### Less common:

- Abdominal or stomach pain or discomfort
- back pain
- bladder pain
- · bloody or cloudy urine
- · difficult, burning, or painful urination
- dry mouth
- · frequent urge to urinate
- heartburn

- itching skin
- · lower back or side pain
- muscle spasms
- vomiting

SITE -- https://www.drugs.com/sfx/zohydro-er-side-effects.html

#### **DEPODUR**

GENERIC NAME: MORPHINE

**NARCOTIC** 

Call your doctor right away if you notice any of these side effects:

- Pain, burning, or swelling where the IV is given
- · Shortness of breath, trouble breathing
- · Skin rash, itching, or hives
- · Slow heartbeat
- Swelling in the legs, ankles, or feet
- Trouble going to the bathroom (urinating)

If you notice these less serious side effects, talk with your doctor:

- Constipation
- · Drowsiness, dizziness, or confusion
- Nausea and vomiting
- Sweating

SITE -- http://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0011276/?report=details#side\_effects It can treat moderate to severe pain. It can also treat narcotic drug addiction

# DISKETS

GENERIC NAME: MORPHINE

NARCOTIC

"Call your doctor right away if you notice any of these side effects:"

- Blue lips, fingernails, or skin
- Extreme dizziness or weakness, shallow breathing, slow or uneven heartbeat, sweating, seizures, cold or clammy skin
  - Fast, pounding, or uneven heartbeat
  - · Severe confusion, lightheadedness, dizziness, fainting
  - · Severe constipation, stomach pain, or vomiting
  - · Trouble breathing or slow breathing

"If you notice these less serious side effects, talk with your doctor:"

- Mild constipation, nausea, or vomiting
- · Mild sleepiness or tiredness

SITE-- http://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0011124/?report=details#side effects

# **OPANA**

GENERIC NAME: OXYMORPHONE

**NARCOTIC** 

"Check with your doctor immediately if any of the following side effects occur:"

Less common

- · Blurred vision
- confusion

- · decreased urination
- · difficult or labored breathing
- · dizziness, faintness, or lightheadedness when getting up suddenly from a lying or sitting position
- · dry mouth
- fast, pounding, racing, or irregular heartbeat or pulse
- headache
- nervousness
- pounding in the ears
- rapid breathing
- sunken eyes
- sweating
- · swelling of the hands, ankles, or feet
- thirst
- tightness in the chest
- · unusual tiredness or weakness
- wrinkled skin

#### Rare

- · Abdominal or stomach pain
- chest pain or discomfort
- chills
- cold sweats
- cough
- · decrease in consciousness
- decrease in urine volume
- difficulty in passing urine(dribbling)
- difficulty with sleeping
- difficulty with swallowing
- disorientation
- drowsiness to profound coma
- fever
- hallucination
- · hives, itching, or skin rash
- hyperventilation
- hoarseness
- · irregular, slow, or shallow breathing
- irritability
- irritation
- joint pain, stiffness, or swelling
- lethargy
- painful urination
- pale or blue lips, fingernails, or skin
- puffiness or swelling of the eyelidsor around the eyes, face, lips, or tongue
- redness of the skin
- restlessness
- severe constipation
- severe vomiting
- shaking

· trouble in holding or releasing urine

"Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:"

# More common

- Difficulty having a bowel movement (stool)
- · feeling of constant movement of self or surroundings
- increased sweating
- · nausea or vomiting
- · relaxed and calm
- sensation of spinning
- sleepiness

# Less common

- Acid or sour stomach
- belching
- · decreased appetite
- · decreased weight
- diarrhea
- discouragement
- excess air or gas in the stomach or intestines
- · feeling of warmth
- feeling sad or empty
- full or bloated feeling
- heartburn
- indigestion
- lack of appetite
- · loss of interest or pleasure
- passing gas
- pressure in the stomach
- redness of the face, neck, arms, and occasionally, upper chest
- stomach discomfort or upset
- swelling of the abdominal or stomach area
- tiredness
- trouble concentrating

# Rare

- Blistering, crusting, irritation, itching, or reddening of the skin
- cracked, dry, scaly skin
- · difficulty with thinking or concentrating
- disturbed color perception
- double vision
- · false or unusual sense of well-being
- feeling jittery
- halos around lights
- loss of vision
- mental depression
- night blindness
- · nightmares or unusually vivid dreams
- overbright appearance of lights

- sudden sweating
- tunnel vision
- · welts

SITE -- http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0046215/#DDIC602601.side\_effects\_section

#### BUPRENEX

#### GENERIC NAME: BUPRENORPHINE

#### NARCOTIC

"Call your doctor right away if you notice any of these side effects:"

- Dark urine or pale stools, nausea, vomiting, loss of appetite, stomach pain, yellow skin or eyes
- Extreme dizziness or weakness, shallow breathing, sweating, seizures, cold or clammy skin
- Fast, pounding, or uneven heartbeat
- · Lightheadedness, dizziness, or fainting
- Seizures
- · Trouble breathing or slow breathing

"If you notice these less serious side effects, talk with your doctor:"

- Anxiety, depression, or nervousness
- Constipation
- · Headache, pain, weakness or tired feeling, or trouble sleeping
- · Increased sweating
- · Warmth or redness in your face, neck, or chest

SITE -- http://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0023948/?report=details#side effects

## DILAUDID

#### GENERIC NAME: HYDROMORPHONE

## NARCOTIC

"Check with your doctor immediately if any of the following side effects occur:"

# Less common or rare

- Agitation
- · bloody, black, or tarry stools
- blurred vision
- changes in behavior
- chest pain or discomfort
- convulsions
- decreased urination
- dry mouth
- fast, pounding, slow or irregular heartbeat
- lightheadedness, dizziness, or fainting
- · mood or mental changes
- rapid breathing
- severe stomach pain, cramping, or burning
- stiff neck
- sunken eyes
- · thoughts of killing oneself
- trouble breathing
- unusual tiredness
- vomiting of material that looks like coffee grounds, severe and continuing

· wrinkled skin

"Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:"

## More common

- Difficulty having a bowel movement (stool)
- difficulty with moving
- joint pain
- · muscle pain or stiffness
- nausea

#### Less common

- · Acid or sour stomach
- back pain
- belching
- bloating or swelling of the face, arms, hands, lower legs, or feet
- diarrhea
- discouragement
- feeling sad or empty
- heartburn
- indigestion
- irritability
- · loss of interest or pleasure
- muscle spasms
- pain in the arms or legs
- stomach discomfort, upset, or pain
- tingling of the hands or feet
- trouble concentrating
- · unusual weight gain or loss

# Less common or rare

- Being forgetful
- · bleeding after defecation
- clumsiness
- continuing ringing or buzzing or other unexplained noise in the ears
- crying
- delusions of persecution, mistrust, suspiciousness, or combativeness
- difficulty with swallowing
- difficulty with walking
- double vision
- excess air or gas in the stomach or intestines
- feeling of constant movement of self or surroundings
- full feeling
- increased appetite
- joint pain, stiffness, or swelling
- · loss in sexual ability, desire, drive, or performance
- loss of balance
- · low body temperature
- muscle aches
- muscle twitching or jerking

- · overactive reflexes
- · rhythmic movement of muscles
- runny nose
- · seeing, hearing, or feeling things that are not there
- sensation of spinning
- shivering
- slurred speech
- sneezing
- · swelling of the feet or lower legs
- trouble with speaking

SITE -- http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0045734/#DDIC603247.side\_effects\_section

#### **ULTRAM**

GENERIC NAME: TRAMADOL

# **NARCOTIC**

"Check with your doctor immediately if any of the following side effects occur:"

# Less Common Or Rare

- Abdominal or stomach fullness
- abnormal or decreased touch sensation
- blisters under the skin
- bloating
- · blood in the urine
- · blood pressure increased
- blurred vision
- change in walking and balance
- chest pain or discomfort
- chills
- convulsions (seizures)
- darkened urine
- difficult urination
- dizziness or lightheadedness when getting up from a lying or sitting position
- fainting
- fast heartbeat
- frequent urge to urinate
- · gaseous abdominal or stomach pain
- heart rate increased
- indigestion
- irregular heartbeat
- loss of memory
- · numbness and tingling of the face, fingers, or toes
- numbness, tingling, pain, or weakness in the hands or feet
- pain in the arms, legs, or lower back, especially pain in the calves or heels upon exertion
- pain or discomfort in the arms, jaw, back, or neck
- pains in the stomach, side or abdomen, possibly radiating to the back
- pale bluish-colored or cold hands or feet
- · recurrent fever
- seeing, hearing, or feeling things that are not there

- trouble concentrating
- unusual feeling of excitement
- weakness

# Less Common Or Rare

- Abnormal dreams
- appetite decreased
- back pain
- bladder pain
- · blistering, crusting, irritation, itching, or reddening of the skin
- · bloody or cloudy urine
- · body aches or pain
- · change in hearing
- clamminess
- cold flu-like symptoms
- confusion
- · cough producing mucus
- · cracked, dry, or scaly skin
- decreased interest in sexual intercourse
- difficult, burning, or painful urination
- difficulty with moving
- disturbance in attention
- ear congestion
- ear drainage
- · earache or pain in ear
- excessive gas
- fall
- · false or unusual sense of well-being
- · feeling hot
- feeling jittery
- · flushing or redness of the skin
- general feeling of bodily discomfort
- goosebumps
- headache, severe and throbbing
- hoarseness
- hot flashes
- · inability to have or keep an erection
- · itching, pain, redness, swelling, tenderness, or warmth on the skin
- joint sprain
- joint stiffness
- joint swelling
- loss in sexual ability, desire, drive, or performance
- loss of voice
- · lower back or side pain
- · muscle aching or cramping
- muscle injury
- · muscle pain or stiffness
- · muscle spasms or twitching

- · severe cramping
- severe nausea
- · severe redness, swelling, and itching of the skin
- shortness of breath
- sweats
- · trembling and shaking of the handsor feet
- trouble performing routine tasks
- weak or absent pulses in the legs
- yellow eyes or skin

"Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:"

## More common

- · Abdominal or stomach pain
- agitation
- anxiety
- constipation
- cough
- diarrhea
- discouragement
- drowsiness
- dry mouth
- · feeling of warmth
- feeling sad or empty
- feeling unusually cold
- fever
- · general feeling of discomfort or illness
- headache
- heartburn
- irritability
- itching of the skin
- joint pain
- loss of appetite
- loss of interest or pleasure
- loss of strength or weakness
- · muscle aches and pains
- nausea
- nervousness
- · redness of the face, neck, arms, and occasionally, upper chest
- restlessness
- runny nose
- shivering
- skin rash
- · sleepiness or unusual drowsiness
- sore throat
- stuffy nose
- sweating
- tiredness

- nasal congestion
- neck pain
- · night sweats
- pain
- pain in the limbs
- pain or tenderness around the eyesand cheekbones
- · pain, swelling, or redness in the joints
- skin discoloration
- swelling
- swelling of the hands, ankles, feet, or lower legs
- tightness of the chest
- trouble in holding or releasing urine
- · trouble with sleeping
- · troubled breathing
- · weight increased or decreased

"After you stop using this medicine, it may still produce some side effects that need attention. During this period of time, check with your doctor immediately if you notice the following side effects:"

- Gooseflesh
- · high blood pressure
- · increased sweating
- increased yawning
- shivering or trembling
- · unusually large pupils

SITE -- http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0044659/#DDIC601787.side\_effects\_section

# DURAGESIC

GENERIC NAME: FENTANYL

## NARCOTIC

"Check with your doctor immediately if any of the following side effects occur:"

# More common

- Black, tarry stools
- blurred vision
- chest pain
- confusion
- convulsions
- cough
- decreased urine
- · difficult or labored breathing
- dizziness
- dry mouth
- fainting
- · fever or chills
- increased thirst
- irregular heartbeat
- lightheadedness
- loss of appetite
- · lower back or side pain

- · mood changes
- · muscle pain or cramp
- nausea or vomiting
- nervousness
- · numbness or tingling in the hands, feet, or lips
- painful or difficult urination
- pale skin
- pounding in the ears
- rapid breathing
- sneezing
- sore throat
- sunken eyes
- swelling of the hands, ankles, feet, or lower legs
- tightness in the chest
- · troubled breathing with exertion
- · ulcers, sores, or white spots in the mouth
- · unusual bleeding or bruising
- · unusual tiredness or weakness
- · wrinkled skin

#### Less Common

- · Abdominal or stomach pain
- · change in walking and balance
- · clumsiness or unsteadiness
- · decreased awareness or responsiveness
- · decreased frequency of urination
- headache
- muscle twitching or jerking
- pounding in the ears
- · rhythmic movement of the muscles
- · seeing, hearing, or feeling things that are not there
- seizures
- severe constipation
- severe sleepiness
- · shakiness in the legs, arms, hands, or feet
- · slow or fast heartbea
- · thinking abnormalities
- · trembling or shaking of the hands or feet

"Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:"

# More Common

- · Back pain
- diarrhea
- difficulty having a bowel movement(stool)
- difficulty with moving
- discouragement
- · feeling sad or empty
- irritability

- · lack or loss of strength
- · loss of interest or pleasure
- muscle stiffness
- pain in the joints
- · sleepiness or unusual drowsiness
- tiredness
- · trouble concentrating
- trouble sleeping
- weight loss

## Less common

- Changes in vision
- excessive muscle tone
- · Feeling of constant movement of self or surroundings
- feeling of warmth or heat
- flushing or redness of the skin, especially on the face and neck
- irritation, pain, or sores at the site of application
- itching skin
- muscle tension or tightness
- rash
- sensation of spinning
- sweating

SITE -- http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0044868/#DDIC600673.side\_effects\_section

Some patients with more severe pain take prescription narcotics others only take over the counter drugs such as acetaminophen (Tylenol and its generics). Many people believe that acetaminophen is a safe alternative to taking perception narcotics. However, over 80,000 Americans visit ERs due to taking too much acetaminophen. Acetaminophen is now the leading cause of liver failure in this country

Other patients may try to avoid taking prescription medications and take ibuprofen and other NSAIDS instead; raising their risk of having a heart attack or stroke.

It is extremely important to note that for some patients with chronic pain in their muscle, joint, bones and/or neuropathic/nerve pain is so severe that it requires the use of prescription narcotic pain relievers such as codeine, OxyContin, and hydrocodone, fentanyl, morphine, et al as noted above. The use of prescription narcotic painkillers is extremely dangerous.

Prescriptions for painkillers have climbed 300% in the past decade causing 46 deaths per day which equals almost 17,000 Americans dying each year from overdose. Also, for every one death more than 30 Americans go to the ER for opioid/painkiller complications totaling more than 510,000.

One of the most dangerous factors of using prescription opioids is the fact that tolerance builds extremely quickly. Patients may start out on a very low dose that numbs their pain; but within just a few months of taking the prescription exactly as ordered they are taking very dangerous, deadly overdose levels to have the same pain numbing effects.

In as short as a few months to 1+ year a patient may be taking 5 to 10 fold more prescription opioids for them to work causing a profound chance for addiction, overdose and/or death.

7. Chronic pain causes severe suffering and severely impaired the patient's ability to care on activities of daily living in many ways. Chronic pain may cause pain in a patient's muscles, joints, bones, organs, and tissues. It may be sharp, stabbing, throbbing, deep, aching, burning, stinging, pinching, twisting, and/or neuropathic/nerve like. The pain could be localized to one part of their body or it could be all over their body or any combination there of. Patients with chronic pain may have pain levels ranging from mild to moderate to severe to completely debilitating.

Patients with chronic pain may be in such distress that have to lessen their work load. Their pain may make it hard to concentrate on their work; so they may make mistakes or have their performance decline. They may end up having to work from home and might end up quitting their job.

Patients with chronic pain may be suffering so much that they cannot enjoy time with family and friends. They may not be able to go out for dinners, to see shows, sporting events, celebrations, etc. Other patients will have pain so severe they cannot even take part of family/friend gatherings/celebrations at home. They may be in such horrible pain that they cannot partake in activities they once did even in their own homes.

Chronic pain patients are at high risk of developing depression because of their circumstances. They may be in constant or near constant pain and that coupled with their inability to do tasks and activities like they could in the past; makes depression likely to happen.

8. There are no prescription medications to alleviate suffering that does not also cause suffering in and of itself. All of the conventionally prescribed medications have many adverse side effects that cause the patient to suffer and while certain other medications can be prescribed to help alleviate the side effects; those medications also can cause their own side effects.

That is especially true in the case of prescription painkillers.

There are a few non prescription medical therapies that are used with limited success. Most non prescription therapies have little benefit to helping in the long run and do not lead to a patient being cured of their fibromyalgia. The therapies can be cathartic such as stress management techniques, meditation and yoga. Some patients do find limited benefit from accupuncture. However it is usually not enough to completely eradicate or heavily eradicate their pain.

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9. Medical marijuana has been medically, scientifically, and anecdotally proven to be very effective in treating chronic pain. Two cannabinoids found in cannabis, tetrahydrocannabinol (THC) and cannabidiol (CBD), are very effective at lowering pain levels associated with acute pain conditions, chronic pain conditions, spasticity, neuropathic/nerve pain, headaches, and migraines; among others.

THC and CBD help in pain management and treatment because they activate the two main cannabinoid receptors, CB1 and CB2, of the body's endocannabinoid system. CB1 and CB2 regulate the release of neurotransmitter and central nervous system immune cells to manage the patient's pain levels.

There are a vast amount of studies supporting medical marijuana's effectiveness in managing and treating pain.

Medical marijuana has demonstrated the ability to significantly lower pain levels in patients suffering from neuropathic/nerve pain along with nociceptive pain. Nociceptive pain is pain that is that from tissue damage and is usually sharp, aching and/or throbbing. Medical marijuana has even shown it can help manage pain that has not been helped by other treatments.

Studies have found that using medical marijuana for the management of pain is a safe practice. After a year of using marijuana regularly patients with chronic pain were found to be at no greater a risk of serious adverse effects than those who don't uses marijuana.

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# Cannabinoids for treatment of chronic non-cancer pain; a systematic review of randomized trials

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Abstract Go to:

Effective therapeutic options for patients living with chronic pain are limited. The pain relieving effect of cannabinoids remains unclear. A systematic review of randomized controlled trials (RCTs) examining cannabinoids in the treatment of chronic non-cancer pain was conducted according to the PRISMA statement update on the QUORUM guidelines for reporting systematic reviews that evaluate health care interventions. Cannabinoids studied included smoked cannabis, oromucosal extracts of cannabis based medicine, nabilone, dronabinol and a novel THC analogue. Chronic non-cancer pain conditions included neuropathic pain, fibromyalgia, rheumatoid arthritis, and mixed chronic pain. Overall the quality of trials was excellent. Fifteen of the eighteen trials that met the inclusion criteria demonstrated a significant analgesic effect of cannabinoid as compared with placebo and several reported significant improvements in sleep. There were no serious adverse effects. Adverse effects most commonly reported were generally well tolerated, mild to moderate in severity and led to withdrawal from the studies in only a few cases. Overall there is evidence that cannabinoids are safe and modestly effective in neuropathic pain with preliminary evidence of efficacy in fibromyalgia and rheumatoid arthritis. The context of the need for additional treatments for chronic pain is reviewed. Further large studies of longer duration examining specific cannabinoids in homogeneous populations are required.

#### Linked Article

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Keywords: cannabinoids, chronic non-cancer pain, neuropathic pain, systematic review

Introduction Go to:

Chronic pain is common and debilitating with too few effective therapeutic options. Cannabinoids represent a relatively new pharmacological option as part of a multimodel treatment plan. With increasing knowledge of the endocannabinoid system [1–3] and compelling preclinical work supporting that cannabinoid agonists are analgesic



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[4, 5] there is increasing attention on their potential role in the management of pain [6–9]. A previous systematic review done a decade ago identified the need for further randomized controlled trials (RCTs) evaluating cannabinoids in the management of chronic pain indicating that there was insufficient evidence to introduce cannabinoids into widespread use for pain at that time [10]. A subsequent review identified a moderate analgesic effect but indicated this may be offset by potentially serious harm [11]. This conclusion of serious harm mentioned in the more recent review is not consistent with our clinical experience. In addition there have been a number of additional RCTs published since this review. We therefore conducted an updated systematic review examining RCTs of cannabinoids in the management of chronic pain.

Methods Go to:

We followed the PRISMA update on the QUORUM statement guidelines for reporting systematic reviews that evaluate health care interventions [12].

#### Systematic search

A literature search was undertaken to retrieve RCTs on the efficacy of cannabinoids in the treatment for chronic pain. The databases searched were: PubMed, Embase, CINAHL (EBSCO), PsycInfo (EBSCO), The Cochrane Library (Wiley), ISI Web of Science, ABI Inform (Proquest), Dissertation Abstracts (Proquest), Academic Search Premier (EBSCO), Clinical Trials.gov, TrialsCentral.org, individual pharmaceutical company trials sites for Eli Lilly and GlaxoSmithKline, OAIster (OCLC) and Google Scholar. None of the searches was limited by language or date and were carried out between September 7 and October 7, 2010. The search retrieved all articles assigned the Medical Subject Headings (MeSH) Cannabis, Cannabinoids, Cannabidiol, Marijuana Smoking and Tetrahydrocannibinol as well as those assigned the Substance Name tetrahydrocannabinol-cannabidiol combination. To this set was added those articles containing any of the keywords cannabis, cannabinoid, marijuana, marihuana, dronabinol or tetrahydrocannibinol. Members of this set containing the MeSH heading Pain or the title keyword 'pain' were passed through the 'Clinical Queries: therapy/narrow' filter to arrive at the final results set. For the pain aspect, the phrase 'Chronic pain' along with title keyword 'pain' was used to retrieve the relevant literature. We contacted authors of original reports to obtain additional information. Bibliographies of included articles were checked for additional references.

#### Inclusion and exclusion criteria

Included were RCTs comparing a cannabinoid with a placebo or active control group where the primary outcome was pain in subjects with chronic non-cancer pain. Relevant pain outcomes included any scale measuring pain, for example the numeric rating scale for pain (NRS), visual analogue scale for pain (VAS), the Neuropathy Pain Scale or the McGill Pain Scale. We excluded (i) trials with fewer than 10 participants, (ii) trials reporting on acute or experimental pain or pain caused by cancer, (iii) preclinical studies and (iv) abstracts, letters and posters where the full study was not published.

#### Data extraction and validity scoring

One author (ML) did the initial screen of abstracts, retrieved reports and excluded articles that clearly did not meet the inclusion criteria. Both authors independently read the included articles and completed an assessment of the methodological validity using the modified seven point, four item Oxford scale [13, 14] (Figure 1). After reading the complete articles it was clear that several additional papers did not meet inclusion criteria and these were excluded. Discrepancies on the quality assessment scale were resolved by discussion. Trials that did not include randomization were not included and a score of 1 on this item of the Oxford scale was required and the maximum score was 7.

9. of 9



Figure 1
Modified Oxford scale

Information about the specific diagnosis of pain, agent and doses used, pain outcomes, secondary outcomes (sleep, function, quality of life), summary measures, trial duration and adverse events was collected. Information on adverse events was collected regarding serious adverse events, drug related withdrawals and most frequently reported side effects. A serious adverse event according to Health Canada and ICH<sup>1</sup> guidance documents is defined as any event that results in death, is life threatening, requires prolonged hospitalization, results in persistent of significant disability or incapacity or results in congenital anomaly or birth defects [15].

Results Go to:

#### Trial flow

Eighty abstracts were identified of which 58 did not meet inclusion criteria on the initial review of records (
Figure 2). Twenty-two RCTs comparing a cannabinoid with either a placebo or active control group where pain was listed as an outcome were found and full text articles were reviewed, four further studies were excluded, two because pain was not the primary outcome (Zajicek [16, 17]), one because there were fewer than 10 participants in the study (Rintala [18]). A further study was excluded because there were two studies reporting on what appeared to be the same group of participants (Salim [19], Karst [20]), in this case we included the first study in which the pain outcomes were reported (Karst). References of the included trials were reviewed for additional trials meeting inclusion criteria. This revealed no further studies. Eighteen trials met the study criteria for inclusion. We did not retrieve any unpublished data. Given the different cannabinoids, regimens, clinical conditions, different follow-up periods, and outcome measures used in these trials, pooling of data for meta-analysis was inappropriate. Results were therefore summarized qualitatively.

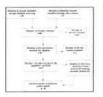


Figure 2
Flow diagram of systematic review

# Primary outcome - efficacy

Eighteen trials published between 2003 and 2010 involving a total of 766 completed participants met inclusion criteria (Table 1). The quality of the trials was very good with a mean score of 6.1 on the 7 point modified Oxford scale. The majority (15 trials) demonstrated a significant analgesic effect for the cannabinoid agent being investigated. Several trials also noted significant improvements in sleep [21–24]. Treatment effects were generally modest, mean duration of treatment was 2.8 weeks (range 6 h–6 weeks) and adverse events were mild and well tolerated.



Table 1

Randomized controlled trials examining cannabinoids in treatment of chronic non-cancer pain

#### Cannabis

Four trials examined smoked cannabis as compared with placebo. All examined populations with neuropathic pain and two involved neuropathic pain in HIV neuropathy [21, 25–27]. All four trials found a positive effect with no serious adverse effects. The median treatment duration was 8.5 days treatment (range 6 h–14 days).

#### Oromucosal extracts of cannabis based medicine (CBM)

Seven placebo controlled trials examined CBM [22-24, 28-30]. Five examined participants with neuropathic pain, one rheumatoid arthritis and one a mixed group of people with chronic pain, many of whom had neuropathic pain. Six of the seven trials demonstrated a positive analgesic effect. Of note in the one trial examining pain in rheumatoid arthritis, the CBM was associated with a significant decrease in disease activity as measured by the 28 joint disease activity score (DAS28) [23].

#### Nabilone

Four trials studied nabilone [31–34]. Three of these trials were placebo controlled and found a significant analgesic effect in spinal pain [34], fibromylagia [32] and spasticity related pain [33]. The fourth compared a daily dose of nabilone 2 mg with dihydrocodeine 240 mg in neuropathic pain. Mean baseline pain was 69.6 mm on the 100 mm VAS and dropped to 59.93 mm for participants taking nabilone and 58.58 mm for those taking dihydrocodeine [31].

#### **Dronabinol**

Two trials involved dronabinol. The earlier trial found that dronabinol 10 mg day<sup>-1</sup> led to significant reduction in central pain in multiple sclerosis [35], a subsequent trial found that dronabinol at both 10 and 20 mg day<sup>-1</sup> led to significantly greater analysis and better relief than placebo as adjuvant treatment for a group of participants with mixed diagnoses of chronic pain on opioid therapy [36].

# THC-11-oic acid analogue (CT-3 or ajulemic acid)

Two studies reported on various aspects of this trial examining ajulemic acid in a group of participants with neuropathic pain with hyperalgesia or allodynia [37, 38]. Nineteen of 21 completed the trial. It was found that ajulemic acid led to significant improvement in pain intensity at 3 h but no difference at 8 h as compared with placebo.

#### Secondary outcome - level of function

Several trials included secondary outcome measures relating to level of function. Two trials examining cannabis based medicines included the Pain Disability Index (PDI) [24, 30]. Numikko found that six of seven functional areas assessed by the PDI demonstrated significant improvement on CBM (-5.61) as compared with placebo (0.24) (estimated mean difference -5.85, P = 0.003) in 125 participants with neuropathic pain while Berman [24] noted no significant difference from placebo in 48 participants with central pain from brachial plexus avulsion. Two studies included the Barthel index for activities of daily living (ADL) [28, 33] and noted no significant improvement in ADLs with nabilone for spasticity related pain [33] or with CBMs for multiple sclerosis [28]. In one trial examining nabilone for the treatment of fibromyalgia the FIQ [39] demonstrated significant improvement as compared with placebo. This measure includes a number of questions regarding function in several areas including shopping, meal preparation, ability to do laundry, vacuum, climb stairs and ability to work. The FIQ also includes questions relating to pain, fatigue, stiffness and mood. The total scores presented in this study were not presented separately so the reader cannot be certain. However given that the majority of questions relate to function it is likely that there were some improvements in function.

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# Drug related adverse effects

The most common adverse events according to the Health Canada definition described above and in <u>Table 1</u>, The most common adverse events consisted of sedation, dizziness, dry mouth, nausea and disturbances in concentration. Other adverse events included poor co-ordination, ataxia, headache, paranoid thinking, agitation, dissociation, euphoria and dysphoria. Adverse effects were generally described as well tolerated, transient or mild to moderate and not leading to withdrawal from the study. This is a significant difference from the withdrawal rates seen in studies of other analgesics such as opioids where the rates of abandoning treatment are in the range of 33% [40]. Except where specifically noted in <u>Table 1</u> there was no specific mention of whether adverse effects caused limitations in function. The most severe treatment related event in the entire sample was a fractured leg related to a fall that was thought to be related to dizziness [34]. Details regarding specific trials are presented in <u>Table 1</u>.

**Discussion** Go to:

#### Efficacy and harm

All of the trials included in this review were conducted since 2003. No trials prior to this date satisfied our inclusion criteria. This review has identified 18 trials that taken together have demonstrated a modest analgesic effect in chronic non-cancer pain, 15 of these were in neuropathic pain with five in other types of pain, one in fibromyalgia, one in rheumatoid arthritis, one as an adjunct to opioids in patients with mixed chronic pain and two in mixed chronic pain. Several trials reported significant improvements in sleep. There were no serious adverse events. Drug related adverse effects were generally described as well tolerated, transient or mild to moderate and most commonly consisted of sedation, dizziness, dry mouth, nausea and disturbances in concentration.

#### Limitations

The main limitations to our findings are short trial duration, small sample sizes and modest effect sizes. Thus there is a need for larger trials of longer duration so that efficacy and safety, including potential for abuse, can be examined over the long term in a greater number of patients. It is also important to recognize that cannabinoids may only reduce pain intensity to a modest degree. It remains for the patients to decide whether this is clinically meaningful.

#### The context of chronic pain

Pain is poorly managed throughout the world. Eighty percent of the world population has no or insufficient access to treatment for moderate to severe pain [41]. Chronic pain affects approximately one in five people in the developed world [42–46] and two in five in less well resourced countries [47]. Children are not spared [48, 49] and the prevalence increases with age [43, 50]. The magnitude of the problem is increasing. Many people with diseases such as cancer, HIV and cardiovascular disease are now surviving their acute illness with resultant increase in quantity of life, but in many cases, poor quality of life due to persistent pain caused either by the ongoing illness or nerve damage caused by the disease after resolution or cure of the disease. In many cases the pain is also caused by the treatments such as surgery, chemotherapy or radiotherapy needed to treat the disease [51–53].

Chronic pain is associated with the worst quality of life as compared with other chronic diseases such as chronic heart, lung or kidney disease [50]. Chronic pain is associated with double the risk of suicide as compared with those living with no chronic pain [54].

In this context, patients living with chronic pain require improved access to care and additional therapeutic

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options. Given that this systematic review has identified 18 RCTs demonstrating a modest analgesic effect of cannabinoids in chronic pain that are safe, we conclude that it is reasonable to consider cannabinoids as a treatment option in the management of chronic neuropathic pain with evidence of efficacy in other types of chronic pain such as fibromyalgia and rheumatoid arthritis as well. Of special importance is the fact that two of the trials examining smoked cannabis [25, 26] demonstrated a significant analgesic effect in HIV neuropathy, a type of pain that has been notoriously resistant to other treatments normally used for neuropathic pain [52]. In the trial examining cannabis based medicines in rheumatoid arthritis a significant reduction in disease activity was also noted, which is consistent with pre-clinical work demonstrating that cannabinoids are anti-inflammatory [55, 56].

Conclusion Go to:

In conclusion this systematic review of 18 recent good quality randomized trials demonstrates that cannabinoids are a modestly effective and safe treatment option for chronic non-cancer (predominantly neuropathic) pain. Given the prevalence of chronic pain, its impact on function and the paucity of effective therapeutic interventions, additional treatment options are urgently needed. More large scale trials of longer duration reporting on pain and level of function are required.

Footnotes Go to:

<sup>1</sup>International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use.

# **Competing Interests**

Go to:

Go to:

The authors have no competing interests.

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# A survey of cannabis (marijuana) use and self-reported benefit in men with chronic prostatitis/chronic pelvic pain syndrome

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Abstract Go to:

#### Introduction:

Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) is a chronic pelvic pain condition largely refractory to treatment. Cannabis (marijuana) use has been reported for a wide variety of chronic pain conditions, but no study has examined prevalence of cannabis use, symptom benefit or side effects, or frequency in CP/CPPS.

#### Methods:

Participants were recruited from an outpatient CP/CPPS urology clinic (n = 98) and online through the Prostatitis Foundation website (n = 244). Participants completed questionnaires (demographics, CP/CPPS, depression, cannabis).

## Results:

The clinic sample included Canadian patients and the online sample included primarily American patients. Due to differences, groups were examined separately. Almost 50% of respondents reported using cannabis (clinic n = 49; online n = 89). Of the cannabis users, 36.8% of clinic and 75% of online respondents reported that it improved their symptoms. Most of the respondents (from the clinic and online groups) reported that cannabis improved their mood, pain, muscle spasms, and sleep. However, they did not note any improvements for weakness, fatigue, numbness, ambulation, and urination. Overall, the effectiveness of cannabis for CP/CPPS was "somewhat/very effective" (57% clinic; 63% online). There were no differences between side effects or choice of consumption and most reported using cannabis rarely.

#### Conclusions:

These are the first estimates in men suffering from CP/CPPS and suggest that while cannabis use is prevalent, its

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medical use and benefit are unknown. This is an understudied area and the benefit or hazard for cannabis use awaits further study.

Introduction Go to:

Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) is characterized by pain in the perineum, pelvic, and suprapubic areas or the external genitalia with variable degrees of voiding or ejaculatory disturbances. The prevalence is about 7.1% (range: 2.2%–16%), with a 6.7% median. CP/CPPS symptoms do not routinely remit, with 66% of community-based samples experiencing symptoms 1 year later, and patients showing no changes in pain, disability, or catastrophizing over 2 years later. CP/CPPS etiology is unclear and medical treatments are largely ineffective. Medications (antimicrobials, alpha-blockers, anti-inflammatories), as well as phytotherapy, biofeedback, thermal therapies, and pelvic floor training have been examined and may provide mild benefit, but most men continue to experience chronic pain.

Physicians may use opioids to manage CP/CPPS pain, but their efficacy is limited and physicians fear tolerance, misuse, and side effects, such as nausea/vomiting or sedation. Chronic pain patients are turning to alternate forms of symptom relief, yet no research on this is available for CP/CPPS. Cannabis sativa has been used for pain and symptom relief for thousands of years. In Canada and several American states, patients use medical cannabis for severe intractable illnesses. As an addition to opioid treatment for chronic pain, vaporized cannabis results in pain reduction without altering plasma opioid levels. Moreover, 71% of the available randomized controlled studies concluded that cannabinoids were associated with pain relief, with low adverse effects, and good tolerance. Cannabis may be used in conjunction with or substitute for prescription opiates resulting in reduced opiate use. Wide ranging types, quantities, and frequency of cannabis use for pain relief have been reported, with chronic non-cancer pain patients reporting previous use (15%) or current use (10%).

We examined cannabis prevalence among men experiencing CP/CPPS-like symptoms from a tertiary care urology department and from an online group. Although previous work has not examined cannabis use in CP/CPPS, it was expected that use would echo previous pain studies. We also solicited patient self-reports on the side effects or potential benefits, frequency, and indication of future cannabis use.

Methods Go to:

# Participants/procedure

Identical online and outpatient surveys were administered to an online community-based sample and a tertiary care outpatient CP/CPPS clinic sample. All participants remained anonymous and received no financial compensation. Clinic patients were approached after their appointments and briefed about this Research Ethics Board-approved study. Interested participants then provided written consent and received a package (letter of information, debriefing form, questionnaires, postage-paid return envelope) to complete and mail back. The online sample was recruited through the Prostatitis Foundation. Participants were a self-selected "availability" sample from site visitors. All participants were required to read and write in English. All questionnaires were in English.

#### Measures

**Demographics** Participants completed questions on demographics (age, CP/CPPS diagnosis, health problems, tobacco use, medication use).

**Medical symptoms** The National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI)<sup>14</sup> assessed prostatitis-like symptoms and their impact on daily life (pain, urinary symptoms, quality of life) providing a score range from 0 to 43. The self-administered NIH-CPSI provides a valid, psychometrically robust outcome

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measure.  $\frac{14}{2}$  Confirmation of CP/CPPS cases was based on NIH-CPSI pain/discomfort in perineum and/or with ejaculation and NIH-CPSI total pain score of  $\geq 4$  (0–21), used in the community  $\frac{15-17}{2}$  and in the general population  $\frac{18}{2}$  studies.

**Depression** The Patient Health Questionnaire 9 (PHQ-9)<sup>19</sup> is a reliable and valid self-report measure using 9 items to assess depressive symptoms. An item sum was used for the indexation of depression.

Experience with cannabis We used a 21-question descriptive survey on experience with cannabis; questions were binary (yes/no), multiple choice, and rating scales. Questions included whether participants had ever used cannabis, the purpose of use, relief of pain/effects with use, potential side effects, usage frequency, and usage method. Participants rated personal experience with different modes of delivery using Likert scale-style responses.

Data analysis Scores were excluded if >15% of the items were missing on measures. Participants who provided ≥85% of items on a particular measure had the missing items imputed using means replacement procedures. As a check on generalizability, primary comparisons between the online and clinic data were computed for age and domains of NIH-CPSI (quality of life pain, urinary), and the PHQ-9. If outcomes differed significantly, online and clinical samples would be examined separately. Due to the exploratory nature, unadjusted t-tests and descriptive analyses (chi-square) were used to evaluate differences between cannabis users and non-users.

Results Go to:

The total sample of participants was comprised of an online self-reported CP/CPPS sample (n = 376) and a tertiary care outpatient CP/CPPS clinic sample (n = 100). Two participants were excluded from the clinic sample and 35% (n = 132) of the online sample was excluded due to incomplete data. In the end, we had 244 online and 98 clinic participants. Missing data pattern for the online group was random.

The online group was on average 10 years younger than the clinic group (p < 0.001), with an average age of 44.57 (standard deviation 13.96) for the full sample (<u>Table 1</u>). The clinic sample was Canadian and the online sample was primarily American.



Table 1 Sample demographics

The online group reported more depressive symptoms, pain, poorer quality of life, and worse symptom scores ( Table 2). For the remaining analyses, samples were examined across groups. Most of clinic (63.3%) and online (79.1%) participants reported a score of 4 or above on prostatitis cut scores ( $\chi^2 = 9.24$ , p = 0.013). While the clinic and online groups did not differ in terms tobacco use ( $\chi^2 = 1.17$ , p = 0.340), the online group (63.1%) consumed more medication for pain, mood, sleep, or spasms than the clinic group (47.4%) ( $\chi^2 = 7.00$ , p = 0.01). There were no group differences when asked if they had ever used cannabis ( $\chi^2 = 0.87$ ,  $\chi^2 = 0.390$ ) (yes 50% clinic, 44.3% online). Examining only those previously using, 36.8% clinic and 75% of the online groups reported that cannabis improved their symptoms ( $\chi^2 = 7.63$ ,  $\chi^2 = 0.006$ ).



Table 2

Psychological and NIH-CPSI differences between clinic and online participants

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Participants were questioned whether cannabis use made their symptoms "worse/no better" to "slightly/much better" (Table 3). The large majority of online and half of clinic participants reported that cannabis improved their mood by a "slightly/much better" degree (Fisher's exact test p = 0.026). Across both groups, cannabis' effects made pain "slightly/much better" ( $\chi^2 = 2.48$ , p = 0.619), as with muscle spasms ( $\chi^2 = 0.51$ , p = 0.474), sleep ( $\chi^2 = 0.54$ , p = 0.461), and a borderline majority for nausea ( $\chi^2 = 0.51$ , p = 0.474). Also a minority of participants reported "slightly/much better" improvement in weakness ( $\chi^2 = 3.11$ , p = 0.078), fatigue ( $\chi^2 = 3.40$ , p = 0.065), numbness ( $\chi^2 = 1.16$ , p = 0.281), ambulating ( $\chi^2 = 0.64$ , p = 0.423), and urination (Fisher's exact test p = 0.432). When asked on overall effectiveness of cannabis for CP/CPPS, most participants (57% clinic, 63% online) reported cannabis as "somewhat/very effective" ( $\chi^2 = 7.89$ , p = 0.051).



<u>Table 3</u>
Cannabis illness-symptom effects across clinic and online participants

There was an even distribution of side effects reported by the groups, with most suggesting "none' to "mild" side effects from cannabis use (70.3% clinic, 70.8% online) ( $\chi^2 = 0.05$ , p = 0.972) (Table 4). Also, if offered a choice, participants reported similar preferences for cannabis method across groups ( $\chi^2 = 1.99$ , p = 0.370), but smoking was a leading choice. There were no differences when asked about the preferred form of cannabis they had used ( $\chi^2 = 2.59$ , p = 0.274), although most participants listed herbal option (buds, sinsemilla, hydrophonic). In current cannabis users, frequency did not differ between groups ( $\chi^2 = 0.27$ , p = 0.88), with most respondents using "rarely" (73.3% clinic, 77.3% online).



Table 4
Side effects, preferred choice, and form used for cannabis across groups

Discussion Go to:

This is the first study to document the initial prevalence and patterns of cannabis use in men suffering from CP/CPPS from an outpatient urology clinic and online. Almost 50% of participants used cannabis and almost 3/4 reported using it for symptom relief. These figures are bigger than those in other studies. The samples were treated as separate during analyses because the online group was younger, reported greater depression, pain, and diminished quality of life. Interestingly, while examining only those having used cannabis, fewer clinic respondents reported benefit compared to the online group. This almost doubling of the reported benefit by the online group may be related to symptom/disease severity differences in this study. The present data cannot describe factors underlying differences in benefit across groups, but this study is consistent with the suggestion that chronic pain is associated with lifetime marijuana use.

Physicians should be aware and question patients on cannabis use. Despite a lack of information on the mechanisms of glycinergic cannabinoids for pain, cannabidiol, a major nonpsychoactive component of cannabis, suppressed chronic inflammatory pain in mice. Furthermore, the use of cannabis was not associated with analgesic tolerance in rats. It appears that cannabinoids' anti-inflammatory action stimulates cannabinoid receptors. However, contrasting results about cannabis side effects discouraged the authors for suggesting its chronic use for pain relief due to associated cognitive deficits and gastrointestinal toxicity.

The online group reported greater distress and NIH-CPSI symptoms, but both groups showed trends where most reported improved symptoms like mood, pain, muscle spasms and sleep. However, no improvements were in

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weakness, fatigue, numbness, or ambulation. Improved symptoms for some patients might reflect the shared effects that pain/muscle spasm can have in regard to improving sleep and ultimately mood. Current research shows that unresolved chronic pain, continuing disease, obesity, and sleeping problems predict the persistence of pain, while issues like mood are weakly associated.<sup>24</sup> Of other note, cannabis use was not helpful for urinary symptoms, which can be very bothersome in patients with CP/CPPS.

This survey showed that the side effects of cannabis appear minimal, with most patients reporting "none' to "mild" side effects. More detailed information on the amount of cannabis use, the types used (medical vs. other) would be important to provide a more detailed pattern of examining benefits. If offered a choice on how to use cannabis, participants reported smoking as the preferred methods – this is similar with other studies. There were no differences by groups – the herbal form was endorsed by most respondents. In regard to current frequency of use, most participants reported using cannabis "rarely;" further study into usage patterns may shed some light on whether participants use cannabis primarily to manage pain flares or muscle spasms, or to aid with sleep. If usage is associated with intermittent pains, as flares, then that may reflect the rarity of reported use.

Our study has its limitations. This initial survey cannot qualify the benefits/risks of cannabis use in CP/CPPS, and simply suggests rates for further comparison. Sample size was an issue in some analyses because finer detail in questions, such as symptom benefit, had to be collapsed into 2 categories ("worse/no change" and "slightly/much better") from original categories ("much worse," "slightly worse," "no change," "slightly better," "much better"). Larger samples are necessary to gather more accurate patterns of use and benefit.

Although our samples were not randomized or stratified, they represent tertiary care outpatient males diagnosed with CP/CPPS, as well as community-based men with CP/CPPS-like symptoms. More online participants reported a prostatitis cut score. Perhaps the clinic men experienced reduced symptoms under the care of a specialist, but there was no opportunity to verify this in our study. Future research should also collect healthcare utilization and previous treatments prior to the onset of cannabis use. This data would allow contrasts and provide insight into medical comorbidities prior to cannabis use. It would also be interesting to examine the associations between psychological pre-cannabis use pain-associated comorbidities, like catastrophizing, and patterns of use.

Conclusion Go to:

This is the first study to examine and report on cannabis usage and benefit in participants with CP/CPPS from a tertiary care and community "availability" sample. The current data suggest that almost 50% of men with CP/CPPS-like symptoms have used cannabis in their lifetimes and that a minority of clinic patients versus most online participants reported cannabis benefit. Future research should examine larger representative samples to further document usage patterns, fuller CP/CPPS symptom benefit, and associated factors with usage in predictive models. The ultimate study would be a randomized controlled trial prospectively evaluating the efficacy and safety of cannabis compared to either placebo or an active comparator.

Footnotes Go to:

Competing interests: Authors declare no competing financial or personal interests.

This paper has been peer-reviewed.

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