MMY-042

#### 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. 24:6l-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 Addre
	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").
	1 oure He Syndrome
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
	`X 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.

#### **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.
	Diagnosis of Tourette Syndrome. Tics include:
• ,	· chughing
•	grunting repeating/muttering/talking to self
	throat clearing finger tapping
6.	suffering, describe the extent to which the treatments causing suffering are generally accepted by the medical
	Overall medications have been ineffective, but
	I had terrible side effects to geodon. I
	couldn't sit still \$ felt like I was crawling
7	Dut of my skin.
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. (see attached)
e <u>Cn</u>	ranic Pain: upper back, neck, eyes & nasal passages from
211	ing .
	Extreme excessive sweating & overheating
	Dut of Controll tics have lead to difficulty breathing Describe the availability of conventional medical therapies other than those that cause suffering to alleviate suffering
0.	caused by the condition and/or the treatment thereof.  I've tried Cognitive behavioral therapy \$
	numerous medications over the last 13
	years without relief of tics.
	Terrer of the same
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.]
	I locable of triachlast is
	installed various afficles and supporting

literature.

## 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 letter From Lisa A. Stackhouse, D.O.. she wrote the letter on a prescription pad.

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 Petition	ner	Date 8-29-16	

# 7. (continued)

Difficulty breathing passing out in extreme have led to me passing out in extreme cases.

- \* Social anxiety because of tics \$ excessive sweating-missed important excessive sweating-missed important excessive sweating-missed important excessive sweating-missed important excessive sweating-missed important
- \* Tourette's has negatively impacted relationships with family & friends, Father askes me to leave room. Girlfriend upset tics lead to lack of intimacy. Friends upset I never want to go out.
  - \* I're been on disability for about loyears. Stanggled to work with tics, especially on phone calls. I have a lot of issues sleeping causing at night, causing issues working during the day.



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#### Tourette Syndrome – Medical Marijuana Research Overview

| IN 8 American Adults Use Marijuai New Poll Finds

Arizona to Vote on Adult Use Mariju

30 September, 2015

Tourette syndrome is a nervous system disorder that affects 1 of every 360 children ages 6 through 17. Studies have shown marijuana safely reduces the frequency of tics associated with the syndrome.

#### Overview of Tourette Syndrome

Tourette syndrome is a condition of the nervous system that develops during childhood. The syndrome is characterized by ties, which ties are characterized as being motor, which means unusual repetitive movements of the body, or vocal, which are involuntary sounds made with the voice. For example, a person with Tourette's may repeatedly shrug their shoulders or uncontrollably blurt out grunting sounds. Ties are also classified as simple, which are sudden, brief, repetitive and involving a limited number of muscles, and complex, which are distinct and coordinated movements that involve several muscle groups.

According to the Centers for Disease Control and Prevention, the tics associated with Tourette syndrome typically begin between the ages of 5 and 10.

The tics can grow in intensity and frequency when a child is stressed or excited. The tics commonly decrease throughout the teenage and adult years and in some cases can disappear entirely. Many with Tourette's, however, have tics worsen with age.

The cause of Tourette's remains unknown, but according to Mayo Clinic, theories include genetic mutations or brain abnormalities. While not life-threatening, Tourette's can still pose lifestyle difficulties for those who are diagnosed. The syndrome is often associated with other related conditions like attention-deficit/hyperactivity disorder, obsessive-compulsive disorder, learning disabilities, depression, and sleep and anxiety disorders

There is no cure for Tourette's, so focus of treatment is on managing the tics so that they don't cause pain or injury or adversely affect the quality of one's school, work or social life. No medications completely eliminate symptoms, but some can limit the frequency of tics. In addition, antidepressants and psychotherapy and behavior therapy are used to assist in symptom management.

#### Findings: Effects of Cannabis on Tourette Syndrome

Research has shown that cannabis can be effective in suppressing ties and also in the treatment of the syndrome's associated behavioral problems (Muller-Vahl, 2013). One study measuring the effects of a single cannabis treatment on adult Tourette's syndrome patients found a significant

tof tics and obsessive-compulsive behavior compared to placebo (Muller-Vahl, et al., 2002). Demonstrating cannabis potential longertion benefits, nother study discovered a significant difference in the reduction of tics compared to placebo in Tourette's patients after six weeks of cannabis treatments. reported a reduction tics in patients after six weeks of cannabis treatments, reported a reduction tics in patients. Tourette's with no serious adverse effects or impairment on neuropsychological performance (Muller-Vahl, 2003).

Tourette syndrome patients being treated with cannabis have shown to experience no impairments in verbal and visual memory, reaction time, intelligence, sustained attention, divided attention, vigilance or mood compared to placebo treatment (Muller-Vahl, et al., 2002) Therefore, regular cannabis use to manage the symptoms associated with Tourette's appears to have no acute or long-term cognitive effects (Muller-Vahl, et al., 2003)

#### States That Have Approved Medical Marijuana for Tourette Syndrome

Currently, Illinois, Minnesota and Ohio have approved medical marijuana specifically for the treatment of Tourette syndrome

A number of other states will consider allowing medical marijuana to be used for the treatment of Tourette syndrome with the recommendation from a physician. These states include: California (any debilitating illness where the medical use of marijuana has been recommended by a physician),

Cof60cticut (other medical conditions may be approved by the Department of Consumer Protection), Massachusetts (other conditions as determined in Shares within a part of the conditions and the conditions subject to approval), Nevada (other conditions subject to approval), Oregon (other conditions subject to approval), Rhode Island (other conditions subject to approval), and Washington (any "terminal or debilitating condition").

In Washington D.C., any condition can be approved for medical marijuana as long as a DC-licensed physician recommends the treatment.

Foursten additional states have approved medical marijuana for the treatment of spasms (motor ties), which is a symptom commonly associated with Tourette's. These states include: Arizona, California, Colorado, Delaware, Florida, Hawaii, Maryland, Michigan, Montana, Nevada, New Hampshire, Or., and, Rhode Island and Washington.

#### Recent Studies on Cannabis' Effect on Tourette Syndrome

- Six weeks of cannabis treatment reduced ties in patients with Tourette's with no serious adverse effects or impairment on neuropsychological performance
  - Cannabinoids reduce symptoms of Tourette's syndrome (http://www.ncbi.nlm.nih.gov/pubmed/14521482)
- A significant reduction in ties was seen in Tourette's syndrome patients after six weeks of cannabis treatment.

  Delta 9-tetrahydrocannabinol (THC) is effective in the treatment of ties in Tourette syndrome. a 6-week randomized trial.

  (http://www.ncbi.nlm.nih.gov/pubmed/12716250)

#### References

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Muller-Vahl, K.R. (2003, October). Cannabinoids reduce symptoms of Tourette's syndrome. Expert Opinion on Pharmacology, 4(10), 1717-25

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\* Cannabidiol (CBD) is a naturally-occurring constituent of the industrial hemp plant

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#### **Working to Reform Marijuana Laws**

#### Tourette's Syndrome

Tourette's syndrome (TS) is a complex neuropsychiatric disorder of unknown etiology that is characterized by involuntary vocal tics. Severity of this condition varies widely among patients. Though there is no cure for Tourette's syndrome, the condition often improves with age. Experts estimate that 100,000 Americans are afflicted with TS.

A review of the scientific literature reveals several clinical trials investigating the use of cannabinoids for the treatment of TS. Writing in the March 1999 issue of the *American Journal of Psychiatry*, investigators at Germany's Medical School of Hanover, Department of Clinical Psychiatry and Psychotherapy, reported successful treatment of Tourette's syndrome with a single dose of 10 mg of delta-9-THC in a 25-year-old male patient in an uncontrolled open clinical trial.[1] Investigators reported that the subject's total tic severity score fell from 41 to 7 within two hours following cannabinoid therapy, and that improvement was observed for a total of seven hours. "For the first time, patients' subjective experiences when smoking marijuana were confirmed by using a valid and reliable rating scale," authors concluded.

Investigators again confirmed these preliminary results in a randomized, double-blind, placebo-controlled, crossover, single dose trial of THC in 12 adult TS patients. Researchers reported a "significant improvement of tics and obsessive-compulsive behavior (OCB) after treatment with delta-9-THC compared to placebo." [2] Investigators reported no cognitive impairment in subjects following THC administration[3] and concluded, "THC is effective and safe in treating tics and OCB in TS." [4]

Investigators confirmed these results in a second randomized, double-blind, placebo-controlled trial involving 24 patients administered daily doses of up to 10 mg of THC over a six-week period. Researchers reported that subjects experienced a significant reduction in tics following long-term cannabinoid treatment,[5] and suffered no detrimental effects on learning, recall or verbal memory.[6] A trend toward significant improvement of verbal memory span during and after therapy was also observed.

A 2003 review of the data published in the journal *Expert Opinions in Pharmacotherapy*, reported that in adult TS patients, "Therapy with delta-9-THC should be tried ... if well established drugs either fail to improve tics or cause significant adverse effects."[7] A 2013 review similarly concludes: "[B]y many experts THC is recommended for the treatment of TS in adult patients, when first line treatments failed to improve the tics. In treatment



#### **Working to Reform Marijuana Laws**

resistant adult patients, therefore, treatment with THC should be taken into consideration."[8]

#### REFERENCES

- [1] Muller-Vahl et al. 1999. Treatment of Tourette's syndrome with delta-9-tetrahydrocannabinol. *American Journal of Psychiatry* 156: 495.
- [2] Muller-Vahl et al. 2002. Treatment of Tourette's syndrome with Delta-9-tetrahydrocannabinol (THC): a randomized crossover trial. *Pharmacopsychiatry* 35: 57-61.
- [3] Muller-Vahl et al. 2001. Influence of treatment of Tourette syndrome with delta9-tetrahydrocannabinol (delta9-THC) on neuropsychological performance. *Pharmacopsychiatry* 34: 19-24.
- [4] Muller-Vahl et al. 2002. op. cit.
- [5] Muller-Vahl et al. 2003. Delta 9-tetrahydrocannabinol (THC) is effective in the treatment of tics in Tourette syndrome: a 6-week randomized trial. *Journal of Clinical Psychiatry* 64: 459-65.
- [6] Muller-Vahl et al. 2003. Treatment of Tourette syndrome with delta-9-tetrahydrocannabinol (delta 9-THC): no influence on neuropsychological performance. *Neuropsychopharmacology* 28: 384-8.
- [7] Kirsten Muller-Vahl. 2003. Cannabinoids reduce symptoms of Tourette's syndrome. Expert Opinions in Pharmacotherapy 4: 1717-25.
- [8] Kirsten Muller-Vahl. 2013. Treatment of Tourette syndrome with cannabinoids. *Behavioral Neurology* 27: 119-124.

# Tourette Association Funds 8 New Grants to Study Tourette Syndrome

#### Striatal Circuit Mechanisms for Tourette Syndrome



Kristen Ade, Ph.D.

Duke University Medical Center, Durham, NC

\$40,000

Approximately one half of patients with TS are also diagnosed with obsessive compulsive disorder (OCD). The high degree of overlap between these two psychiatric disorders suggests that they may arise from similar dysfunction

in the brain, and a number of studies indicate that dysfunction within a region called the striatum may underlie both TS and OCD. Using a novel method to evaluate neural activity, I previously found abnormalities in striatal activity in a mouse model of OCD. In this study, I will investigate whether OCD-like behaviors and similar striatal circuit abnormalities are observed in a mouse model of TS interactions of the Histamine and Dopamine systems in Tourette Syndrome.

#### Behavioral and Physiological Phenotypes Induced by an Early Loss of Striatal Cholinergic Interneurons: Proving Face Validity for a Novel Mouse Model of Tourette Syndrome



Juan E. Belforte, Ph.D.
University of Buenos Aires School of Medicine,
Buenos Aires, Argentina
\$120,000

The basal ganglia are a group of subcortical nuclei that control several aspects of voluntary movement and the striatum is their primary region receiving

information to be processed. The activity of neurons in the striatum is controlled by cells called interneurons. Postmortem studies from Tourette Syndrome patients showed that one particular kind, the striatal cholinergic interneuron, is reduced in these patients. However, it is still unknown if the loss of cholinergic cells is responsible for Tourette's symptoms. We will mimic this cell loss in rodents and explore whether the emerging behavioral symptoms are compatible with the ones of Tourette Syndrome.

# Network Architecture of the Brain in Tourette Syndrome and its Phenotypic Subgroups



Deanna J. Greene, Ph.D. Washington University School of Medicine, Saint Louis, MO \$150,000

Tourette Syndrome (TS) is a complex, heterogeneous neuropsychiatric disorder for which the underlying brain mechanisms are not well understood. We aim to take a comprehensive approach, investigating the structure and

function of the whole brain, to better this understanding. We will use sophisticated classification methods to identify brain network function and structure, measured with MRI, that distinguishes children with and without TS. We will also use graph theory methods to identify subgroups of TS based on whole brain MRI data. The results from this project have the potential to pinpoint new brain markers of TS and help understand its heterogeneity.

## Expedited Therapeutic Outcomes with Habit Reversal Training for Youth with Chronic Tic Disorders



Joseph F. McGuire, Ph.D.
University of California Los Angeles, Los Angeles, CA
\$40,000

Behavioral interventions, such as the Comprehensive Behavioral Intervention for Tics (CBIT) reduce the severity of tics. While many people who receive CBIT experience some benefit, only about half experience a clinically

meaningful response. Recent research has identified several medications (called cognitive enhancers) that may increase the learning that occurs during treatments like CBIT to produce greater and/ or accelerated improvement in symptoms. This study seeks to examine if one of these medications (called d-cycloserine, DCS) can accelerate improvements for children receiving behavior therapy.

#### Determining the Long-Term Effects of Comprehensive Behavioral Intervention for Tics: A Nine Year Follow-up of Original Child CBIT Study Participants



John Piacentini, Ph.D.
University of California Los Angeles, Los Angeles, CA
\$150,000

The Tourette Association Behavioral Sciences Consortium showed that the Comprehensive Behavioral Intervention for Tics (CBIT) is a safe and effective treatment for tics. CBIT is now a front-line and

widely-used treatment for tics. Although research shows that CBIT continues to help 6 months after successful treatment and may also help to reduce anxiety, social difficulties, and stress on families, questions remain regarding the long-term benefits of this treatment. This study will contact the original child CBIT study participants, most of whom are now adults, to assess their current tics, related problems and overall functioning.

## Somatic Attention and Inhibiting Response to Urges in Tourette Syndrome



Cheryl A. Richards, Ph.D. Washington University School of Medicine, Saint Louis, MO

\$150,000

The underlying causes of tics are still unknown. We will examine to what extent somatic attention, such as focusing on physical sensations,

and motor inhibition failure contribute to tics. We will study two groups of people: people with TS and people who do not have TS. We expect that people with TS will exhibit more brain activity when focusing on spontaneous physical sensations compared to the other subjects. We also expect that activity in certain brain regions will be associated with successful tic suppression by people with TS and successful eye blink suppression by people in both groups.

#### A Double-Blind, Randomized, Placebo-Controlled Crossover Pilot Trial of Medical Cannabis in Adults with Tourette Syndrome



Paul Sandor, M.D. Toronto Western Hospital, Toronto, Canada \$75,000

For many individuals with Tourette Syndrome (TS), available medications do not help with their symptoms, or cause significant side effects. There is some evidence that inhaled cannabis can be helpful and

well-tolerated in adults with TS, but this has not been well studied. Our goal is to carry out a study of vaporized cannabis for tics in adults with TS. We will compare three different types of medical cannabis in terms of how much they help tics, and how much they cause side effects.

#### Prevalence of TD and Tics among a Community-Recruited Sample of Adults from Haiti



Catherine Striley, Ph.D.

University of Florida College of Medicine, Gainesville, FL

\$150,000

Community Health Workers will go door-to-door in Carrefour, Haiti to look for symptoms of Tourette Syndrome (TS) and chronic tic disorder (CTD) in adults, aged 18 to 65, using a study-specific video screener.

Participants will be videotaped while taking the computerized assessment and these videos will be sent to specialists in the US to confirm current symptoms. Results will help determine the true prevalence in this population and whether or not current estimates of prevalence are the result of biased diagnosis and reduced access to treatment, or if they reflect a real difference in prevalence in populations of African descent.

#### Tourette Association Research Grant and Fellowship Program

The Tourette Association accepts research grant proposals from researchers in basic and clinical studies on all aspects of Tourette Syndrome.

For more information visit www.tourette.org/Research/research\_resgrantawards.html

# Endogenous Cannabinoids in Basal Ganglia and their Potential Participation in Tourette Syndrome

#### July 5, 2016

Our lab studies the mechanisms of formation and inactivation of the endocannabinoids, brain marijuana-like substances that serve as central components of a signaling system involved in the control of cognition, emotion and pain. Physiological experiments show that anandamide (the best known of the endocannabinoids) may be as important in regulating brain functions as other better understood neurotransmitters such as dopamine and serotonin. Anandamide and other endocannabinoids are released from neurons by a unique mechanism: they are stored in the membrane of neurons in the form of phospholipid precursors, which are cleaved by enzymes stimulated by receptor activation. After release, the endocannabinoids activate a receptor protein on the surface of neighboring cells, and are rapidly eliminated to stop their biological actions. We are interested in understanding at the molecular and cellular level how the endocannabinoids are released and inactivated, and in determining what may be their physiological functions. A primary role of the endocannabinoid system may be to regulate movement by modulating the activity of the neurotransmitter dopamine. Our experiments suggest that dopamine triggers the release of anandamide, which in turn may act as a brake preventing excess dopamine activity. Thus a dysfunction of this neurotransmitter balance may participate in neurological



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Behav Neurol. 2013;27(1):119-24. doi: 10.3233/BEN-120276.

#### Treatment of Tourette syndrome with cannabinoids.

Müller-Vahl KR1.

#### Author information

#### Abstract

Cannabinoids have been used for hundred of years for medical purposes. To day, the cannabinoid delta-9-tetrahydrocannabinol (THC) and the cannabis extract nabiximols are approved for the treatment of nausea, anorexia and spasticity, respectively. In Tourette syndrome (TS) several anecdotal reports provided evidence that marijuana might be effective not only in the suppression of tics, but also in the treatment of associated behavioural problems. At the present time there are only two controlled trials available investigating the effect of THC in the treatment of TS. Using both self and examiner rating scales, in both studies a significant tic reduction could be observed after treatment with THC compared to placebo, without causing significant adverse effects. Available data about the effect of THC on obsessive-compulsive symptoms are inconsistent. According to a recent Cochrane review on the efficacy of cannabinoids in TS, definite conclusions cannot be drawn, because longer trials including a larger number of patients are missing. Notwithstanding this appraisal, by many experts THC is recommended for the treatment of TS in adult patients, when first line treatments failed to improve the tics. In treatment resistant adult patients, therefore, treatment with THC should be taken into consideration.

PMID: 23187140 DOI: 10.3233/BEN-120276

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