

MONTANANS FOR RESPONSIBLE LEGISLATION 2/17/11

SB 336

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It has become clear that the Montana Medical Marijuana Act, passed in 2004 by over 60% of Montana's voters, has not been implemented as planned. The law's ambiguity not only creates problems for our peace officers in regards to enforcement, but its 'grey areas' have left our state's seriously ill open to the exploitations and abuses of an opportunistic few. Yet deep as these flaws may be, they are still not without proper remedy.

MRL represents the very people Montana voted to protect in 2004 -- the very same people crying out today for reform -- the proper kind of reform.

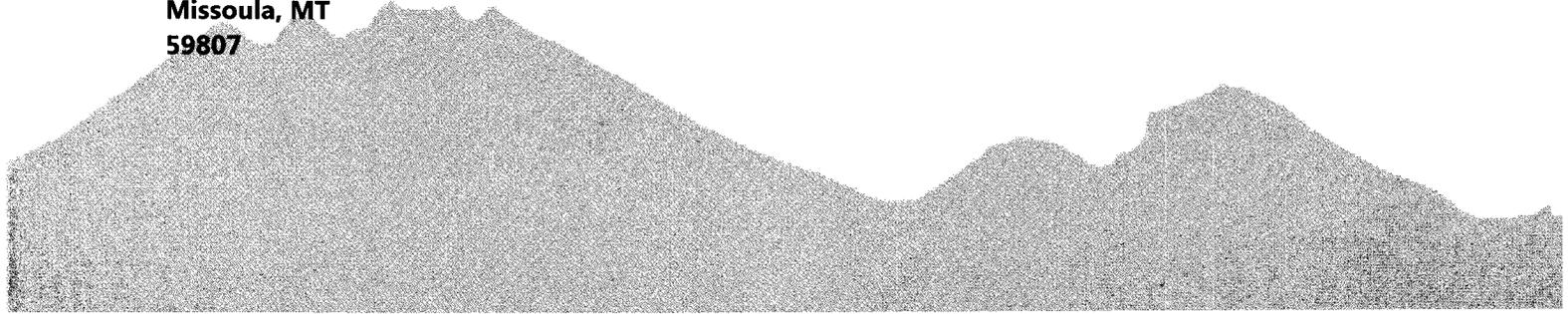
Our constituents require the protection from prosecution afforded under Montana's Medical Marijuana Act, and understand that neither illness, nor its treatment, is a crime. They demand stricter standards of medical care, coupled with statute requiring continuing education for their physicians in this fledgling field of cannabis science. Our supporters ask for a clear allowance, by statute, of lab testing for cannabinoid therapeutics to ensure their collective safety.

I look forward to working with lawmakers throughout this session to develop a workable, regulatory model -- one that honors the spirit of I-148, and one that preserves the safety of the people Montana voted to protect in 2004.

"Montanans for Responsible Legislation is a nonprofit public education group working to ensure safe access for, and the equal treatment of, both medical cannabis patient and provider. Through civil litigation, public education, and our lobbying activities with the Montana State Senate and House of Representatives these goals are achieved. We serve as an unbiased, community supported interface with the state legislature -- voicing the concerns and desires of the greater Montana Cannabis community."

Thank you,

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PTSD Information & Treatment

By Harold Cohen, Ph.D.

Post-traumatic stress disorder (PTSD) is a debilitating mental disorder that follows experiencing or witnessing an extremely traumatic, tragic, or terrifying event. People with PTSD usually have persistent frightening thoughts and memories of their ordeal and feel emotionally numb, especially with people they were once close to.

PTSD, once referred to as "**shell shock**" or **battle fatigue**, was first brought to public attention by war veterans, but it can result from any number of traumatic incidents. These include kidnapping, serious accidents such as car or train wrecks, natural disasters such as floods or earthquakes, violent attacks such as a mugging, rape, or torture, or being held captive. The event that triggers it may be something that threatened the person's life or the life of someone close to him or her. Or it could be something witnessed, such as mass destruction after a plane crash.

Most people with posttraumatic stress disorder repeatedly re-live the trauma in the form of nightmares and disturbing recollections during the day. The nightmares or recollections may come and go, and a person may be free of them for weeks at a time, and then experience them daily for no particular reason. They may also experience sleep problems, depression, feeling detached or numb, or being easily startled. They may lose interest in things they used to enjoy and have trouble feeling affectionate. They may feel irritable, more aggressive than before, or even violent. Seeing things that remind them of the incident may be very distressing, which could lead them to avoid certain places or situations that bring back those memories. Anniversaries of the event are often very difficult.

PTSD can occur at any age, including childhood. The disorder can be accompanied by depression, substance abuse, or anxiety. Symptoms may be mild or severe -- people may become easily irritated or have violent outbursts. In severe cases, they may have trouble working or socializing. In general, the symptoms seem to be worse if the event that triggered them was initiated by a person -- such as a murder, as opposed to a flood.

Ordinary events can serve as reminders of the trauma and trigger flashbacks or intrusive images. A flashback may make the person lose touch with reality and reenact the event for a period of seconds or hours, or very rarely, days. A person having a flashback, which can come in the form of images, sounds, smells, or feelings, usually believes that the traumatic event is happening all over again.

Posttraumatic stress disorder can be treated, usually with a combination of psychotherapy and medications (for specific symptom relief, such as for the common accompanying depressive feelings). People with PTSD should seek out a therapist or psychologists with specific experience and background in treatment posttraumatic stress disorder.

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Abstract

This is the report of an open label clinical trial to evaluate the effects of nabilone, an endocannabinoid receptor agonist, on treatment-resistant nightmares in patients diagnosed with posttraumatic stress disorder (PTSD). Methods: Charts of 47 patients diagnosed with PTSD and having continuing nightmares in spite of conventional antidepressants and hypnotics were reviewed after adjunctive treatment with nabilone was initiated. These patients had been referred to a psychiatric specialist outpatient clinic between 2004 and 2006. The majority of patients (72%) receiving nabilone experienced either cessation of nightmares or a significant reduction in nightmare intensity. Subjective improvement in sleep time, the quality of sleep, and the reduction of daytime flashbacks and nightsweats were also noted by some patients. The results of this study indicate the potential benefits of nabilone, a synthetic cannabinoid, in patients with PTSD experiencing poor control of nightmares with standard pharmacotherapy. This is the first report of the use of nabilone (Cesamet; Valeant Canada, Ltd., Montreal, Canada) for the management of treatment-resistant nightmares in PTSD.

Background

The Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR), defines posttraumatic stress disorder (PTSD) as the development of characteristic symptoms following exposure to an extreme traumatic stressor, involving direct personal experience of an event that involves actual or threatened death or serious injury or other threat to the physical integrity of another person, or learning about unexpected or violent death, serious harm or threat of death, or injury experienced by a family member or other close associate. The person's response must involve intense fear, helplessness, or horror (in children, disorganized or agitated behavior). There are many characteristic symptoms of PTSD including the persistent, intrusive recollections or re-experience of the original event (via dreams or nightmares and dissociative flashbacks), numbing and avoidance, and increased arousal [1]. The experience of these symptoms leads to functional impairment.

Although PTSD is often associated with military casualties, the majority of cases are related to traumatic events occurring in the general population. Such events may include physical or sexual abuse, traffic or natural disasters, and interpersonal violence. The lifetime prevalence of PTSD is 8.2% in the United States, and a Canadian study puts this rate at 9.2%[2,3]. PTSD's lifetime prevalence is higher than that of other anxiety disorders, including panic disorder, obsessive compulsive disorder, and generalized anxiety disorder.

Guidelines for the management of PTSD now exist [4]. However, recommended first-line and second-line agents, used alone or in combination to treat symptoms including nightmares, often show limited effectiveness in many patients. Subsequently, some patients may continue to experience symptoms, including debilitating nightmares, for years or decades. The negative impact of nightmares and the side effects of some of the current psychotherapeutic

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medications may potentiate other symptoms of PTSD, including those related to anxiety and depression. Other comorbid psychiatric conditions may also worsen. Commonly, patients with PTSD are receiving more than one medication. Polypharmacy is associated with the potential for side effects and drug interactions, thus possibly creating compliance and quality-of-life issues. On the basis of these experiences, there is a definite clinical need for a medication that is effective in treating nightmares related to PTSD, with positive effects on sleep and little potential for side effects or drug interaction.

Selective serotonin reuptake inhibitors (SSRIs) are considered first-line agents in the pharmacological treatment of PTSD in the United States (e.g., paroxetine and sertraline). Second-line agents include venlafaxine, prazosin, monoamine oxidase inhibitors, and tricyclic antidepressants. Other agents used in PTSD include atypical antipsychotics and anticonvulsants [5].

Sleep disturbances, mainly insomnia and nightmares, are present in about 70% of those with PTSD. The estimates of nightmares vary from 24.8%[6] to 60.0%[7].

Various medications have been used in attempts to control PTSD sleep disturbances, including nightmares. A review of the abovementioned classes of medications, as well as other specific agents such as clonidine and cyproheptadine, concludes, "to date an insufficient number of controlled studies are published to formulate evidence-based guidelines. Drawing on the available data it can be concluded that there is limited but promising evidence for prazosin and olanzapine for managing PTSD nightmares and insomnia"[8]. That article also points out that objective parameters for insomnia and nightmares need to be developed. The fact that so many agents have been used in attempts to manage nightmares highlights that management of these is difficult, and that there is room to explore other potentially useful classes of medications. Anecdotal reports of relief from psychiatric symptoms, with the use of marijuana or a pharmaceutical endocannabinoid receptor agonist, have created interest in investigating the role of the endocannabinoid system in PTSD and other mood disorders [5]. The endocannabinoid system has been implicated in the control of various behaviors including eating, addiction, and memory and in mediating both anxiolytic effects and pain responses [6–8]. Endocannabinoids are thought to exert an effect through a variety of interactions with the CNS related to PTSD. These include the hypothalamic–pituitary–adrenocortical (HPA) axis, function of the hippocampus and amygdala, and control of cortical regulation of memory processes [9–11].

The endocannabinoid system comprises two G-protein-coupled receptors (CB₁ and CB₂), possibly one or more atypical receptors, and several ligands (notably anandamide and 2-arachidonolglycerol [2-A]). The CB₁ receptor is distributed primarily within the CNS, particularly in the cerebellum, basal ganglia, amygdala, cerebral cortex, and hippocampus [12,13]. The CB₂ is mostly distributed peripherally [13,14]. The cannabinoid receptors show pronounced selectivity in their binding and even have distinct binding sites for different classes of ligands [14]. This selectivity may partially explain why different agonists for the same CB receptor show differing therapeutic and side effect profiles. For example, at therapeutic doses, nabilone does not appear to produce the psychological high of inhaled marijuana.

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Nabilone (Cesamet; Valeant Canada, Ltd., Montreal, Canada), an endocannabinoid receptor (CB₁ and CB₂) agonist, has been in use in Europe and Canada for over 25 years and was recently granted approval in the United States for the treatment of chemotherapy-induced nausea and vomiting. The identification and cloning of cannabinoid receptors in humans have led to a better understanding of the possible mechanisms of action of nabilone and support its potential use and safety in multiple clinical settings and various patient populations [12–26].

Rational for Therapeutic Trial of Nabilone in Patients with PTSD

Patients with PTSD can be desperate to obtain relief from their symptoms and frequently turn to self-medication, including the use of alcohol and cannabis. On the basis of observations published in a single case study that mentioned nabilone's reduction of nightmares when it was employed to replace a patient's use of smoked marijuana for the relief of PTSD symptoms [22], the author of this current report decided to initiate nabilone as pharmacotherapy for several patients whose nightmares were not adequately controlled with standard therapies. When the initial three patients experienced abolition of their nightmares, it was decided to use nabilone in subsequent clinical cases with similar presentations and record the effect on nightmares.

Methods

All 47 patients who agreed to participate in this clinical study had been referred to the author's private clinic for the management of PTSD by other physicians. The clinic specialized in the management of psychological trauma. Diagnoses for the study were confirmed by DSM-IV-TR criteria using a recognized PTSD questionnaire, the Posttraumatic Stress Diagnostic Scale [9]. All patients had at least a 2-year history of PTSD-related nightmares that had not responded to conventional therapies ([Tables 1](#) and [2](#)). Eligibility for this study stipulated that current nightmare frequency was a minimum of once weekly.

	Total
Total number of patients studied	47
Mean age, years ± SD	44 ± 9
Range	26–68
Women/men	27/20
Time since PTSD onset (range in years)	2–30

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Table 1. Population profile

	Total
Repetitive childhood trauma (sexual/physical abuse)	18
Civilian adult trauma (accident, rape, injury, workplace trauma, and life-threatening illness)	18
Combat-associated trauma	11
Total	47

Table 2. Type of trauma

Nightmares were considered "treatment-resistant" when these persisted in spite of conventional medications employed for PTSD. Although these medications provided relief for various PTSD symptom clusters, as reported by the patients in this study, nightmares persisted unchanged and continued to cause clinical distress.

The author had to rely on subjective reports of nightmare presence and subsequent relief with the use of nabilone since, at present, there is no reliable test to objectively measure the presence or intensity of nightmares.

All patients were informed that nabilone was a synthetic cannabinoid and approved only for antiemetic use. The patients were screened for previous negative experiences with marijuana use and were advised to not use marijuana while taking nabilone. Conditions that were contraindicated with the use of nabilone were excluded from the study (e.g., sensitivity to cannabinoids and psychotic reactions). All patients were on psychotropic medications for PTSD at the start of the study, and a decision was made not to discontinue any of these in order to study the effect of the addition of nabilone. The patients were carefully monitored for any adverse reactions. Potential benefits and side effects were discussed, and the patients were advised to discontinue nabilone if they experienced any uncomfortable side effects. Verbal consent was voluntary, and continuing psychiatric treatment was not contingent on being a volunteer.

Prior to starting nabilone, the patients were given a tracking sheet that asked them to record the intensity of nightmares from 1 to 5 (5 being the most intense) and hours of sleep and provided a space for comments about that night's sleep. This nightly charting began 1 week prior to commencing the trial and weekly thereafter until satisfactory results or the trial being ended due to side effects. Previous medications, which ranged from a single SSRI to polypharmacy, were not changed during the study.

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The patients were started at a dose of 0.5 mg 1 h prior to bedtime (the first patient was started at 1.0 mg based on dose availability. Soon after, the 0.5-mg capsule became available). The patients were seen within 7 days of initiating nabilone in order to determine dose response and monitor for side effects. Titration of nabilone was indicated if the medication was well tolerated and effective control of nightmare symptoms had not been achieved. The patients continued to be seen weekly until a satisfactory response was achieved or nabilone was stopped due to side effects. All doses were kept below the maximum 6 mg daily, as per the Cesamet (nabilone) product monograph [28]. Patients having a positive response to nightmare cessation or reduction were permitted to continue nabilone therapy and were individually monitored for its use in ongoing therapy. All patients gave consent for a review of their clinical charts in order that their response to nabilone therapy be documented.

Results

For 47 patients, standard PTSD medications being maintained, the usual starting dose was 0.5 mg and was titrated up or down to effect. The average effective dose of nabilone was 0.5 mg one hour before bedtime, with an effective dose range of 0.2 mg to 4.0 mg nightly. Thirty-four (72%) patients experienced total cessation or lessening of severity of nightmares (28 patients had total cessation of nightmares and 6 had satisfactory reduction). The discontinuation of medication was successful in four patients following 4–12 months of nabilone therapy (nightmares did not return or returned at a reduced level, not needing further medication control), whereas the other patients experienced a recurrence of nightmares upon nabilone withdrawal (usually within the first two nights). These patients experienced control of nightmares once nabilone treatment was reinitiated. These patients were asked to attempt withdrawal at least every 6 months, but the therapy was ongoing at the time of this chart review. Three patients, who initially responded positively, were lost to follow-up.

In some cases, the benefits including an improvement in sleep time and a reduction of daytime flashbacks were subjectively noted. Several patients also stated that they no longer experienced nightsweats while on nabilone. Once effective relief of nightmares was achieved, no further increase in nabilone was necessary (patients' doses remained stable). Thirteen (28%) patients experienced mild-to-moderate side effects (shortly following nabilone initiation), leading to discontinuation of nabilone therapy. The side effects experienced included lightheadedness, forgetfulness, dizziness, and headache.

Conclusion

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A chart review of patients diagnosed with PTSD who were referred to a private psychiatric clinic suggests that the synthetic cannabinoid, nabilone, has beneficial effects beyond its official indication in regard to abolishing or greatly reducing nightmares that persisted in spite of treatment with conventional PTSD medications.

The subjects concomitantly received nabilone in addition to the one or more psychiatric medications that they were already taking for 2 years or more. No tolerance to nabilone was observed among the patients. This may indicate its potential longer-term safety and efficacy.

The author recognizes the limits of this study (e.g., there was no placebo control, the measurements were limited to subjective reports to nightmare changes, the study was on a small number of patients, and there was a selective bias by nature of referrals to a specific clinic from which the patients were selected). Nonetheless, on the basis of these retrospective findings, nabilone appears to be a significant treatment for nightmares in the PTSD population. This initial positive clinical report on 34 of the 47 patients will hopefully inspire other physicians to consider using nabilone in those with persistent PTSD nightmares. Nabilone should be evaluated further through randomized clinical trials involving PTSD patients, including studies looking at its effects on the full spectrum of PTSD symptoms. Baseline and follow-up polysomnography recordings for patients on nabilone therapy would likely provide useful information. In addition, nabilone's effect in other anxiety disorders and primary parasomnias may be the areas to investigate.

Addendum

Since this study was done, Health Canada has approved a 0.25-mg capsule of nabilone. This would be the preferred starting dose of this author. The United States has only the 1-mg capsule available, so dilution by a pharmacist for the initial doses is recommended. Available strengths may vary in different countries where nabilone is available.

Conflict of Interest

The authors declare no conflict of interest.

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